Mr. MCDERMOTT. And left a mess and went on to Iraq, and now we have got two messes on our hands. The gentleman is absolutely right, what is happening in Afghanistan is a terrible mess.

Mr. DELAHUNT. To think that our military, as it has in Iraq, performed so professionally and admirably in Afghanistan, and now we are on the verge of seeing Afghanistan becoming a failed state.

Nicolas Kristoff, a columnist in the New York Times, says, and again it is this week, in the 2 years since the war in Afghanistan, opium production, and he has given us three choices, virtually been eliminated, declined 30 percent, soared 19-fold and become the major source of the world's heroin. That is what is happening in Afghanistan today.

In two provinces that are religiously conservative parts of Afghanistan, the number of children going to school has quintupled, has risen 40 percent, has plummeted as poor security has closed nearly all the schools there. The right answer is the last one.

This is truly potentially a disaster. President Karzai's brother, Ahmed Karzai, who represents the government in one of the southern provinces, was very blunt to an AP reporter this past Monday: it is like I am seeing the same movie twice, and no one is trying to fix the problem. What was promised to Afghans with the collapse of the Taliban was a new life of hope and change. Those are the words of President Bush, but what was delivered, nothing. There had been no significant changes for people. Karzai says he does not know what to say to people anymore.

We better pay attention to Afghanistan because with the focus now on Iraq, the media is taking the glare of the cameras away from a totally, potentially disastrous situation. They are scheduled to have elections in Afghanistan next June. It is estimated that the need would be for 70,000 police security forces. Does my colleague know how many have been trained? Does the gentleman know how many have been trained? Seven thousand, 7,000. This is, again, a potential foreign policy disaster, not just for this President but for this country.

With that, if the gentleman has anything further to say.

Mr. MCDERMOTT. Mr. Speaker, I think we have said enough for tonight, but this issue will not go away.

One fact that I will finish with, this week now, more people have died in Iraq since the war began than died in the first 3 full years in Vietnam. So if we do not think we have got a developing mess on our hands, just remember how we eased into Vietnam, and this is where we are going if this administration does not begin to develop a plan.

Mr. DELAHUNT. Twenty-six people died today in Turkey, the victims of an act of terrorism. Some 400 were wounded. In the northern part of Iraq, not in the so-called Sunni Triangle, 12 died as a result of acts of terrorism in northern Iraq.

We are in a mess. Let us get our act together. Let us support our President, but let us do it in consultation and make sure that America can continue to be proud and claim that it is great because it is good and it has a moral compass.

RECESS

The SPEAKER pro tempore (Mr. ROGERS of Alabama). Pursuant to clause 12(a) of rule I, the Chair declares the House in recess subject to the call of the Chair.

Accordingly (at midnight), the House stood in recess subject to the call of the Chair.

□ 0117

AFTER RECESS

The recess having expired, the House was called to order by the Speaker pro tempore (Mr. NUNES) at 1 o'clock and 17 minutes a.m.

CONFERENCE REPORT ON H.R. 1, MEDICARE PRESCRIPTION DRUG AND MODERNIZATION ACT OF 2003

Mr. THOMAS submitted the following conference report and statement on the bill (H.R. 1) to amend title XVIII of the Social Security Act to provide for a voluntary program for prescription drug coverage under the Medicare Program, to modernize the Medicare Program, to amend the Internal Revenue Code of 1986 to allow a deduction to individuals for amounts contributed to health savings security accounts and health savings accounts, to provide for the disposition of unused health benefits in cafeteria plans and flexible spending arrangements, and for other purposes:

CONFERENCE REPORT (H. REPT. 108–391)

The committee of conference on the disagreeing votes of the two Houses on the amendments of the Senate to the bill (H.R. 1), to amend title XVIII of the Social Security Act to provide for a voluntary program for prescription drug coverage under the Medicare Program, to modernize the Medicare Program, to amend the Internal Revenue Code of 1986 to allow a deduction to individuals for amounts contributed to health savings security accounts and health savings accounts, to provide for the disposition of unused health benefits in cafeteria plans and flexible spending arrangements, and for other purposes, having met, after full and free conference, have agreed to recommend and do recommend to their respective Houses as follows:

That the House recede from its disagreement to the amendment of the Senate to the text of the bill and agree to the same with an amendment as follows:

In lieu of the matter proposed to be inserted by the Senate amendment, insert the following.

SECTION 1. SHORT TITLE; AMENDMENTS TO SOCIAL SECURITY ACT; REFERENCES TO BIPA AND SECRETARY; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Medicare Prescription Drug, Improvement, and Modernization Act of 2003''.

(b) AMENDMENTS TO SOCIAL SECURITY ACT.—Except as otherwise specifically provided, whenever in division A of this Act an amendment is expressed in terms of an amendment to or repeal of a section or other provision, the reference shall be considered to be made to that section or other provision of the Social Security Act.

(c) BIPA; SECRETARY.—In this Act:

(1) BIPA.—The term ''BIPA'' means the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, as enacted into law by section 1(a)(6) of Public Law 106–554.

(2) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

(d) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

Sec. 1. Short title; amendments to Social Security Act; references to BIPA and Secretary; table of contents.

TITLE I—MEDICARE PRESCRIPTION DRUG BENEFIT

Sec. 101. Medicare prescription drug benefit.

''PART D—VOLUNTARY PRESCRIPTION DRUG BENEFIT PROGRAM

''Subpart 1—Part D Eligible Individuals and Prescription Drug Benefits

''Sec. 1860D–1. Eligibility, enrollment, and information.

''Sec. 1860D–2. Prescription drug benefits.

''Sec. 1860D–3. Access to a choice of qualified prescription drug coverage.

''Sec. 1860D–4. Beneficiary protections for qualified prescription drug coverage.

''Subpart 2—Prescription Drug Plans; PDP Sponsors; Financing

''Sec. 1860D–11. PDP regions; submission of bids; plan approval.

''Sec. 1860D–12. Requirements for and contracts with prescription drug plan (PDP) sponsors.

''Sec. 1860D–13. Premiums; late enrollment penalty.

''Sec. 1860D–14. Premium and cost-sharing subsidies for low-income individuals.

''Sec. 1860D–15. Subsidies for part D eligible individuals for qualified prescription drug coverage.

''Sec. 1860D–16. Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.

''Subpart 3—Application to Medicare Advantage Program and Treatment of Employer-Sponsored Programs and Other Prescription Drug Plans

''Sec. 1860D–21. Application to Medicare Advantage program and related managed care programs.

''Sec. 1860D–22. Special rules for employer-sponsored programs.

''Sec. 1860D–23. State pharmaceutical assistance programs.

''Sec. 1860D–24. Coordination requirements for plans providing prescription drug coverage.

''Subpart 4—Medicare Prescription Drug Discount Card and Transitional Assistance Program

''Sec. 1860D–31. Medicare prescription drug discount card and transitional assistance program.

''Subpart 5—Definitions and Miscellaneous Provisions

''Sec. 1860D–41. Definitions; treatment of references to provisions in part C.

''Sec. 1860D–42. Miscellaneous provisions.
Sec. 102. Medicare Advantage conforming amendments.
Sec. 103. Medicaid amendments.
Sec. 104. Medigap amendments.
Sec. 105. Additional provisions relating to medicare prescription drug discount card and transitional assistance program.
Sec. 106. State Pharmaceutical Assistance Transition Commission.
Sec. 107. Studies and reports.
Sec. 108. Grants to physicians to implement electronic prescription drug programs.
Sec. 109. Expanding the work of medicare Quality Improvement Organizations to include parts C and D.
Sec. 110. Conflict of interest study.
Sec. 111. Study on employment-based retiree health coverage.

TITLE II—MEDICARE ADVANTAGE

Subtitle A—Implementation of Medicare Advantage Program

Sec. 201. Implementation of Medicare Advantage program.

Subtitle B—Immediate Improvements

Sec. 211. Immediate improvements.

Subtitle C—Offering of Medicare Advantage (MA) Regional Plans; Medicare Advantage Competition

Sec. 221. Establishment of MA regional plans.
Sec. 222. Competition program beginning in 2006.
Sec. 223. Effective date.

Subtitle D—Additional Reforms

Sec. 231. Specialized MA plans for special needs individuals.
Sec. 232. Avoiding duplicative State regulation.
Sec. 233. Medicare MSAs.
Sec. 234. Extension of reasonable cost contracts.
Sec. 235. 2-year extension of municipal health service demonstration projects.
Sec. 236. Payment by PACE providers for medicare and medicaid services furnished by noncontract providers.
Sec. 237. Reimbursement for Federally qualified health centers providing services under MA plans.
Sec. 238. Institute of Medicine evaluation and report on health care performance measures.

Subtitle E—Comparative Cost Adjustment (CCA) Program

Sec. 241. Comparative Cost Adjustment (CCA) program.

TITLE III—COMBATTING WASTE, FRAUD, AND ABUSE

Sec. 301. Medicare secondary payor (MSP) provisions.
Sec. 302. Payment for durable medical equipment; competitive acquisition of certain items and services.
Sec. 303. Payment reform for covered outpatient drugs and biologicals.
Sec. 304. Extension of application of payment reform for covered outpatient drugs and biologicals to other physician specialties.
Sec. 305. Payment for inhalation drugs.
Sec. 306. Demonstration project for use of recovery audit contractors.
Sec. 307. Pilot program for national and State background checks on direct patient access employees of long-term care facilities or providers.

TITLE IV—RURAL PROVISIONS

Subtitle A—Provisions Relating to Part A Only

Sec. 401. Equalizing urban and rural standardized payment amounts under the medicare inpatient hospital prospective payment system.
Sec. 402. Enhanced disproportionate share hospital (DSH) treatment for rural hospitals and urban hospitals with fewer than 100 beds.
Sec. 403. Adjustment to the medicare inpatient hospital prospective payment system wage index to revise the labor-related share of such index.
Sec. 404. More frequent update in weights used in hospital market basket.
Sec. 405. Improvements to critical access hospital program.
Sec. 406. Medicare inpatient hospital payment adjustment for low-volume hospitals.
Sec. 407. Treatment of missing cost reporting periods for sole community hospitals.
Sec. 408. Recognition of attending nurse practitioners as attending physicians to serve hospice patients.
Sec. 409. Rural hospice demonstration project.
Sec. 410. Exclusion of certain rural health clinic and federally qualified health center services from the prospective payment system for skilled nursing facilities.
Sec. 410A. Rural community hospital demonstration program.

Subtitle B—Provisions Relating to Part B Only

Sec. 411. 2-year extension of hold harmless provisions for small rural hospitals and sole community hospitals under the prospective payment system for hospital outpatient department services.
Sec. 412. Establishment of floor on work geographic adjustment.
Sec. 413. Medicare incentive payment program improvements for physician scarcity.
Sec. 414. Payment for rural and urban ambulance services.
Sec. 415. Providing appropriate coverage of rural air ambulance services.
Sec. 416. Treatment of certain clinical diagnostic laboratory tests furnished to hospital outpatients in certain rural areas.
Sec. 417. Extension of telemedicine demonstration project.
Sec. 418. Report on demonstration project permitting skilled nursing facilities to be originating telehealth sites; authority to implement.

Subtitle C—Provisions Relating to Parts A and B

Sec. 421. 1-year increase for home health services furnished in a rural area.
Sec. 422. Redistribution of unused resident positions.

Subtitle D—Other Provisions

Sec. 431. Providing safe harbor for certain collaborative efforts that benefit medically underserved populations.
Sec. 432. Office of Rural Health Policy improvements.
Sec. 433. MedPAC study on rural hospital payment adjustments.
Sec. 434. Frontier extended stay clinic demonstration project.

TITLE V—PROVISIONS RELATING TO PART A

Subtitle A—Inpatient Hospital Services

Sec. 501. Revision of acute care hospital payment updates.
Sec. 502. Revision of the indirect medical education (IME) adjustment percentage.
Sec. 503. Recognition of new medical technologies under inpatient hospital prospective payment system.
Sec. 504. Increase in Federal rate for hospitals in Puerto Rico.
Sec. 505. Wage index adjustment reclassification reform.
Sec. 506. Limitation on charges for inpatient hospital contract health services provided to Indians by medicare participating hospitals.
Sec. 507. Clarifications to certain exceptions to medicare limits on physician referrals.
Sec. 508. 1-Time appeals process for hospital wage index classification.

Subtitle B—Other Provisions

Sec. 511. Payment for covered skilled nursing facility services.
Sec. 512. Coverage of hospice consultation services.
Sec. 513. Study on portable diagnostic ultrasound services for beneficiaries in skilled nursing facilities.

TITLE VI—PROVISIONS RELATING TO PART B

Subtitle A—Provisions Relating to Physicians' Services

Sec. 601. Revision of updates for physicians' services.
Sec. 602. Treatment of physicians' services furnished in Alaska.
Sec. 603. Inclusion of podiatrists, dentists, and optometrists under private contracting authority.
Sec. 604. GAO study on access to physicians' services.
Sec. 605. Collaborative demonstration-based review of physician practice expense geographic adjustment data.
Sec. 606. MedPAC report on payment for physicians' services.

Subtitle B—Preventive Services

Sec. 611. Coverage of an initial preventive physical examination.
Sec. 612. Coverage of cardiovascular screening blood tests.
Sec. 613. Coverage of diabetes screening tests.
Sec. 614. Improved payment for certain mammography services.

Subtitle C—Other Provisions

Sec. 621. Hospital outpatient department (HOPD) payment reform.
Sec. 622. Limitation of application of functional equivalence standard.
Sec. 623. Payment for renal dialysis services.
Sec. 624. 2-year moratorium on therapy caps; provisions relating to reports.
Sec. 625. Waiver of part B late enrollment penalty for certain military retirees; special enrollment period.
Sec. 626. Payment for services furnished in ambulatory surgical centers.
Sec. 627. Payment for certain shoes and inserts under the fee schedule for orthotics and prosthetics.
Sec. 628. Payment for clinical diagnostic laboratory tests.
Sec. 629. Indexing part B deductible to inflation.
Sec. 630. 5-year authorization of reimbursement for all medicare part B services furnished by certain Indian hospitals and clinics.

Subtitle D—Additional Demonstrations, Studies, and Other Provisions

Sec. 641. Demonstration project for coverage of certain prescription drugs and biologicals.
Sec. 642. Extension of coverage of Intravenous Immune Globulin (IVIG) for the treatment of primary immune deficiency diseases in the home.
Sec. 643. MedPAC study of coverage of surgical first assisting services of certified registered nurse first assistants.
Sec. 644. MedPAC study of payment for cardiothoracic surgeons.
Sec. 645. Studies relating to vision impairments.
Sec. 646. Medicare health care quality demonstration programs.
Sec. 647. MedPAC study on direct access to physical therapy services.
Sec. 648. Demonstration project for consumer-directed chronic outpatient services.

Sec. 649. Medicare care management performance demonstration.
Sec. 650. GAO study and report on the propagation of concierge care.
Sec. 651. Demonstration of coverage of chiropractic services under medicare.

TITLE VII—PROVISIONS RELATING TO PARTS A AND B

Subtitle A—Home Health Services

Sec. 701. Update in home health services.
Sec. 702. Demonstration project to clarify the definition of homebound.
Sec. 703. Demonstration project for medical adult day care services.
Sec. 704. Temporary suspension of OASIS requirement for collection of data on non-medicare and non-medicaid patients.
Sec. 705. MedPAC study on medicare margins of home health agencies.
Sec. 706. Coverage of religious nonmedical health care institution services furnished in the home.

Subtitle B—Graduate Medical Education

Sec. 711. Extension of update limitation on high cost programs.
Sec. 712. Exception to initial residency period for geriatric residency or fellowship programs.
Sec. 713. Treatment of volunteer supervision.

Subtitle C—Chronic Care Improvement

Sec. 721. Voluntary chronic care improvement under traditional fee-for-service.
Sec. 722. Medicare Advantage quality improvement programs.
Sec. 723. Chronically ill medicare beneficiary research, data, demonstration strategy.

Subtitle D—Other Provisions

Sec. 731. Improvements in national and local coverage determination process to respond to changes in technology.
Sec. 732. Extension of treatment of certain physician pathology services under medicare.
Sec. 733. Payment for pancreatic islet cell investigational transplants for medicare beneficiaries in clinical trials.
Sec. 734. Restoration of medicare trust funds.
Sec. 735. Modifications to Medicare Payment Advisory Commission (MedPAC).
Sec. 736. Technical amendments.

TITLE VIII—COST CONTAINMENT

Subtitle A—Cost Containment

Sec. 801. Inclusion in annual report of medicare trustees of information on status of medicare trust funds.
Sec. 802. Presidential submission of legislation.
Sec. 803. Procedures in the House of Representatives.
Sec. 804. Procedures in the Senate.

Subtitle B—Income-Related Reduction in Part B Premium Subsidy

Sec. 811. Income-related reduction in part B premium subsidy.

TITLE IX—ADMINISTRATIVE IMPROVEMENTS, REGULATORY REDUCTION, AND CONTRACTING REFORM

Sec. 900. Administrative improvements within the Centers for Medicare & Medicaid Services (CMS).

Subtitle A—Regulatory Reform

Sec. 901. Construction; definition of supplier.
Sec. 902. Issuance of regulations.
Sec. 903. Compliance with changes in regulations and policies.
Sec. 904. Reports and studies relating to regulatory reform.

Subtitle B—Contracting Reform

Sec. 911. Increased flexibility in medicare administration.
Sec. 912. Requirements for information security for medicare administrative contractors.

Subtitle C—Education and Outreach

Sec. 921. Provider education and technical assistance.
Sec. 922. Small provider technical assistance demonstration program.
Sec. 923. Medicare Beneficiary Ombudsman.
Sec. 924. Beneficiary outreach demonstration program.
Sec. 925. Inclusion of additional information in notices to beneficiaries about skilled nursing facility benefits.
Sec. 926. Information on medicare-certified skilled nursing facilities in hospital discharge plans.

Subtitle D—Appeals and Recovery

Sec. 931. Transfer of responsibility for medicare appeals.
Sec. 932. Process for expedited access to review.
Sec. 933. Revisions to medicare appeals process.
Sec. 934. Prepayment review.
Sec. 935. Recovery of overpayments.
Sec. 936. Provider enrollment process; right of appeal.
Sec. 937. Process for correction of minor errors and omissions without pursuing appeals process.
Sec. 938. Prior determination process for certain items and services; advance beneficiary notices.
Sec. 939. Appeals by providers when there is no other party available.
Sec. 940. Revisions to appeals timeframes and amounts.
Sec. 940A. Mediation process for local coverage determinations.

Subtitle E—Miscellaneous Provisions

Sec. 941. Policy development regarding evaluation and management (E & M) documentation guidelines.
Sec. 942. Improvement in oversight of technology and coverage.
Sec. 943. Treatment of hospitals for certain services under medicare secondary payor (MSP) provisions.
Sec. 944. EMTALA improvements.
Sec. 945. Emergency Medical Treatment and Labor Act (EMTALA) Technical Advisory Group.
Sec. 946. Authorizing use of arrangements to provide core hospice services in certain circumstances.
Sec. 947. Application of OSHA bloodborne pathogens standard to certain hospitals.
Sec. 948. BIPA-related technical amendments and corrections.
Sec. 949. Conforming authority to waive a program exclusion.
Sec. 950. Treatment of certain dental claims.
Sec. 951. Furnishing hospitals with information to compute DSH formula.
Sec. 952. Revisions to reassignment provisions.
Sec. 953. Other provisions.

TITLE X—MEDICAID AND MISCELLANEOUS PROVISIONS

Subtitle A—Medicaid Provisions

Sec. 1001. Medicaid disproportionate share hospital (DSH) payments.
Sec. 1002. Clarification of inclusion of inpatient drug prices charged to certain public hospitals in the best price exemptions for the medicaid drug rebate program.
Sec. 1003. Extension of moratorium.

Subtitle B—Miscellaneous Provisions

Sec. 1011. Federal reimbursement of emergency health services furnished to undocumented aliens.
Sec. 1012. Commission on Systemic Interoperability.
Sec. 1013. Research on outcomes of health care items and services.
Sec. 1014. Health care that works for all Americans: Citizens Health Care Working Group.
Sec. 1015. Funding start-up administrative costs for medicare reform.
Sec. 1016. Health care infrastructure improvement program.

TITLE XI—ACCESS TO AFFORDABLE PHARMACEUTICALS

Subtitle A—Access to Affordable Pharmaceuticals

Sec. 1101. 30-month stay-of-effectiveness period.
Sec. 1102. Forfeiture of 180-day exclusivity period.
Sec. 1103. Bioavailability and bioequivalence.
Sec. 1104. Conforming amendments.

Subtitle B—Federal Trade Commission Review

Sec. 1111. Definitions.
Sec. 1112. Notification of agreements.
Sec. 1113. Filing deadlines.
Sec. 1114. Disclosure exemption.
Sec. 1115. Enforcement.
Sec. 1116. Rulemaking.
Sec. 1117. Savings clause.
Sec. 1118. Effective date.

Subtitle C—Importation of Prescription Drugs

Sec. 1121. Importation of prescription drugs.
Sec. 1122. Study and report on importation of drugs.
Sec. 1123. Study and report on trade in pharmaceuticals.

TITLE XII—TAX INCENTIVES FOR HEALTH AND RETIREMENT SECURITY

Sec. 1201. Health savings accounts.
Sec. 1202. Exclusion from gross income of certain Federal subsidies for prescription drug plans.
Sec. 1203. Exception to information reporting requirements related to certain health arrangements.

TITLE I—MEDICARE PRESCRIPTION DRUG BENEFIT

SEC. 101. MEDICARE PRESCRIPTION DRUG BENEFIT.

(a) IN GENERAL.—Title XVIII is amended—

(1) by redesignating part D as part E; and

(2) by inserting after part C the following new part:

''PART D—VOLUNTARY PRESCRIPTION DRUG BENEFIT PROGRAM

''Subpart 1—Part D Eligible Individuals and Prescription Drug Benefits

''ELIGIBILITY, ENROLLMENT, AND INFORMATION

''SEC. 1860D–1. (a) PROVISION OF QUALIFIED PRESCRIPTION DRUG COVERAGE THROUGH ENROLLMENT IN PLANS.—

''(1) IN GENERAL.—Subject to the succeeding provisions of this part, each part D eligible individual (as defined in paragraph (3)(A)) is entitled to obtain qualified prescription drug coverage (described in section 1860D–2(a)) as follows:

''(A) FEE-FOR-SERVICE ENROLLEES MAY RECEIVE COVERAGE THROUGH A PRESCRIPTION DRUG PLAN.—A part D eligible individual who is not enrolled in an MA plan may obtain qualified prescription drug coverage through enrollment in a prescription drug plan (as defined in section 1860D–41(a)(14)).

''(B) MEDICARE ADVANTAGE ENROLLEES.—

''(i) ENROLLEES IN A PLAN PROVIDING QUALIFIED PRESCRIPTION DRUG COVERAGE RECEIVE COVERAGE THROUGH THE PLAN.—A part D eligible individual who is enrolled in an MA–PD plan obtains such coverage through such plan.

''(ii) LIMITATION ON ENROLLMENT OF MA PLAN ENROLLEES IN PRESCRIPTION DRUG PLANS.—Except as provided in clauses (iii) and (iv), a part D eligible individual who is enrolled in an MA plan may not enroll in a prescription drug plan under this part.

''(iii) PRIVATE FEE-FOR-SERVICE ENROLLEES IN MA PLANS NOT PROVIDING QUALIFIED PRESCRIPTION DRUG COVERAGE PERMITTED TO ENROLL IN A PRESCRIPTION DRUG PLAN.—A part D eligible individual who is enrolled in an MA private fee-for-service plan (as defined in section 1859(b)(2))

that does not provide qualified prescription drug coverage may obtain qualified prescription drug coverage through enrollment in a prescription drug plan.

''(iv) ENROLLEES IN MSA PLANS PERMITTED TO ENROLL IN A PRESCRIPTION DRUG PLAN.—A part D eligible individual who is enrolled in an MSA plan (as defined in section 1859(b)(3)) may obtain qualified prescription drug coverage through enrollment in a prescription drug plan.

''(2) COVERAGE FIRST EFFECTIVE JANUARY 1, 2006.—Coverage under prescription drug plans and MA–PD plans shall first be effective on January 1, 2006.

''(3) DEFINITIONS.—For purposes of this part:

''(A) PART D ELIGIBLE INDIVIDUAL.—The term 'part D eligible individual' means an individual who is entitled to benefits under part A or enrolled under part B.

''(B) MA PLAN.—The term 'MA plan' has the meaning given such term in section 1859(b)(1).

''(C) MA–PD PLAN.—The term 'MA–PD plan' means an MA plan that provides qualified prescription drug coverage.

''(b) ENROLLMENT PROCESS FOR PRESCRIPTION DRUG PLANS.—

''(1) ESTABLISHMENT OF PROCESS.—

''(A) IN GENERAL.—The Secretary shall establish a process for the enrollment, disenrollment, termination, and change of enrollment of part D eligible individuals in prescription drug plans consistent with this subsection.

''(B) APPLICATION OF MA RULES.—In establishing such process, the Secretary shall use rules similar to (and coordinated with) the rules for enrollment, disenrollment, termination, and change of enrollment with an MA–PD plan under the following provisions of section 1851:

''(i) RESIDENCE REQUIREMENTS.—Section 1851(b)(1)(A), relating to residence requirements.

''(ii) EXERCISE OF CHOICE.—Section 1851(c) (other than paragraph (3)(A) of such section), relating to exercise of choice.

''(iii) COVERAGE ELECTION PERIODS.—Subject to paragraphs (2) and (3) of this subsection, section 1851(e) (other than subparagraphs (B) and (C) of paragraph (2) and the second sentence of paragraph (4) of such section), relating to coverage election periods, including initial periods, annual coordinated election periods, special election periods, and election periods for exceptional circumstances.

''(iv) COVERAGE PERIODS.—Section 1851(f), relating to effectiveness of elections and changes of elections.

''(v) GUARANTEED ISSUE AND RENEWAL.—Section 1851(g) (other than paragraph (2) of such section and clause (i) and the second sentence of clause (ii) of paragraph (3)(C) of such section), relating to guaranteed issue and renewal.

''(vi) MARKETING MATERIAL AND APPLICATION FORMS.—Section 1851(h), relating to approval of marketing material and application forms.

In applying clauses (ii), (iv), and (v) of this subparagraph, any reference to section 1851(e) shall be treated as a reference to such section as applied pursuant to clause (iii) of this subparagraph.

''(C) SPECIAL RULE.—The process established under subparagraph (A) shall include, in the case of a part D eligible individual who is a full-benefit dual eligible individual (as defined in section 1935(c)(6)) who has failed to enroll in a prescription drug plan or an MA–PD plan, for the enrollment in a prescription drug plan that has a monthly beneficiary premium that does not exceed the premium assistance available under section 1860D–14(a)(1)(A)). If there is more than one such plan available, the Secretary shall enroll such an individual on a random basis among all such plans in the PDP region. Nothing in the previous sentence shall prevent such an individual from declining or changing such enrollment.

''(2) INITIAL ENROLLMENT PERIOD.—

''(A) PROGRAM INITIATION.—In the case of an individual who is a part D eligible individual as of November 15, 2005, there shall be an initial enrollment period that shall be the same as the annual, coordinated open election period described in section 1851(e)(3)(B)(iii), as applied under paragraph (1)(B)(iii).

''(B) CONTINUING PERIODS.—In the case of an individual who becomes a part D eligible individual after November 15, 2005, there shall be an initial enrollment period which is the period under section 1851(e)(1), as applied under paragraph (1)(B)(iii) of this section, as if 'entitled to benefits under part A or enrolled under part B' were substituted for 'entitled to benefits under part A and enrolled under part B', but in no case shall such period end before the period described in subparagraph (A).

''(3) ADDITIONAL SPECIAL ENROLLMENT PERIODS.—The Secretary shall establish special enrollment periods, including the following:

''(A) INVOLUNTARY LOSS OF CREDITABLE PRESCRIPTION DRUG COVERAGE.—

''(i) IN GENERAL.—In the case of a part D eligible individual who involuntarily loses creditable prescription drug coverage (as defined in section 1860D–13(b)(4)).

''(ii) NOTICE.—In establishing special enrollment periods under clause (i), the Secretary shall take into account when the part D eligible individuals are provided notice of the loss of creditable prescription drug coverage.

''(iii) FAILURE TO PAY PREMIUM.—For purposes of clause (i), a loss of coverage shall be treated as voluntary if the coverage is terminated because of failure to pay a required beneficiary premium.

''(iv) REDUCTION IN COVERAGE.—For purposes of clause (i), a reduction in coverage so that the coverage no longer meets the requirements under section 1860D–13(b)(5) (relating to actuarial equivalence) shall be treated as an involuntary loss of coverage.

''(B) ERRORS IN ENROLLMENT.—In the case described in section 1837(h) (relating to errors in enrollment), in the same manner as such section applies to part B.

''(C) EXCEPTIONAL CIRCUMSTANCES.—In the case of part D eligible individuals who meet such exceptional conditions (in addition to those conditions applied under paragraph (1)(B)(iii)) as the Secretary may provide.

''(D) MEDICAID COVERAGE.—In the case of an individual (as determined by the Secretary) who is a full-benefit dual eligible individual (as defined in section 1935(c)(6)).

''(E) DISCONTINUANCE OF MA–PD ELECTION DURING FIRST YEAR OF ELIGIBILITY.—In the case of a part D eligible individual who discontinues enrollment in an MA–PD plan under the second sentence of section 1851(e)(4) at the time of the election of coverage under such sentence under the original medicare fee-for-service program.

''(4) INFORMATION TO FACILITATE ENROLLMENT.—

''(A) IN GENERAL.—Notwithstanding any other provision of law but subject to subparagraph (B), the Secretary may provide to each PDP sponsor and MA organization such identifying information about part D eligible individuals as the Secretary determines to be necessary to facilitate efficient marketing of prescription drug plans and MA–PD plans to such individuals and enrollment of such individuals in such plans.

''(B) LIMITATION.—

''(i) PROVISION OF INFORMATION.—The Secretary may provide the information under subparagraph (A) only to the extent necessary to carry out such subparagraph.

''(ii) USE OF INFORMATION.—Such information provided by the Secretary to a PDP sponsor or an MA organization may be used by such sponsor or organization only to facilitate marketing of, and enrollment of part D eligible individuals in, prescription drug plans and MA–PD plans.

''(5) REFERENCE TO ENROLLMENT PROCEDURES FOR MA–PD PLANS.—For rules applicable to enrollment, disenrollment, termination, and change of enrollment of part D eligible individuals in MA–PD plans, see section 1851.

''(6) REFERENCE TO PENALTIES FOR LATE ENROLLMENT.—Section 1860D–13(b) imposes a late enrollment penalty for part D eligible individuals who—

''(A) enroll in a prescription drug plan or an MA–PD plan after the initial enrollment period described in paragraph (2); and

''(B) fail to maintain continuous creditable prescription drug coverage during the period of non-enrollment.

''(c) PROVIDING INFORMATION TO BENEFICIARIES.—

''(1) ACTIVITIES.—The Secretary shall conduct activities that are designed to broadly disseminate information to part D eligible individuals (and prospective part D eligible individuals) regarding the coverage provided under this part. Such activities shall ensure that such information is first made available at least 30 days prior to the initial enrollment period described in subsection (b)(2)(A).

''(2) REQUIREMENTS.—The activities described in paragraph (1) shall—

''(A) be similar to the activities performed by the Secretary under section 1851(d), including dissemination (including through the toll-free telephone number 1–800–MEDICARE) of comparative information for prescription drug plans and MA–PD plans; and

''(B) be coordinated with the activities performed by the Secretary under such section and under section 1804.

''(3) COMPARATIVE INFORMATION.—

''(A) IN GENERAL.—Subject to subparagraph (B), the comparative information referred to in paragraph (2)(A) shall include a comparison of the following with respect to qualified prescription drug coverage:

''(i) BENEFITS.—The benefits provided under the plan.

''(ii) MONTHLY BENEFICIARY PREMIUM.—The monthly beneficiary premium under the plan.

''(iii) QUALITY AND PERFORMANCE.—The quality and performance under the plan.

''(iv) BENEFICIARY COST-SHARING.—The cost-sharing required of part D eligible individuals under the plan.

''(v) CONSUMER SATISFACTION SURVEYS.—The results of consumer satisfaction surveys regarding the plan conducted pursuant to section 1860D–4(d).

''(B) EXCEPTION FOR UNAVAILABILITY OF INFORMATION.—The Secretary is not required to provide comparative information under clauses (iii) and (v) of subparagraph (A) with respect to a plan—

''(i) for the first plan year in which it is offered; and

''(ii) for the next plan year if it is impracticable or the information is otherwise unavailable.

''(4) INFORMATION ON LATE ENROLLMENT PENALTY.—The information disseminated under paragraph (1) shall include information concerning the methodology for determining the late enrollment penalty under section 1860D–13(b).

''PRESCRIPTION DRUG BENEFITS

''SEC. 1860D–2. (a) REQUIREMENTS.—

''(1) IN GENERAL.—For purposes of this part and part C, the term 'qualified prescription drug coverage' means either of the following:

''(A) STANDARD PRESCRIPTION DRUG COVERAGE WITH ACCESS TO NEGOTIATED PRICES.—Standard prescription drug coverage (as defined in subsection (b)) and access to negotiated prices under subsection (d).

''(B) ALTERNATIVE PRESCRIPTION DRUG COVERAGE WITH AT LEAST ACTUARIALLY EQUIVALENT BENEFITS AND ACCESS TO NEGOTIATED PRICES.—Coverage of covered part D drugs which meets the alternative prescription drug coverage requirements of subsection (c) and access to negotiated prices under subsection (d), but only if the benefit design of such coverage is approved by the Secretary, as provided under subsection (c).

''(2) PERMITTING SUPPLEMENTAL PRESCRIPTION DRUG COVERAGE.—

''(A) IN GENERAL.—Subject to subparagraph (B), qualified prescription drug coverage may include supplemental prescription drug coverage consisting of either or both of the following:

''(i) CERTAIN REDUCTIONS IN COST-SHARING.—

''(I) IN GENERAL.—A reduction in the annual deductible, a reduction in the coinsurance percentage, or an increase in the initial coverage limit with respect to covered part D drugs, or any combination thereof, insofar as such a reduction or increase increases the actuarial value of benefits above the actuarial value of basic prescription drug coverage.

''(II) CONSTRUCTION.—Nothing in this paragraph shall be construed as affecting the application of subsection (c)(3).

''(ii) OPTIONAL DRUGS.—Coverage of any product that would be a covered part D drug but for the application of subsection (e)(2)(A).

''(B) REQUIREMENT.—A PDP sponsor may not offer a prescription drug plan that provides supplemental prescription drug coverage pursuant to subparagraph (A) in an area unless the sponsor also offers a prescription drug plan in the area that only provides basic prescription drug coverage.

''(3) BASIC PRESCRIPTION DRUG COVERAGE.—For purposes of this part and part C, the term 'basic prescription drug coverage' means either of the following:

''(A) Coverage that meets the requirements of paragraph (1)(A).

''(B) Coverage that meets the requirements of paragraph (1)(B) but does not have any supplemental prescription drug coverage described in paragraph (2)(A).

''(4) APPLICATION OF SECONDARY PAYOR PROVISIONS.—The provisions of section 1852(a)(4) shall apply under this part in the same manner as they apply under part C.

''(5) CONSTRUCTION.—Nothing in this subsection shall be construed as changing the computation of incurred costs under subsection (b)(4).

''(b) STANDARD PRESCRIPTION DRUG COVERAGE.—For purposes of this part and part C, the term 'standard prescription drug coverage' means coverage of covered part D drugs that meets the following requirements:

''(1) DEDUCTIBLE.—

''(A) IN GENERAL.—The coverage has an annual deductible—

''(i) for 2006, that is equal to $250; or

''(ii) for a subsequent year, that is equal to the amount specified under this paragraph for the previous year increased by the percentage specified in paragraph (6) for the year involved.

''(B) ROUNDING.—Any amount determined under subparagraph (A)(ii) that is not a multiple of $5 shall be rounded to the nearest multiple of $5.

''(2) BENEFIT STRUCTURE.—

''(A) 25 PERCENT COINSURANCE.—The coverage has coinsurance (for costs above the annual deductible specified in paragraph (1) and up to the initial coverage limit under paragraph (3)) that is—

''(i) equal to 25 percent; or

''(ii) actuarially equivalent (using processes and methods established under section 1860D–11(c)) to an average expected payment of 25 percent of such costs.

''(B) USE OF TIERS.—Nothing in this part shall be construed as preventing a PDP sponsor or an MA organization from applying tiered copayments under a plan, so long as such tiered copayments are consistent with subparagraph (A)(ii).

''(3) INITIAL COVERAGE LIMIT.—

''(A) IN GENERAL.—Except as provided in paragraph (4), the coverage has an initial coverage limit on the maximum costs that may be recognized for payment purposes (including the annual deductible)—

''(i) for 2006, that is equal to $2,250; or

''(ii) for a subsequent year, that is equal to the amount specified in this paragraph for the previous year, increased by the annual percentage increase described in paragraph (6) for the year involved.

''(B) ROUNDING.—Any amount determined under subparagraph (A)(ii) that is not a multiple of $10 shall be rounded to the nearest multiple of $10.

''(4) PROTECTION AGAINST HIGH OUT-OF-POCKET EXPENDITURES.—

''(A) IN GENERAL.—

''(i) IN GENERAL.—The coverage provides benefits, after the part D eligible individual has incurred costs (as described in subparagraph (C)) for covered part D drugs in a year equal to the annual out-of-pocket threshold specified in subparagraph (B), with cost-sharing that is equal to the greater of—

''(I) a copayment of $2 for a generic drug or a preferred drug that is a multiple source drug (as defined in section 1927(k)(7)(A)(i)) and $5 for any other drug; or

''(II) coinsurance that is equal to 5 percent.

''(ii) ADJUSTMENT OF AMOUNT.—For a year after 2006, the dollar amounts specified in clause (i)(I) shall be equal to the dollar amounts specified in this subparagraph for the previous year, increased by the annual percentage increase described in paragraph (6) for the year involved. Any amount established under this clause that is not a multiple of a 5 cents shall be rounded to the nearest multiple of 5 cents.

''(B) ANNUAL OUT-OF-POCKET THRESHOLD.—

''(i) IN GENERAL.—For purposes of this part, the 'annual out-of-pocket threshold' specified in this subparagraph—

''(I) for 2006, is equal to $3,600; or

''(II) for a subsequent year, is equal to the amount specified in this subparagraph for the previous year, increased by the annual percentage increase described in paragraph (6) for the year involved.

''(ii) ROUNDING.—Any amount determined under clause (i)(II) that is not a multiple of $50 shall be rounded to the nearest multiple of $50.

''(C) APPLICATION.—In applying subparagraph (A)—

''(i) incurred costs shall only include costs incurred with respect to covered part D drugs for the annual deductible described in paragraph (1), for cost-sharing described in paragraph (2), and for amounts for which benefits are not provided because of the application of the initial coverage limit described in paragraph (3), but does not include any costs incurred for covered part D drugs which are not included (or treated as being included) in the plan's formulary; and

''(ii) such costs shall be treated as incurred only if they are paid by the part D eligible individual (or by another person, such as a family member, on behalf of the individual), under section 1860D–14, or under a State Pharmaceutical Assistance Program and the part D eligible individual (or other person) is not reimbursed through insurance or otherwise, a group health plan, or other third-party payment arrangement (other than under such section or such a Program) for such costs.

''(D) INFORMATION REGARDING THIRD-PARTY REIMBURSEMENT.—

''(i) PROCEDURES FOR EXCHANGING INFORMATION.—In order to accurately apply the requirements of subparagraph (C)(ii), the Secretary is authorized to establish procedures, in coordination with the Secretary of the Treasury and the Secretary of Labor—

''(I) for determining whether costs for part D eligible individuals are being reimbursed through insurance or otherwise, a group health plan, or other third-party payment arrangement; and

''(II) for alerting the PDP sponsors and MA organizations that offer the prescription drug plans and MA–PD plans in which such individuals are enrolled about such reimbursement arrangements.

''(ii) AUTHORITY TO REQUEST INFORMATION FROM ENROLLEES.—A PDP sponsor or an MA organization may periodically ask part D eligible individuals enrolled in a prescription drug plan or an MA–PD plan offered by the sponsor or organization whether such individuals have or expect to receive such third-party reimbursement. A material misrepresentation of the information described in the preceding sentence by an individual (as defined in standards set by the Secretary and determined through a process established by the Secretary) shall constitute grounds for termination of enrollment in any plan under section 1851(g)(3)(B) (and as applied under this part under section 1860D–1(b)(1)(B)(v)) for a period specified by the Secretary.

''(5) CONSTRUCTION.—Nothing in this part shall be construed as preventing a PDP sponsor or an MA organization offering an MA–PD plan from reducing to 0 the cost-sharing otherwise applicable to preferred or generic drugs.

''(6) ANNUAL PERCENTAGE INCREASE.—The annual percentage increase specified in this paragraph for a year is equal to the annual percentage increase in average per capita aggregate expenditures for covered part D drugs in the United States for part D eligible individuals, as determined by the Secretary for the 12-month period ending in July of the previous year using such methods as the Secretary shall specify.

''(c) ALTERNATIVE PRESCRIPTION DRUG COVERAGE REQUIREMENTS.—A prescription drug plan or an MA–PD plan may provide a different prescription drug benefit design from standard prescription drug coverage so long as the Secretary determines (consistent with section 1860D–11(c)) that the following requirements are met and the plan applies for, and receives, the approval of the Secretary for such benefit design:

''(1) ASSURING AT LEAST ACTUARIALLY EQUIVALENT COVERAGE.—

''(A) ASSURING EQUIVALENT VALUE OF TOTAL COVERAGE.—The actuarial value of the total coverage is at least equal to the actuarial value of standard prescription drug coverage.

''(B) ASSURING EQUIVALENT UNSUBSIDIZED VALUE OF COVERAGE.—The unsubsidized value of the coverage is at least equal to the unsubsidized value of standard prescription drug coverage. For purposes of this subparagraph, the unsubsidized value of coverage is the amount by which the actuarial value of the coverage exceeds the actuarial value of the subsidy payments under section 1860D–15 with respect to such coverage.

''(C) ASSURING STANDARD PAYMENT FOR COSTS AT INITIAL COVERAGE LIMIT.—The coverage is designed, based upon an actuarially representative pattern of utilization, to provide for the payment, with respect to costs incurred that are equal to the initial coverage limit under subsection (b)(3) for the year, of an amount equal to at least the product of—

''(i) the amount by which the initial coverage limit described in subsection (b)(3) for the year exceeds the deductible described in subsection (b)(1) for the year; and

''(ii) 100 percent minus the coinsurance percentage specified in subsection (b)(2)(A)(i).

''(2) MAXIMUM REQUIRED DEDUCTIBLE.—The deductible under the coverage shall not exceed the deductible amount specified under subsection (b)(1) for the year.

''(3) SAME PROTECTION AGAINST HIGH OUT-OF-POCKET EXPENDITURES.—The coverage provides the coverage required under subsection (b)(4).

''(d) ACCESS TO NEGOTIATED PRICES.—

''(1) ACCESS.—

''(A) IN GENERAL.—Under qualified prescription drug coverage offered by a PDP sponsor offering a prescription drug plan or an MA organization offering an MA–PD plan, the sponsor or organization shall provide enrollees with access to negotiated prices used for payment for covered part D drugs, regardless of the fact that no benefits may be payable under the coverage with respect to such drugs because of the application of a deductible or other cost-sharing or an initial coverage limit (described in subsection (b)(3)).

''(B) NEGOTIATED PRICES.—For purposes of this part, negotiated prices shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs, and include any dispensing fees for such drugs.

''(C) MEDICAID-RELATED PROVISIONS.—The prices negotiated by a prescription drug plan, by an MA–PD plan with respect to covered part D drugs, or by a qualified retiree prescription drug plan (as defined in section 1860D–22(a)(2)) with respect to such drugs on behalf of part D eligible individuals, shall (notwithstanding any other provision of law) not be taken into account for the purposes of establishing the best price under section 1927(c)(1)(C).

''(2) DISCLOSURE.—A PDP sponsor offering a prescription drug plan or an MA organization offering an MA–PD plan shall disclose to the Secretary (in a manner specified by the Secretary) the aggregate negotiated price concessions described in paragraph (1)(B) made available to the sponsor or organization by a manufacturer which are passed through in the form of lower subsidies, lower monthly beneficiary prescription drug premiums, and lower prices through pharmacies and other dispensers. The provisions of section 1927(b)(3)(D) apply to information disclosed to the Secretary under this paragraph.

''(3) AUDITS.—To protect against fraud and abuse and to ensure proper disclosures and accounting under this part and in accordance with section 1857(d)(2)(B) (as applied under section 1860D–12(b)(3)(C)), the Secretary may conduct periodic audits, directly or through contracts, of the financial statements and records of PDP sponsors with respect to prescription drug plans and MA organizations with respect to MA–PD plans.

''(e) COVERED PART D DRUG DEFINED.—

''(1) IN GENERAL.—Except as provided in this subsection, for purposes of this part, the term 'covered part D drug' means—

''(A) a drug that may be dispensed only upon a prescription and that is described in subparagraph (A)(i), (A)(ii), or (A)(iii) of section 1927(k)(2); or

''(B) a biological product described in clauses (i) through (iii) of subparagraph (B) of such section or insulin described in subparagraph (C) of such section and medical supplies associated with the injection of insulin (as defined in regulations of the Secretary),

and such term includes a vaccine licensed under section 351 of the Public Health Service Act and any use of a covered part D drug for a medically accepted indication (as defined in section 1927(k)(6)).

''(2) EXCLUSIONS.—

''(A) IN GENERAL.—Such term does not include drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under section 1927(d)(2), other than subparagraph (E) of such section (relating to smoking cessation agents), or under section 1927(d)(3).

''(B) MEDICARE COVERED DRUGS.—A drug prescribed for a part D eligible individual that would otherwise be a covered part D drug under this part shall not be so considered if payment for such drug as so prescribed and dispensed or administered with respect to that individual is available (or would be available but for the application of a deductible) under part A or B for that individual.

''(3) APPLICATION OF GENERAL EXCLUSION PROVISIONS.—A prescription drug plan or an MA–PD plan may exclude from qualified prescription drug coverage any covered part D drug—

''(A) for which payment would not be made if section 1862(a) applied to this part; or

''(B) which is not prescribed in accordance with the plan or this part.

Such exclusions are determinations subject to reconsideration and appeal pursuant to subsections (g) and (h), respectively, of section 1860D–4.

''ACCESS TO A CHOICE OF QUALIFIED PRESCRIPTION DRUG COVERAGE

''SEC. 1860D–3. (a) ASSURING ACCESS TO A CHOICE OF COVERAGE.—

''(1) CHOICE OF AT LEAST TWO PLANS IN EACH AREA.—The Secretary shall ensure that each part D eligible individual has available, consistent with paragraph (2), a choice of enrollment in at least 2 qualifying plans (as defined in paragraph (3)) in the area in which the individual resides, at least one of which is a prescription drug plan. In any such case in which such plans are not available, the part D eligible individual shall be given the opportunity to enroll in a fallback prescription drug plan.

''(2) REQUIREMENT FOR DIFFERENT PLAN SPONSORS.—The requirement in paragraph (1) is not satisfied with respect to an area if only one entity offers all the qualifying plans in the area.

''(3) QUALIFYING PLAN DEFINED.—For purposes of this section, the term 'qualifying plan' means—

''(A) a prescription drug plan; or

''(B) an MA–PD plan described in section 1851(a)(2)(A)(i) that provides—

''(i) basic prescription drug coverage; or

''(ii) qualified prescription drug coverage that provides supplemental prescription drug coverage so long as there is no MA monthly supplemental beneficiary premium applied under the plan, due to the application of a credit against such premium of a rebate under section 1854(b)(1)(C).

''(b) FLEXIBILITY IN RISK ASSUMED AND APPLICATION OF FALLBACK PLAN.—In order to ensure access pursuant to subsection (a) in an area—

''(1) the Secretary may approve limited risk plans under section 1860D–11(f) for the area; and

''(2) only if such access is still not provided in the area after applying paragraph (1), the Secretary shall provide for the offering of a fallback prescription drug plan for that area under section 1860D–11(g).

''BENEFICIARY PROTECTIONS FOR QUALIFIED PRESCRIPTION DRUG COVERAGE

''SEC. 1860D–4. (a) DISSEMINATION OF INFORMATION.—

''(1) GENERAL INFORMATION.—

''(A) APPLICATION OF MA INFORMATION.—A PDP sponsor shall disclose, in a clear, accurate, and standardized form to each enrollee with a prescription drug plan offered by the sponsor under this part at the time of enrollment and at least annually thereafter, the information described in section 1852(c)(1) relating to such plan, insofar as the Secretary determines appropriate with respect to benefits provided under this part, and including the information described in subparagraph (B).

''(B) DRUG SPECIFIC INFORMATION.—The information described in this subparagraph is information concerning the following:

''(i) Access to specific covered part D drugs, including access through pharmacy networks.

''(ii) How any formulary (including any tiered formulary structure) used by the sponsor functions, including a description of how a part D eligible individual may obtain information on the formulary consistent with paragraph (3).

''(iii) Beneficiary cost-sharing requirements and how a part D eligible individual may obtain information on such requirements, including tiered or other copayment level applicable to each drug (or class of drugs), consistent with paragraph (3).

''(iv) The medication therapy management program required under subsection (c).

''(2) DISCLOSURE UPON REQUEST OF GENERAL COVERAGE, UTILIZATION, AND GRIEVANCE INFORMATION.—Upon request of a part D eligible individual who is eligible to enroll in a prescription drug plan, the PDP sponsor offering such plan shall provide information similar (as determined by the Secretary) to the information described in subparagraphs (A), (B), and (C) of section 1852(c)(2) to such individual.

''(3) PROVISION OF SPECIFIC INFORMATION.—

''(A) RESPONSE TO BENEFICIARY QUESTIONS.—Each PDP sponsor offering a prescription drug plan shall have a mechanism for providing specific information on a timely basis to enrollees upon request. Such mechanism shall include access to information through the use of a toll-free telephone number and, upon request, the provision of such information in writing.

''(B) AVAILABILITY OF INFORMATION ON CHANGES IN FORMULARY THROUGH THE INTERNET.—A PDP sponsor offering a prescription drug plan shall make available on a timely basis through an Internet website information on specific changes in the formulary under the plan (including changes to tiered or preferred status of covered part D drugs).

''(4) CLAIMS INFORMATION.—A PDP sponsor offering a prescription drug plan must furnish to each enrollee in a form easily understandable to such enrollees—

''(A) an explanation of benefits (in accordance with section 1806(a) or in a comparable manner); and

''(B) when prescription drug benefits are provided under this part, a notice of the benefits in relation to—

''(i) the initial coverage limit for the current year; and

''(ii) the annual out-of-pocket threshold for the current year.

Notices under subparagraph (B) need not be provided more often than as specified by the Secretary and notices under subparagraph (B)(ii) shall take into account the application of section 1860D–2(b)(4)(C) to the extent practicable, as specified by the Secretary.

''(b) ACCESS TO COVERED PART D DRUGS.—

''(1) ASSURING PHARMACY ACCESS.—

''(A) PARTICIPATION OF ANY WILLING PHARMACY.—A prescription drug plan shall permit the participation of any pharmacy that meets the terms and conditions under the plan.

''(B) DISCOUNTS ALLOWED FOR NETWORK PHARMACIES.—For covered part D drugs dispensed through in-network pharmacies, a prescription drug plan may, notwithstanding subparagraph (A), reduce coinsurance or copayments for part D eligible individuals enrolled in the plan below the level otherwise required. In no case shall such a reduction result in an increase in payments made by the Secretary under section 1860D–15 to a plan.

''(C) CONVENIENT ACCESS FOR NETWORK PHARMACIES.—

''(i) IN GENERAL.—The PDP sponsor of the prescription drug plan shall secure the participation in its network of a sufficient number of pharmacies that dispense (other than by mail order) drugs directly to patients to ensure convenient access (consistent with rules established by the Secretary).

''(ii) APPLICATION OF TRICARE STANDARDS.—The Secretary shall establish rules for convenient access to in-network pharmacies under this subparagraph that are no less favorable to enrollees than the rules for convenient access to pharmacies included in the statement of work of solicitation (#MDA906–03–R–0002) of the Department of Defense under the TRICARE Retail Pharmacy (TRRx) as of March 13, 2003.

''(iii) ADEQUATE EMERGENCY ACCESS.—Such rules shall include adequate emergency access for enrollees.

''(iv) CONVENIENT ACCESS IN LONG-TERM CARE FACILITIES.—Such rules may include standards with respect to access for enrollees who are residing in long-term care facilities and for pharmacies operated by the Indian Health Service, Indian tribes and tribal organizations, and urban Indian organizations (as defined in section 4 of the Indian Health Care Improvement Act).

''(D) LEVEL PLAYING FIELD.—Such a sponsor shall permit enrollees to receive benefits (which may include a 90-day supply of drugs or

biologicals) through a pharmacy (other than a mail order pharmacy), with any differential in charge paid by such enrollees.

''(E) NOT REQUIRED TO ACCEPT INSURANCE RISK.—The terms and conditions under subparagraph (A) may not require participating pharmacies to accept insurance risk as a condition of participation.

''(2) USE OF STANDARDIZED TECHNOLOGY.—

''(A) IN GENERAL.—The PDP sponsor of a prescription drug plan shall issue (and reissue, as appropriate) such a card (or other technology) that may be used by an enrollee to assure access to negotiated prices under section 1860D–2(d).

''(B) STANDARDS.—

''(i) IN GENERAL.—The Secretary shall provide for the development, adoption, or recognition of standards relating to a standardized format for the card or other technology required under subparagraph (A). Such standards shall be compatible with part C of title XI and may be based on standards developed by an appropriate standard setting organization.

''(ii) CONSULTATION.—In developing the standards under clause (i), the Secretary shall consult with the National Council for Prescription Drug Programs and other standard setting organizations determined appropriate by the Secretary.

''(iii) IMPLEMENTATION.—The Secretary shall develop, adopt, or recognize the standards under clause (i) by such date as the Secretary determines shall be sufficient to ensure that PDP sponsors utilize such standards beginning January 1, 2006.

''(3) REQUIREMENTS ON DEVELOPMENT AND APPLICATION OF FORMULARIES.—If a PDP sponsor of a prescription drug plan uses a formulary (including the use of tiered cost-sharing), the following requirements must be met:

''(A) DEVELOPMENT AND REVISION BY A PHARMACY AND THERAPEUTIC (P&T) COMMITTEE.—

''(i) IN GENERAL.—The formulary must be developed and reviewed by a pharmacy and therapeutic committee. A majority of the members of such committee shall consist of individuals who are practicing physicians or practicing pharmacists (or both).

''(ii) INCLUSION OF INDEPENDENT EXPERTS.—Such committee shall include at least one practicing physician and at least one practicing pharmacist, each of whom—

''(I) is independent and free of conflict with respect to the sponsor and plan; and

''(II) has expertise in the care of elderly or disabled persons.

''(B) FORMULARY DEVELOPMENT.—In developing and reviewing the formulary, the committee shall—

''(i) base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, such as randomized clinical trials, pharmacoeconomic studies, outcomes research data, and on such other information as the committee determines to be appropriate; and

''(ii) take into account whether including in the formulary (or in a tier in such formulary) particular covered part D drugs has therapeutic advantages in terms of safety and efficacy.

''(C) INCLUSION OF DRUGS IN ALL THERAPEUTIC CATEGORIES AND CLASSES.—

''(i) IN GENERAL.—The formulary must include drugs within each therapeutic category and class of covered part D drugs, although not necessarily all drugs within such categories and classes.

''(ii) MODEL GUIDELINES.—The Secretary shall request the United States Pharmacopeia to develop, in consultation with pharmaceutical benefit managers and other interested parties, a list of categories and classes that may be used by prescription drug plans under this paragraph and to revise such classification from time to time to reflect changes in therapeutic uses of covered part D drugs and the additions of new covered part D drugs.

''(iii) LIMITATION ON CHANGES IN THERAPEUTIC CLASSIFICATION.—The PDP sponsor of a prescription drug plan may not change the therapeutic categories and classes in a formulary other than at the beginning of each plan year except as the Secretary may permit to take into account new therapeutic uses and newly approved covered part D drugs.

''(D) PROVIDER AND PATIENT EDUCATION.—The PDP sponsor shall establish policies and procedures to educate and inform health care providers and enrollees concerning the formulary.

''(E) NOTICE BEFORE REMOVING DRUG FROM FORMULARY OR CHANGING PREFERRED OR TIER STATUS OF DRUG.—Any removal of a covered part D drug from a formulary and any change in the preferred or tiered cost-sharing status of such a drug shall take effect only after appropriate notice is made available (such as under subsection (a)(3)) to the Secretary, affected enrollees, physicians, pharmacies, and pharmacists.

''(F) PERIODIC EVALUATION OF PROTOCOLS.—In connection with the formulary, the sponsor of a prescription drug plan shall provide for the periodic evaluation and analysis of treatment protocols and procedures.

The requirements of this paragraph may be met by a PDP sponsor directly or through arrangements with another entity.

''(c) COST AND UTILIZATION MANAGEMENT; QUALITY ASSURANCE; MEDICATION THERAPY MANAGEMENT PROGRAM.—

''(1) IN GENERAL.—The PDP sponsor shall have in place, directly or through appropriate arrangements, with respect to covered part D drugs, the following:

''(A) A cost-effective drug utilization management program, including incentives to reduce costs when medically appropriate, such as through the use of multiple source drugs (as defined in section 1927(k)(7)(A)(i)).

''(B) Quality assurance measures and systems to reduce medication errors and adverse drug interactions and improve medication use.

''(C) A medication therapy management program described in paragraph (2).

''(D) A program to control fraud, abuse, and waste.

Nothing in this section shall be construed as impairing a PDP sponsor from utilizing cost management tools (including differential payments) under all methods of operation.

''(2) MEDICATION THERAPY MANAGEMENT PROGRAM.—

''(A) DESCRIPTION.—

''(i) IN GENERAL.—A medication therapy management program described in this paragraph is a program of drug therapy management that may be furnished by a pharmacist and that is designed to assure, with respect to targeted beneficiaries described in clause (ii), that covered part D drugs under the prescription drug plan are appropriately used to optimize therapeutic outcomes through improved medication use, and to reduce the risk of adverse events, including adverse drug interactions. Such a program may distinguish between services in ambulatory and institutional settings.

''(ii) TARGETED BENEFICIARIES DESCRIBED.—Targeted beneficiaries described in this clause are part D eligible individuals who—

''(I) have multiple chronic diseases (such as diabetes, asthma, hypertension, hyperlipidemia, and congestive heart failure);

''(II) are taking multiple covered part D drugs; and

''(III) are identified as likely to incur annual costs for covered part D drugs that exceed a level specified by the Secretary.

''(B) ELEMENTS.—Such program may include elements that promote—

''(i) enhanced enrollee understanding to promote the appropriate use of medications by enrollees and to reduce the risk of potential adverse events associated with medications, through beneficiary education, counseling, and other appropriate means;

''(ii) increased enrollee adherence with prescription medication regimens through medication refill reminders, special packaging, and other compliance programs and other appropriate means; and

''(iii) detection of adverse drug events and patterns of overuse and underuse of prescription drugs.

''(C) DEVELOPMENT OF PROGRAM IN COOPERATION WITH LICENSED PHARMACISTS.—Such program shall be developed in cooperation with licensed and practicing pharmacists and physicians.

''(D) COORDINATION WITH CARE MANAGEMENT PLANS.—The Secretary shall establish guidelines for the coordination of any medication therapy management program under this paragraph with respect to a targeted beneficiary with any care management plan established with respect to such beneficiary under a chronic care improvement program under section 1807.

''(E) CONSIDERATIONS IN PHARMACY FEES.—The PDP sponsor of a prescription drug plan shall take into account, in establishing fees for pharmacists and others providing services under such plan, the resources used, and time required to, implement the medication therapy management program under this paragraph. Each such sponsor shall disclose to the Secretary upon request the amount of any such management or dispensing fees. The provisions of section 1927(b)(3)(D) apply to information disclosed under this subparagraph.

''(d) CONSUMER SATISFACTION SURVEYS.—In order to provide for comparative information under section 1860D–1(c)(3)(A)(v), the Secretary shall conduct consumer satisfaction surveys with respect to PDP sponsors and prescription drug plans in a manner similar to the manner such surveys are conducted for MA organizations and MA plans under part C.

''(e) ELECTRONIC PRESCRIPTION PROGRAM.—

''(1) APPLICATION OF STANDARDS.—As of such date as the Secretary may specify, but not later than 1 year after the date of promulgation of final standards under paragraph (4)(D), prescriptions and other information described in paragraph (2)(A) for covered part D drugs prescribed for part D eligible individuals that are transmitted electronically shall be transmitted only in accordance with such standards under an electronic prescription drug program that meets the requirements of paragraph (2).

''(2) PROGRAM REQUIREMENTS.—Consistent with uniform standards established under paragraph (3)—

''(A) PROVISION OF INFORMATION TO PRESCRIBING HEALTH CARE PROFESSIONAL AND DISPENSING PHARMACIES AND PHARMACISTS.—An electronic prescription drug program shall provide for the electronic transmittal to the prescribing health care professional and to the dispensing pharmacy and pharmacist of the prescription and information on eligibility and benefits (including the drugs included in the applicable formulary, any tiered formulary structure, and any requirements for prior authorization) and of the following information with respect to the prescribing and dispensing of a covered part D drug:

''(i) Information on the drug being prescribed or dispensed and other drugs listed on the medication history, including information on drug-drug interactions, warnings or cautions, and, when indicated, dosage adjustments.

''(ii) Information on the availability of lower cost, therapeutically appropriate alternatives (if any) for the drug prescribed.

''(B) APPLICATION TO MEDICAL HISTORY INFORMATION.—Effective on and after such date as the Secretary specifies and after the establishment of appropriate standards to carry out this subparagraph, the program shall provide for the electronic transmittal in a manner similar to the manner under subparagraph (A) of information that relates to the medical history concerning the individual and related to a covered part D drug being prescribed or dispensed, upon request of the professional or pharmacist involved.

''(C) LIMITATIONS.—Information shall only be disclosed under subparagraph (A) or (B) if the

disclosure of such information is permitted under the Federal regulations (concerning the privacy of individually identifiable health information) promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996.

''(D) TIMING.—To the extent feasible, the information exchanged under this paragraph shall be on an interactive, real-time basis.

''(3) STANDARDS.—

''(A) IN GENERAL.—The Secretary shall provide consistent with this subsection for the promulgation of uniform standards relating to the requirements for electronic prescription drug programs under paragraph (2).

''(B) OBJECTIVES.—Such standards shall be consistent with the objectives of improving—

''(i) patient safety;

''(ii) the quality of care provided to patients; and

''(iii) efficiencies, including cost savings, in the delivery of care.

''(C) DESIGN CRITERIA.—Such standards shall—

''(i) be designed so that, to the extent practicable, the standards do not impose an undue administrative burden on prescribing health care professionals and dispensing pharmacies and pharmacists;

''(ii) be compatible with standards established under part C of title XI, standards established under subsection (b)(2)(B)(i), and with general health information technology standards; and

''(iii) be designed so that they permit electronic exchange of drug labeling and drug listing information maintained by the Food and Drug Administration and the National Library of Medicine.

''(D) PERMITTING USE OF APPROPRIATE MESSAGING.—Such standards shall allow for the messaging of information only if it relates to the appropriate prescribing of drugs, including quality assurance measures and systems referred to in subsection (c)(1)(B).

''(E) PERMITTING PATIENT DESIGNATION OF DISPENSING PHARMACY.—

''(i) IN GENERAL.—Consistent with clause (ii), such standards shall permit a part D eligible individual to designate a particular pharmacy to dispense a prescribed drug.

''(ii) NO CHANGE IN BENEFITS.—Clause (i) shall not be construed as affecting—

''(I) the access required to be provided to pharmacies by a prescription drug plan; or

''(II) the application of any differences in benefits or payments under such a plan based on the pharmacy dispensing a covered part D drug.

''(4) DEVELOPMENT, PROMULGATION, AND MODIFICATION OF STANDARDS.—

''(A) INITIAL STANDARDS.—Not later than September 1, 2005, the Secretary shall develop, adopt, recognize, or modify initial uniform standards relating to the requirements for electronic prescription drug programs described in paragraph (2) taking into consideration the recommendations (if any) from the National Committee on Vital and Health Statistics (as established under section 306(k) of the Public Health Service Act (42 U.S.C. 242k(k))) under subparagraph (B).

''(B) ROLE OF NCVHS.—The National Committee on Vital and Health Statistics shall develop recommendations for uniform standards relating to such requirements in consultation with the following:

''(i) Standard setting organizations (as defined in section 1171(8))

''(ii) Practicing physicians.

''(iii) Hospitals.

''(iv) Pharmacies.

''(v) Practicing pharmacists.

''(vi) Pharmacy benefit managers.

''(vii) State boards of pharmacy.

''(viii) State boards of medicine.

''(ix) Experts on electronic prescribing.

''(x) Other appropriate Federal agencies.

''(C) PILOT PROJECT TO TEST INITIAL STANDARDS.—

''(i) IN GENERAL.—During the 1-year period that begins on January 1, 2006, the Secretary shall conduct a pilot project to test the initial standards developed under subparagraph (A) prior to the promulgation of the final uniform standards under subparagraph (D) in order to provide for the efficient implementation of the requirements described in paragraph (2).

''(ii) EXCEPTION.—Pilot testing of standards is not required under clause (i) where there already is adequate industry experience with such standards, as determined by the Secretary after consultation with effected standard setting organizations and industry users.

''(iii) VOLUNTARY PARTICIPATION OF PHYSICIANS AND PHARMACIES.—In order to conduct the pilot project under clause (i), the Secretary shall enter into agreements with physicians, physician groups, pharmacies, hospitals, PDP sponsors, MA organizations, and other appropriate entities under which health care professionals electronically transmit prescriptions to dispensing pharmacies and pharmacists in accordance with such standards.

''(iv) EVALUATION AND REPORT.—

''(I) EVALUATION.—The Secretary shall conduct an evaluation of the pilot project conducted under clause (i).

''(II) REPORT TO CONGRESS.—Not later than April 1, 2007, the Secretary shall submit to Congress a report on the evaluation conducted under subclause (I).

''(D) FINAL STANDARDS.—Based upon the evaluation of the pilot project under subparagraph (C)(iv)(I) and not later than April 1, 2008, the Secretary shall promulgate uniform standards relating to the requirements described in paragraph (2).

''(5) RELATION TO STATE LAWS.—The standards promulgated under this subsection shall supersede any State law or regulation that—

''(A) is contrary to the standards or restricts the ability to carry out this part; and

''(B) pertains to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to covered part D drugs under this part.

''(6) ESTABLISHMENT OF SAFE HARBOR.—The Secretary, in consultation with the Attorney General, shall promulgate regulations that provide for a safe harbor from sanctions under paragraphs (1) and (2) of section 1128B(b) and an exception to the prohibition under subsection (a)(1) of section 1877 with respect to the provision of nonmonetary remuneration (in the form of hardware, software, or information technology and training services) necessary and used solely to receive and transmit electronic prescription information in accordance with the standards promulgated under this subsection—

''(A) in the case of a hospital, by the hospital to members of its medical staff;

''(B) in the case of a group practice (as defined in section 1877(h)(4)), by the practice to prescribing health care professionals who are members of such practice; and

''(C) in the case of a PDP sponsor or MA organization, by the sponsor or organization to pharmacists and pharmacies participating in the network of such sponsor or organization, and to prescribing health care professionals.

''(f) GRIEVANCE MECHANISM.—Each PDP sponsor shall provide meaningful procedures for hearing and resolving grievances between the sponsor (including any entity or individual through which the sponsor provides covered benefits) and enrollees with prescription drug plans of the sponsor under this part in accordance with section 1852(f).

''(g) COVERAGE DETERMINATIONS AND RECONSIDERATIONS.—

''(1) APPLICATION OF COVERAGE DETERMINATION AND RECONSIDERATION PROVISIONS.—A PDP sponsor shall meet the requirements of paragraphs (1) through (3) of section 1852(g) with respect to covered benefits under the prescription drug plan it offers under this part in the same manner as such requirements apply to an MA organization with respect to benefits it offers under an MA plan under part C.

''(2) REQUEST FOR A DETERMINATION FOR THE TREATMENT OF TIERED FORMULARY DRUG.—In the case of a prescription drug plan offered by a PDP sponsor that provides for tiered cost-sharing for drugs included within a formulary and provides lower cost-sharing for preferred drugs included within the formulary, a part D eligible individual who is enrolled in the plan may request an exception to the tiered cost-sharing structure. Under such an exception, a non-preferred drug could be covered under the terms applicable for preferred drugs if the prescribing physician determines that the preferred drug for treatment of the same condition either would not be as effective for the individual or would have adverse effects for the individual or both. A PDP sponsor shall have an exceptions process under this paragraph consistent with guidelines established by the Secretary for making a determination with respect to such a request. Denial of such an exception shall be treated as a coverage denial for purposes of applying subsection (h).

''(h) APPEALS.—

''(1) IN GENERAL.—Subject to paragraph (2), a PDP sponsor shall meet the requirements of paragraphs (4) and (5) of section 1852(g) with respect to benefits (including a determination related to the application of tiered cost-sharing described in subsection (g)(2)) in a manner similar (as determined by the Secretary) to the manner such requirements apply to an MA organization with respect to benefits under the original medicare fee-for-service program option it offers under an MA plan under part C. In applying this paragraph only the part D eligible individual shall be entitled to bring such an appeal.

''(2) LIMITATION IN CASES ON NONFORMULARY DETERMINATIONS.—A part D eligible individual who is enrolled in a prescription drug plan offered by a PDP sponsor may appeal under paragraph (1) a determination not to provide for coverage of a covered part D drug that is not on the formulary under the plan only if the prescribing physician determines that all covered part D drugs on any tier of the formulary for treatment of the same condition would not be as effective for the individual as the nonformulary drug, would have adverse effects for the individual, or both.

''(3) TREATMENT OF NONFORMULARY DETERMINATIONS.—If a PDP sponsor determines that a plan provides coverage for a covered part D drug that is not on the formulary of the plan, the drug shall be treated as being included on the formulary for purposes of section 1860D–2(b)(4)(C)(i).

''(i) PRIVACY, CONFIDENTIALITY, AND ACCURACY OF ENROLLEE RECORDS.—The provisions of section 1852(h) shall apply to a PDP sponsor and prescription drug plan in the same manner as it applies to an MA organization and an MA plan.

''(j) TREATMENT OF ACCREDITATION.—Subparagraph (A) of section 1852(e)(4) (relating to treatment of accreditation) shall apply to a PDP sponsor under this part with respect to the following requirements, in the same manner as it applies to an MA organization with respect to the requirements in subparagraph (B) (other than clause (vii) thereof) of such section:

''(1) Subsection (b) of this section (relating to access to covered part D drugs).

''(2) Subsection (c) of this section (including quality assurance and medication therapy management).

''(3) Subsection (i) of this section (relating to confidentiality and accuracy of enrollee records).

''(k) PUBLIC DISCLOSURE OF PHARMACEUTICAL PRICES FOR EQUIVALENT DRUGS.—

''(1) IN GENERAL.—A PDP sponsor offering a prescription drug plan shall provide that each pharmacy that dispenses a covered part D drug shall inform an enrollee of any differential between the price of the drug to the enrollee and

the price of the lowest priced generic covered part D drug under the plan that is therapeutically equivalent and bioequivalent and available at such pharmacy.

''(2) TIMING OF NOTICE.—

''(A) IN GENERAL.—Subject to subparagraph (B), the information under paragraph (1) shall be provided at the time of purchase of the drug involved, or, in the case of dispensing by mail order, at the time of delivery of such drug.

''(B) WAIVER.—The Secretary may waive subparagraph (A) in such circumstances as the Secretary may specify.

''Subpart 2—Prescription Drug Plans; PDP Sponsors; Financing

''PDP REGIONS; SUBMISSION OF BIDS; PLAN APPROVAL

''SEC. 1860D–11. (a) ESTABLISHMENT OF PDP REGIONS; SERVICE AREAS.—

''(1) COVERAGE OF ENTIRE PDP REGION.—The service area for a prescription drug plan shall consist of an entire PDP region established under paragraph (2).

''(2) ESTABLISHMENT OF PDP REGIONS.—

''(A) IN GENERAL.—The Secretary shall establish, and may revise, PDP regions in a manner that is consistent with the requirements for the establishment and revision of MA regions under subparagraphs (B) and (C) of section 1858(a)(2).

''(B) RELATION TO MA REGIONS.—To the extent practicable, PDP regions shall be the same as MA regions under section 1858(a)(2). The Secretary may establish PDP regions which are not the same as MA regions if the Secretary determines that the establishment of different regions under this part would improve access to benefits under this part.

''(C) AUTHORITY FOR TERRITORIES.—The Secretary shall establish, and may revise, PDP regions for areas in States that are not within the 50 States or the District of Columbia.

''(3) NATIONAL PLAN.—Nothing in this subsection shall be construed as preventing a prescription drug plan from being offered in more than one PDP region (including all PDP regions).

''(b) SUBMISSION OF BIDS, PREMIUMS, AND RELATED INFORMATION.—

''(1) IN GENERAL.—A PDP sponsor shall submit to the Secretary information described in paragraph (2) with respect to each prescription drug plan it offers. Such information shall be submitted at the same time and in a similar manner to the manner in which information described in paragraph (6) of section 1854(a) is submitted by an MA organization under paragraph (1) of such section.

''(2) INFORMATION DESCRIBED.—The information described in this paragraph is information on the following:

''(A) COVERAGE PROVIDED.—The prescription drug coverage provided under the plan, including the deductible and other cost-sharing.

''(B) ACTUARIAL VALUE.—The actuarial value of the qualified prescription drug coverage in the region for a part D eligible individual with a national average risk profile for the factors described in section 1860D–15(c)(1)(A) (as specified by the Secretary).

''(C) BID.—Information on the bid, including an actuarial certification of—

''(i) the basis for the actuarial value described in subparagraph (B) assumed in such bid;

''(ii) the portion of such bid attributable to basic prescription drug coverage and, if applicable, the portion of such bid attributable to supplemental benefits;

''(iii) assumptions regarding the reinsurance subsidy payments provided under section 1860D–15(b) subtracted from the actuarial value to produce such bid; and

''(iv) administrative expenses assumed in the bid.

''(D) SERVICE AREA.—The service area for the plan.

''(E) LEVEL OF RISK ASSUMED.—

''(i) IN GENERAL.—Whether the PDP sponsor requires a modification of risk level under clause (ii) and, if so, the extent of such modification. Any such modification shall apply with respect to all prescription drug plans offered by a PDP sponsor in a PDP region. This subparagraph shall not apply to an MA–PD plan.

''(ii) RISK LEVELS DESCRIBED.—A modification of risk level under this clause may consist of one or more of the following:

''(I) INCREASE IN FEDERAL PERCENTAGE ASSUMED IN INITIAL RISK CORRIDOR.—An equal percentage point increase in the percents applied under subparagraphs (B)(i), (B)(ii)(I), (C)(i), and (C)(ii)(I) of section 1860D–15(e)(2). In no case shall the application of previous sentence prevent the application of a higher percentage under section 1869D–15(e)(2)(B)(iii).

''(II) INCREASE IN FEDERAL PERCENTAGE ASSUMED IN SECOND RISK CORRIDOR.—An equal percentage point increase in the percents applied under subparagraphs (B)(ii)(II) and (C)(ii)(II) of section 1860D–15(e)(2).

''(III) DECREASE IN SIZE OF RISK CORRIDORS.—A decrease in the threshold risk percentages specified in section 1860D–15(e)(3)(C).

''(F) ADDITIONAL INFORMATION.—Such other information as the Secretary may require to carry out this part.

''(3) PAPERWORK REDUCTION FOR OFFERING OF PRESCRIPTION DRUG PLANS NATIONALLY OR IN MULTI-REGION AREAS.—The Secretary shall establish requirements for information submission under this subsection in a manner that promotes the offering of such plans in more than one PDP region (including all regions) through the filing of consolidated information.

''(c) ACTUARIAL VALUATION.—

''(1) PROCESSES.—For purposes of this part, the Secretary shall establish processes and methods for determining the actuarial valuation of prescription drug coverage, including—

''(A) an actuarial valuation of standard prescription drug coverage under section 1860D–2(b);

''(B) actuarial valuations relating to alternative prescription drug coverage under section 1860D–2(c)(1);

''(C) an actuarial valuation of the reinsurance subsidy payments under section 1860D–15(b);

''(D) the use of generally accepted actuarial principles and methodologies; and

''(E) applying the same methodology for determinations of actuarial valuations under subparagraphs (A) and (B).

''(2) ACCOUNTING FOR DRUG UTILIZATION.—Such processes and methods for determining actuarial valuation shall take into account the effect that providing alternative prescription drug coverage (rather than standard prescription drug coverage) has on drug utilization.

''(3) RESPONSIBILITIES.—

''(A) PLAN RESPONSIBILITIES.—PDP sponsors and MA organizations are responsible for the preparation and submission of actuarial valuations required under this part for prescription drug plans and MA–PD plans they offer.

''(B) USE OF OUTSIDE ACTUARIES.—Under the processes and methods established under paragraph (1), PDP sponsors offering prescription drug plans and MA organizations offering MA–PD plans may use actuarial opinions certified by independent, qualified actuaries to establish actuarial values.

''(d) REVIEW OF INFORMATION AND NEGOTIATION.—

''(1) REVIEW OF INFORMATION.—The Secretary shall review the information filed under subsection (b) for the purpose of conducting negotiations under paragraph (2).

''(2) NEGOTIATION REGARDING TERMS AND CONDITIONS.—Subject to subsection (i), in exercising the authority under paragraph (1), the Secretary—

''(A) has the authority to negotiate the terms and conditions of the proposed bid submitted and other terms and conditions of a proposed plan; and

''(B) has authority similar to the authority of the Director of the Office of Personnel Management with respect to health benefits plans under chapter 89 of title 5, United States Code.

''(e) APPROVAL OF PROPOSED PLANS.—

''(1) IN GENERAL.—After review and negotiation under subsection (d), the Secretary shall approve or disapprove the prescription drug plan.

''(2) REQUIREMENTS FOR APPROVAL.—The Secretary may approve a prescription drug plan only if the following requirements are met:

''(A) COMPLIANCE WITH REQUIREMENTS.—The plan and the PDP sponsor offering the plan comply with the requirements under this part, including the provision of qualified prescription drug coverage.

''(B) ACTUARIAL DETERMINATIONS.—The Secretary determines that the plan and PDP sponsor meet the requirements under this part relating to actuarial determinations, including such requirements under section 1860D–2(c).

''(C) APPLICATION OF FEHBP STANDARD.—

''(i) IN GENERAL.—The Secretary determines that the portion of the bid submitted under subsection (b) that is attributable to basic prescription drug coverage is supported by the actuarial bases provided under such subsection and reasonably and equitably reflects the revenue requirements (as used for purposes of section 1302(8)(C) of the Public Health Service Act) for benefits provided under that plan, less the sum (determined on a monthly per capita basis) of the actuarial value of the reinsurance payments under section 1860D–15(b).

''(ii) SUPPLEMENTAL COVERAGE.—The Secretary determines that the portion of the bid submitted under subsection (b) that is attributable to supplemental prescription drug coverage pursuant to section 1860D–2(a)(2) is supported by the actuarial bases provided under such subsection and reasonably and equitably reflects the revenue requirements (as used for purposes of section 1302(8)(C) of the Public Health Service Act) for such coverage under the plan.

''(D) PLAN DESIGN.—

''(i) IN GENERAL.—The Secretary does not find that the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain part D eligible individuals under the plan.

''(ii) USE OF CATEGORIES AND CLASSES IN FORMULARIES.—The Secretary may not find that the design of categories and classes within a formulary violates clause (i) if such categories and classes are consistent with guidelines (if any) for such categories and classes established by the United States Pharmacopeia.

''(f) APPLICATION OF LIMITED RISK PLANS.—

''(1) CONDITIONS FOR APPROVAL OF LIMITED RISK PLANS.—The Secretary may only approve a limited risk plan (as defined in paragraph (4)(A)) for a PDP region if the access requirements under section 1860D–3(a) would not be met for the region but for the approval of such a plan (or a fallback prescription drug plan under subsection (g)).

''(2) RULES.—The following rules shall apply with respect to the approval of a limited risk plan in a PDP region:

''(A) LIMITED EXERCISE OF AUTHORITY.—Only the minimum number of such plans may be approved in order to meet the access requirements under section 1860D–3(a).

''(B) MAXIMIZING ASSUMPTION OF RISK.—The Secretary shall provide priority in approval for those plans bearing the highest level of risk (as computed by the Secretary), but the Secretary may take into account the level of the bids submitted by such plans.

''(C) NO FULL UNDERWRITING FOR LIMITED RISK PLANS.—In no case may the Secretary approve a limited risk plan under which the modification of risk level provides for no (or a de minimis) level of financial risk.

''(3) ACCEPTANCE OF ALL FULL RISK CONTRACTS.—There shall be no limit on the number of full risk plans that are approved under subsection (e).

''(4) RISK-PLANS DEFINED.—For purposes of this subsection:

''(A) LIMITED RISK PLAN.—The term 'limited risk plan' means a prescription drug plan that provides basic prescription drug coverage and for which the PDP sponsor includes a modification of risk level described in subparagraph (E) of subsection (b)(2) in its bid submitted for the plan under such subsection. Such term does not include a fallback prescription drug plan.

''(B) FULL RISK PLAN.—The term 'full risk plan' means a prescription drug plan that is not a limited risk plan or a fallback prescription drug plan.

''(g) GUARANTEEING ACCESS TO COVERAGE.—

''(1) SOLICITATION OF BIDS.—

''(A) IN GENERAL.—Separate from the bidding process under subsection (b), the Secretary shall provide for a process for the solicitation of bids from eligible fallback entities (as defined in paragraph (2)) for the offering in all fallback service areas (as defined in paragraph (3)) in one or more PDP regions of a fallback prescription drug plan (as defined in paragraph (4)) during the contract period specified in paragraph (5)).

''(B) ACCEPTANCE OF BIDS.—

''(i) IN GENERAL.—Except as provided in this subparagraph, the provisions of subsection (e) shall apply with respect to the approval or disapproval of fallback prescription drug plans. The Secretary shall enter into contracts under this subsection with eligible fallback entities for the offering of fallback prescription drug plans so approved in fallback service areas.

''(ii) LIMITATION OF 1 PLAN FOR ALL FALLBACK SERVICE AREAS IN A PDP REGION.—With respect to all fallback service areas in any PDP region for a contract period, the Secretary shall approve the offering of only 1 fallback prescription drug plan.

''(iii) COMPETITIVE PROCEDURES.—Competitive procedures (as defined in section 4(5) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(5))) shall be used to enter into a contract under this subsection. The provisions of subsection (d) of section 1874A shall apply to a contract under this section in the same manner as they apply to a contract under such section.

''(iv) TIMING.—The Secretary shall approve a fallback prescription drug plan for a PDP region in a manner so that, if there are any fallback service areas in the region for a year, the fallback prescription drug plan is offered at the same time as prescription drug plans would otherwise be offered.

''(V) NO NATIONAL FALLBACK PLAN.—The Secretary shall not enter into a contract with a single fallback entity for the offering of fallback plans throughout the United States.

''(2) ELIGIBLE FALLBACK ENTITY.—For purposes of this section, the term 'eligible fallback entity' means, with respect to all fallback service areas in a PDP region for a contract period, an entity that—

''(A) meets the requirements to be a PDP sponsor (or would meet such requirements but for the fact that the entity is not a risk-bearing entity); and

''(B) does not submit a bid under section 1860D–11(b) for any prescription drug plan for any PDP region for the first year of such contract period.

For purposes of subparagraph (B), an entity shall be treated as submitting a bid with respect to a prescription drug plan if the entity is acting as a subcontractor of a PDP sponsor that is offering such a plan. The previous sentence shall not apply to entities that are subcontractors of an MA organization except insofar as such organization is acting as a PDP sponsor with respect to a prescription drug plan.

''(3) FALLBACK SERVICE AREA.—For purposes of this subsection, the term 'fallback service area' means, for a PDP region with respect to a year, any area within such region for which the Secretary determines before the beginning of the year that the access requirements of the first sentence of section 1860D–3(a) will not be met for part D eligible individuals residing in the area for the year.

''(4) FALLBACK PRESCRIPTION DRUG PLAN.—For purposes of this part, the term 'fallback prescription drug plan' means a prescription drug plan that—

''(A) only offers the standard prescription drug coverage and access to negotiated prices described in section 1860D–2(a)(1)(A) and does not include any supplemental prescription drug coverage; and

''(B) meets such other requirements as the Secretary may specify.

''(5) PAYMENTS UNDER THE CONTRACT.—

''(A) IN GENERAL.—A contract entered into under this subsection shall provide for—

''(i) payment for the actual costs (taking into account negotiated price concessions described in section 1860D–2(d)(1)(B)) of covered part D drugs provided to part D eligible individuals enrolled in a fallback prescription drug plan offered by the entity; and

''(ii) payment of management fees that are tied to performance measures established by the Secretary for the management, administration, and delivery of the benefits under the contract.

''(B) PERFORMANCE MEASURES.—The performance measures established by the Secretary pursuant to subparagraph (A)(ii) shall include at least measures for each of the following:

''(i) COSTS.—The entity contains costs to the Medicare Prescription Drug Account and to part D eligible individuals enrolled in a fallback prescription drug plan offered by the entity through mechanisms such as generic substitution and price discounts.

''(ii) QUALITY PROGRAMS.—The entity provides such enrollees with quality programs that avoid adverse drug reactions and overutilization and reduce medical errors.

''(iii) CUSTOMER SERVICE.—The entity provides timely and accurate delivery of services and pharmacy and beneficiary support services.

''(iv) BENEFIT ADMINISTRATION AND CLAIMS ADJUDICATION.—The entity provides efficient and effective benefit administration and claims adjudication.

''(6) MONTHLY BENEFICIARY PREMIUM.—Except as provided in section 1860D–13(b) (relating to late enrollment penalty) and subject to section 1860D–14 (relating to low-income assistance), the monthly beneficiary premium to be charged under a fallback prescription drug plan offered in all fallback service areas in a PDP region shall be uniform and shall be equal to 25.5 percent of an amount equal to the Secretary's estimate of the average monthly per capita actuarial cost, including administrative expenses, under the fallback prescription drug plan of providing coverage in the region, as calculated by the Chief Actuary of the Centers for Medicare & Medicaid Services. In calculating such administrative expenses, the Chief Actuary shall use a factor that is based on similar expenses of prescription drug plans that are not fallback prescription drug plans.

''(7) GENERAL CONTRACT TERMS AND CONDITIONS.—

''(A) IN GENERAL.—Except as may be appropriate to carry out this section, the terms and conditions of contracts with eligible fallback entities offering fallback prescription drug plans under this subsection shall be the same as the terms and conditions of contracts under this part for prescription drug plans.

''(B) PERIOD OF CONTRACT.—

''(i) IN GENERAL.—Subject to clause (ii), a contract approved for a fallback prescription drug plan for fallback service areas for a PDP region under this section shall be for a period of 3 years (except as may be renewed after a subsequent bidding process).

''(ii) LIMITATION.—A fallback prescription drug plan may be offered under a contract in an area for a year only if that area is a fallback service area for that year.

''(C) ENTITY NOT PERMITTED TO MARKET OR BRAND FALLBACK PRESCRIPTION DRUG PLANS.—An eligible fallback entity with a contract under this subsection may not engage in any marketing or branding of a fallback prescription drug plan.

''(h) ANNUAL REPORT ON USE OF LIMITED RISK PLANS AND FALLBACK PLANS.—The Secretary shall submit to Congress an annual report that describes instances in which limited risk plans and fallback prescription drug plans were offered under subsections (f) and (g). The Secretary shall include in such report such recommendations as may be appropriate to limit the need for the provision of such plans and to maximize the assumption of financial risk under section subsection (f).

''(i) NONINTERFERENCE.—In order to promote competition under this part and in carrying out this part, the Secretary—

''(1) may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors; and

''(2) may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs.

''(j) COORDINATION OF BENEFITS.—A PDP sponsor offering a prescription drug plan shall permit State Pharmaceutical Assistance Programs and Rx plans under sections 1860D–23 and 1860D–24 to coordinate benefits with the plan and, in connection with such coordination with such a Program, not to impose fees that are unrelated to the cost of coordination.

''REQUIREMENTS FOR AND CONTRACTS WITH PRESCRIPTION DRUG PLAN (PDP) SPONSORS

''SEC. 1860D–12. (a) GENERAL REQUIREMENTS.—Each PDP sponsor of a prescription drug plan shall meet the following requirements:

''(1) LICENSURE.—Subject to subsection (c), the sponsor is organized and licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a prescription drug plan.

''(2) ASSUMPTION OF FINANCIAL RISK FOR UNSUBSIDIZED COVERAGE.—

''(A) IN GENERAL.—Subject to subparagraph (B), to the extent that the entity is at risk the entity assumes financial risk on a prospective basis for benefits that it offers under a prescription drug plan and that is not covered under section 1860D–15(b).

''(B) REINSURANCE PERMITTED.—The plan sponsor may obtain insurance or make other arrangements for the cost of coverage provided to any enrollee to the extent that the sponsor is at risk for providing such coverage.

''(3) SOLVENCY FOR UNLICENSED SPONSORS.—In the case of a PDP sponsor that is not described in paragraph (1) and for which a waiver has been approved under subsection (c), such sponsor shall meet solvency standards established by the Secretary under subsection (d).

''(b) CONTRACT REQUIREMENTS.—

''(1) IN GENERAL.—The Secretary shall not permit the enrollment under section 1860D–1 in a prescription drug plan offered by a PDP sponsor under this part, and the sponsor shall not be eligible for payments under section 1860D–14 or 1860D–15, unless the Secretary has entered into a contract under this subsection with the sponsor with respect to the offering of such plan. Such a contract with a sponsor may cover more than one prescription drug plan. Such contract shall provide that the sponsor agrees to comply with the applicable requirements and standards of this part and the terms and conditions of payment as provided for in this part.

''(2) LIMITATION ON ENTITIES OFFERING FALLBACK PRESCRIPTION DRUG PLANS.—The Secretary shall not enter into a contract with a PDP sponsor for the offering of a prescription drug plan (other than a fallback prescription drug plan) in a PDP region for a year if the sponsor—

''(A) submitted a bid under section 1860D–11(g) for such year (as the first year of a contract period under such section) to offer a fallback prescription drug plan in any PDP region;

''(B) offers a fallback prescription drug plan in any PDP region during the year; or

''(C) offered a fallback prescription drug plan in that PDP region during the previous year.

For purposes of this paragraph, an entity shall be treated as submitting a bid with respect to a prescription drug plan or offering a fallback prescription drug plan if the entity is acting as a subcontractor of a PDP sponsor that is offering such a plan. The previous sentence shall not apply to entities that are subcontractors of an MA organization except insofar as such organization is acting as a PDP sponsor with respect to a prescription drug plan.

''(3) INCORPORATION OF CERTAIN MEDICARE ADVANTAGE CONTRACT REQUIREMENTS.—Except as otherwise provided, the following provisions of section 1857 shall apply to contracts under this section in the same manner as they apply to contracts under section 1857(a):

''(A) MINIMUM ENROLLMENT.—Paragraphs (1) and (3) of section 1857(b), except that—

''(i) the Secretary may increase the minimum number of enrollees required under such paragraph (1) as the Secretary determines appropriate; and

''(ii) the requirement of such paragraph (1) shall be waived during the first contract year with respect to an organization in a region.

''(B) CONTRACT PERIOD AND EFFECTIVENESS.—Section 1857(c), except that in applying paragraph (4)(B) of such section any reference to payment amounts under section 1853 shall be deemed payment amounts under section 1860D–15.

''(C) PROTECTIONS AGAINST FRAUD AND BENEFICIARY PROTECTIONS.—Section 1857(d).

''(D) ADDITIONAL CONTRACT TERMS.—Section 1857(e); except that section 1857(e)(2) shall apply as specified to PDP sponsors and payments under this part to an MA–PD plan shall be treated as expenditures made under part D.

''(E) INTERMEDIATE SANCTIONS.—Section 1857(g) (other than paragraph (1)(F) of such section), except that in applying such section the reference in section 1857(g)(1)(B) to section 1854 is deemed a reference to this part.

''(F) PROCEDURES FOR TERMINATION.—Section 1857(h).

''(c) WAIVER OF CERTAIN REQUIREMENTS TO EXPAND CHOICE.—

''(1) AUTHORIZING WAIVER.—

''(A) IN GENERAL.—In the case of an entity that seeks to offer a prescription drug plan in a State, the Secretary shall waive the requirement of subsection (a)(1) that the entity be licensed in that State if the Secretary determines, based on the application and other evidence presented to the Secretary, that any of the grounds for approval of the application described in paragraph (2) have been met.

''(B) APPLICATION OF REGIONAL PLAN WAIVER RULE.—In addition to the waiver available under subparagraph (A), the provisions of section 1858(d) shall apply to PDP sponsors under this part in a manner similar to the manner in which such provisions apply to MA organizations under part C, except that no application shall be required under paragraph (1)(B) of such section in the case of a State that does not provide a licensing process for such a sponsor.

''(2) GROUNDS FOR APPROVAL.—

''(A) IN GENERAL.—The grounds for approval under this paragraph are—

''(i) subject to subparagraph (B), the grounds for approval described in subparagraphs (B), (C), and (D) of section 1855(a)(2); and

''(ii) the application by a State of any grounds other than those required under Federal law.

''(B) SPECIAL RULES.—In applying subparagraph (A)(i)—

''(i) the ground of approval described in section 1855(a)(2)(B) is deemed to have been met if the State does not have a licensing process in effect with respect to the PDP sponsor; and

''(ii) for plan years beginning before January 1, 2008, if the State does have such a licensing process in effect, such ground for approval described in such section is deemed to have been met upon submission of an application described in such section.

''(3) APPLICATION OF WAIVER PROCEDURES.—With respect to an application for a waiver (or a waiver granted) under paragraph (1)(A) of this subsection, the provisions of subparagraphs (E), (F), and (G) of section 1855(a)(2) shall apply, except that clauses (i) and (ii) of such subparagraph (E) shall not apply in the case of a State that does not have a licensing process described in paragraph (2)(B)(i) in effect.

''(4) REFERENCES TO CERTAIN PROVISIONS.—In applying provisions of section 1855(a)(2) under paragraphs (2) and (3) of this subsection to prescription drug plans and PDP sponsors—

''(A) any reference to a waiver application under section 1855 shall be treated as a reference to a waiver application under paragraph (1)(A) of this subsection; and

''(B) any reference to solvency standards shall be treated as a reference to solvency standards established under subsection (d) of this section.

''(d) SOLVENCY STANDARDS FOR NON-LICENSED ENTITIES.—

''(1) ESTABLISHMENT AND PUBLICATION.—The Secretary, in consultation with the National Association of Insurance Commissioners, shall establish and publish, by not later than January 1, 2005, financial solvency and capital adequacy standards for entities described in paragraph (2).

''(2) COMPLIANCE WITH STANDARDS.—A PDP sponsor that is not licensed by a State under subsection (a)(1) and for which a waiver application has been approved under subsection (c) shall meet solvency and capital adequacy standards established under paragraph (1). The Secretary shall establish certification procedures for such sponsors with respect to such solvency standards in the manner described in section 1855(c)(2).

''(e) LICENSURE DOES NOT SUBSTITUTE FOR OR CONSTITUTE CERTIFICATION.—The fact that a PDP sponsor is licensed in accordance with subsection (a)(1) or has a waiver application approved under subsection (c) does not deem the sponsor to meet other requirements imposed under this part for a sponsor.

''(f) PERIODIC REVIEW AND REVISION OF STANDARDS.—

''(1) IN GENERAL.—Subject to paragraph (2), the Secretary may periodically review the standards established under this section and, based on such review, may revise such standards if the Secretary determines such revision to be appropriate.

''(2) PROHIBITION OF MIDYEAR IMPLEMENTATION OF SIGNIFICANT NEW REGULATORY REQUIREMENTS.—The Secretary may not implement, other than at the beginning of a calendar year, regulations under this section that impose new, significant regulatory requirements on a PDP sponsor or a prescription drug plan.

''(g) PROHIBITION OF STATE IMPOSITION OF PREMIUM TAXES; RELATION TO STATE LAWS.—The provisions of sections 1854(g) and 1856(b)(3) shall apply with respect to PDP sponsors and prescription drug plans under this part in the same manner as such sections apply to MA organizations and MA plans under part C.

''PREMIUMS; LATE ENROLLMENT PENALTY

''SEC. 1860D–13. (a) MONTHLY BENEFICIARY PREMIUM.—

''(1) COMPUTATION.—

''(A) IN GENERAL.—The monthly beneficiary premium for a prescription drug plan is the base beneficiary premium computed under paragraph (2) as adjusted under this paragraph.

''(B) ADJUSTMENT TO REFLECT DIFFERENCE BETWEEN BID AND NATIONAL AVERAGE BID.—

''(i) ABOVE AVERAGE BID.—If for a month the amount of the standardized bid amount (as defined in paragraph (5)) exceeds the amount of the adjusted national average monthly bid amount (as defined in clause (iii)), the base beneficiary premium for the month shall be increased by the amount of such excess.

''(ii) BELOW AVERAGE BID.—If for a month the amount of the adjusted national average monthly bid amount for the month exceeds the standardized bid amount, the base beneficiary premium for the month shall be decreased by the amount of such excess.

''(iii) ADJUSTED NATIONAL AVERAGE MONTHLY BID AMOUNT DEFINED.—For purposes of this subparagraph, the term 'adjusted national average monthly bid amount' means the national average monthly bid amount computed under paragraph (4), as adjusted under section 1860D–15(c)(2).

''(C) INCREASE FOR SUPPLEMENTAL PRESCRIPTION DRUG BENEFITS.—The base beneficiary premium shall be increased by the portion of the PDP approved bid that is attributable to supplemental prescription drug benefits.

''(D) INCREASE FOR LATE ENROLLMENT PENALTY.—The base beneficiary premium shall be increased by the amount of any late enrollment penalty under subsection (b).

''(E) DECREASE FOR LOW-INCOME ASSISTANCE.—The monthly beneficiary premium is subject to decrease in the case of a subsidy eligible individual under section 1860D–14.

''(F) UNIFORM PREMIUM.—Except as provided in subparagraphs (D) and (E), the monthly beneficiary premium for a prescription drug plan in a PDP region is the same for all part D eligible individuals enrolled in the plan.

''(2) BASE BENEFICIARY PREMIUM.—The base beneficiary premium under this paragraph for a prescription drug plan for a month is equal to the product—

''(A) the beneficiary premium percentage (as specified in paragraph (3)); and

''(B) the national average monthly bid amount (computed under paragraph (4)) for the month.

''(3) BENEFICIARY PREMIUM PERCENTAGE.—For purposes of this subsection, the beneficiary premium percentage for any year is the percentage equal to a fraction—

''(A) the numerator of which is 25.5 percent; and

''(B) the denominator of which is 100 percent minus a percentage equal to—

''(i) the total reinsurance payments which the Secretary estimates are payable under section 1860D–15(b) with respect to the coverage year; divided by

''(ii) the sum of—

''(I) the amount estimated under clause (i) for the year; and

''(II) the total payments which the Secretary estimates will be paid to prescription drug plans and MA–PD plans that are attributable to the standardized bid amount during the year, taking into account amounts paid by the Secretary and enrollees.

''(4) COMPUTATION OF NATIONAL AVERAGE MONTHLY BID AMOUNT.—

''(A) IN GENERAL.—For each year (beginning with 2006) the Secretary shall compute a national average monthly bid amount equal to the average of the standardized bid amounts (as defined in paragraph (5)) for each prescription drug plan and for each MA–PD plan described in section 1851(a)(2)(A)(i). Such average does not take into account the bids submitted for MSA plans, MA private fee-for-service plan, and specialized MA plans for special needs individuals, PACE programs under section 1894 (pursuant to section 1860D–21(f)), and under reasonable cost reimbursement contracts under section 1876(h) (pursuant to section 1860D–21(e)).

''(B) WEIGHTED AVERAGE.—

''(i) IN GENERAL.—The monthly national average monthly bid amount computed under subparagraph (A) for a year shall be a weighted average, with the weight for each plan being equal to the average number of part D eligible individuals enrolled in such plan in the reference month (as defined in section 1858(f)(4)).

''(ii) SPECIAL RULE FOR 2006.—For purposes of applying this paragraph for 2006, the Secretary

shall establish procedures for determining the weighted average under clause (i) for 2005.

''(5) STANDARDIZED BID AMOUNT DEFINED.—For purposes of this subsection, the term 'standardized bid amount' means the following:

''(A) PRESCRIPTION DRUG PLANS.—

''(i) BASIC COVERAGE.—In the case of a prescription drug plan that provides basic prescription drug coverage, the PDP approved bid (as defined in paragraph (6)).

''(ii) SUPPLEMENTAL COVERAGE.—In the case of a prescription drug plan that provides supplemental prescription drug coverage, the portion of the PDP approved bid that is attributable to basic prescription drug coverage.

''(B) MA–PD PLANS.—In the case of an MA–PD plan, the portion of the accepted bid amount that is attributable to basic prescription drug coverage.

''(6) PDP APPROVED BID DEFINED.—For purposes of this part, the term 'PDP approved bid' means, with respect to a prescription drug plan, the bid amount approved for the plan under this part.

''(b) LATE ENROLLMENT PENALTY.—

''(1) IN GENERAL.—Subject to the succeeding provisions of this subsection, in the case of a part D eligible individual described in paragraph (2) with respect to a continuous period of eligibility, there shall be an increase in the monthly beneficiary premium established under subsection (a) in an amount determined under paragraph (3).

''(2) INDIVIDUALS SUBJECT TO PENALTY.—A part D eligible individual described in this paragraph is, with respect to a continuous period of eligibility, an individual for whom there is a continuous period of 63 days or longer (all of which in such continuous period of eligibility) beginning on the day after the last date of the individual's initial enrollment period under section 1860D–1(b)(2) and ending on the date of enrollment under a prescription drug plan or MA–PD plan during all of which the individual was not covered under any creditable prescription drug coverage.

''(3) AMOUNT OF PENALTY.—

''(A) IN GENERAL.—The amount determined under this paragraph for a part D eligible individual for a continuous period of eligibility is the greater of—

''(i) an amount that the Secretary determines is actuarially sound for each uncovered month (as defined in subparagraph (B)) in the same continuous period of eligibility; or

''(ii) 1 percent of the base beneficiary premium (computed under subsection (a)(2)) for each such uncovered month in such period.

''(B) UNCOVERED MONTH DEFINED.—For purposes of this subsection, the term 'uncovered month' means, with respect to a part D eligible individual, any month beginning after the end of the initial enrollment period under section 1860D–1(b)(2) unless the individual can demonstrate that the individual had creditable prescription drug coverage (as defined in paragraph (4)) for any portion of such month.

''(4) CREDITABLE PRESCRIPTION DRUG COVERAGE DEFINED.—For purposes of this part, the term 'creditable prescription drug coverage' means any of the following coverage, but only if the coverage meets the requirement of paragraph (5):

''(A) COVERAGE UNDER PRESCRIPTION DRUG PLAN OR MA–PD PLAN.—Coverage under a prescription drug plan or under an MA–PD plan.

''(B) MEDICAID.—Coverage under a medicaid plan under title XIX or under a waiver under section 1115.

''(C) GROUP HEALTH PLAN.—Coverage under a group health plan, including a health benefits plan under chapter 89 of title 5, United States Code (commonly known as the Federal employees health benefits program), and a qualified retiree prescription drug plan (as defined in section 1860D–22(a)(2)).

''(D) STATE PHARMACEUTICAL ASSISTANCE PROGRAM.—Coverage under a State pharmaceutical assistance program described in section 1860D–23(b)(1).

''(E) VETERANS' COVERAGE OF PRESCRIPTION DRUGS.—Coverage for veterans, and survivors and dependents of veterans, under chapter 17 of title 38, United States Code.

''(F) PRESCRIPTION DRUG COVERAGE UNDER MEDIGAP POLICIES.—Coverage under a medicare supplemental policy under section 1882 that provides benefits for prescription drugs (whether or not such coverage conforms to the standards for packages of benefits under section 1882(p)(1)).

''(G) MILITARY COVERAGE (INCLUDING TRICARE).—Coverage under chapter 55 of title 10, United States Code.

''(H) OTHER COVERAGE.—Such other coverage as the Secretary determines appropriate.

''(5) ACTUARIAL EQUIVALENCE REQUIREMENT.—Coverage meets the requirement of this paragraph only if the coverage is determined (in a manner specified by the Secretary) to provide coverage of the cost of prescription drugs the actuarial value of which (as defined by the Secretary) to the individual equals or exceeds the actuarial value of standard prescription drug coverage (as determined under section 1860D–11(c)).

''(6) PROCEDURES TO DOCUMENT CREDITABLE PRESCRIPTION DRUG COVERAGE.—

''(A) IN GENERAL.—The Secretary shall establish procedures (including the form, manner, and time) for the documentation of creditable prescription drug coverage, including procedures to assist in determining whether coverage meets the requirement of paragraph (5).

''(B) DISCLOSURE BY ENTITIES OFFERING CREDITABLE PRESCRIPTION DRUG COVERAGE.—

''(i) IN GENERAL.—Each entity that offers prescription drug coverage of the type described in subparagraphs (B) through (H) of paragraph (4) shall provide for disclosure, in a form, manner, and time consistent with standards established by the Secretary, to the Secretary and part D eligible individuals of whether the coverage meets the requirement of paragraph (5) or whether such coverage is changed so it no longer meets such requirement.

''(ii) DISCLOSURE OF NON-CREDITABLE COVERAGE.—In the case of such coverage that does not meet such requirement, the disclosure to part D eligible individuals under this subparagraph shall include information regarding the fact that because such coverage does not meet such requirement there are limitations on the periods in a year in which the individuals may enroll under a prescription drug plan or an MA–PD plan and that any such enrollment is subject to a late enrollment penalty under this subsection.

''(C) WAIVER OF REQUIREMENT.—In the case of a part D eligible individual who was enrolled in prescription drug coverage of the type described in subparagraphs (B) through (H) of paragraph (4) which is not creditable prescription drug coverage because it does not meet the requirement of paragraph (5), the individual may apply to the Secretary to have such coverage treated as creditable prescription drug coverage if the individual establishes that the individual was not adequately informed that such coverage did not meet such requirement.

''(7) CONTINUOUS PERIOD OF ELIGIBILITY.—

''(A) IN GENERAL.—Subject to subparagraph (B), for purposes of this subsection, the term 'continuous period of eligibility' means, with respect to a part D eligible individual, the period that begins with the first day on which the individual is eligible to enroll in a prescription drug plan under this part and ends with the individual's death.

''(B) SEPARATE PERIOD.—Any period during all of which a part D eligible individual is entitled to hospital insurance benefits under part A and—

''(i) which terminated in or before the month preceding the month in which the individual attained age 65; or

''(ii) for which the basis for eligibility for such entitlement changed between section 226(b) and section 226(a), between 226(b) and section 226A, or between section 226A and section 226(a),

shall be a separate continuous period of eligibility with respect to the individual (and each such period which terminates shall be deemed not to have existed for purposes of subsequently applying this paragraph).

''(c) COLLECTION OF MONTHLY BENEFICIARY PREMIUMS.—

''(1) IN GENERAL.—Subject to paragraphs (2) and (3), the provisions of section 1854(d) shall apply to PDP sponsors and premiums (and any late enrollment penalty) under this part in the same manner as they apply to MA organizations and beneficiary premiums under part C, except that any reference to a Trust Fund is deemed for this purpose a reference to the Medicare Prescription Drug Account.

''(2) CREDITING OF LATE ENROLLMENT PENALTY.—

''(A) PORTION ATTRIBUTABLE TO INCREASED ACTUARIAL COSTS.—With respect to late enrollment penalties imposed under subsection (b), the Secretary shall specify the portion of such a penalty that the Secretary estimates is attributable to increased actuarial costs assumed by the PDP sponsor or MA organization (and not taken into account through risk adjustment provided under section 1860D–15(c)(1) or through reinsurance payments under section 1860D–15(b)) as a result of such late enrollment.

''(B) COLLECTION THROUGH WITHHOLDING.—In the case of a late enrollment penalty that is collected from a part D eligible individual in the manner described in section 1854(d)(2)(A), the Secretary shall provide that only the portion of such penalty estimated under subparagraph (A) shall be paid to the PDP sponsor or MA organization offering the part D plan in which the individual is enrolled.

''(C) COLLECTION BY PLAN.—In the case of a late enrollment penalty that is collected from a part D eligible individual in a manner other than the manner described in section 1854(d)(2)(A), the Secretary shall establish procedures for reducing payments otherwise made to the PDP sponsor or MA organization by an amount equal to the amount of such penalty less the portion of such penalty estimated under subparagraph (A).

''(3) FALLBACK PLANS.—In applying this subsection in the case of a fallback prescription drug plan, paragraph (2) shall not apply and the monthly beneficiary premium shall be collected in the manner specified in section 1854(d)(2)(A) (or such other manner as may be provided under section 1840 in the case of monthly premiums under section 1839).

''PREMIUM AND COST-SHARING SUBSIDIES FOR LOW-INCOME INDIVIDUALS

''SEC. 1860D–14. (a) INCOME-RELATED SUBSIDIES FOR INDIVIDUALS WITH INCOME UP TO 150 PERCENT OF POVERTY LINE.—

''(1) INDIVIDUALS WITH INCOME BELOW 135 PERCENT OF POVERTY LINE.—In the case of a subsidy eligible individual (as defined in paragraph (3)) who is determined to have income that is below 135 percent of the poverty line applicable to a family of the size involved and who meets the resources requirement described in paragraph (3)(D) or who is covered under this paragraph under paragraph (3)(B)(i), the individual is entitled under this section to the following:

''(A) FULL PREMIUM SUBSIDY.—An income-related premium subsidy equal to—

''(i) 100 percent of the amount described in subsection (b)(1), but not to exceed the premium amount specified in subsection (b)(2)(B); plus

''(ii) 80 percent of any late enrollment penalties imposed under section 1860D–13(b) for the first 60 months in which such penalties are imposed for that individual, and 100 percent of any such penalties for any subsequent month.

''(B) ELIMINATION OF DEDUCTIBLE.—A reduction in the annual deductible applicable under section 1860D–2(b)(1) to $0.

''(C) CONTINUATION OF COVERAGE ABOVE THE INITIAL COVERAGE LIMIT.—The continuation of

coverage from the initial coverage limit (under paragraph (3) of section 1860D–2(b)) for expenditures incurred through the total amount of expenditures at which benefits are available under paragraph (4) of such section, subject to the reduced cost-sharing described in subparagraph (D).

''(D) REDUCTION IN COST-SHARING BELOW OUT-OF-POCKET THRESHOLD.—

''(i) INSTITUTIONALIZED INDIVIDUALS.—In the case of an individual who is a full-benefit dual eligible individual and who is an institutionalized individual or couple (as defined in section 1902(q)(1)(B)), the elimination of any beneficiary coinsurance described in section 1860D–2(b)(2) (for all amounts through the total amount of expenditures at which benefits are available under section 1860D–2(b)(4)).

''(ii) LOWEST INCOME DUAL ELIGIBLE INDIVIDUALS.—In the case of an individual not described in clause (i) who is a full-benefit dual eligible individual and whose income does not exceed 100 percent of the poverty line applicable to a family of the size involved, the substitution for the beneficiary coinsurance described in section 1860D–2(b)(2) (for all amounts through the total amount of expenditures at which benefits are available under section 1860D–2(b)(4)) of a copayment amount that does not exceed $1 for a generic drug or a preferred drug that is a multiple source drug (as defined in section 1927(k)(7)(A)(i)) and $3 for any other drug, or, if less, the copayment amount applicable to an individual under clause (iii).

''(iii) OTHER INDIVIDUALS.—In the case of an individual not described in clause (i) or (ii), the substitution for the beneficiary coinsurance described in section 1860D–2(b)(2) (for all amounts through the total amount of expenditures at which benefits are available under section 1860D–2(b)(4)) of a copayment amount that does not exceed the copayment amount specified under section 1860D–2(b)(4)(A)(i)(I) for the drug and year involved.

''(E) ELIMINATION OF COST-SHARING ABOVE ANNUAL OUT-OF-POCKET THRESHOLD.—The elimination of any cost-sharing imposed under section 1860D–2(b)(4)(A).

''(2) OTHER INDIVIDUALS WITH INCOME BELOW 150 PERCENT OF POVERTY LINE.—In the case of a subsidy eligible individual who is not described in paragraph (1), the individual is entitled under this section to the following:

''(A) SLIDING SCALE PREMIUM SUBSIDY.—An income-related premium subsidy determined on a linear sliding scale ranging from 100 percent of the amount described in paragraph (1)(A) for individuals with incomes at or below 135 percent of such level to 0 percent of such amount for individuals with incomes at 150 percent of such level.

''(B) REDUCTION OF DEDUCTIBLE.—A reduction in the annual deductible applicable under section 1860D–2(b)(1) to $50.

''(C) CONTINUATION OF COVERAGE ABOVE THE INITIAL COVERAGE LIMIT.—The continuation of coverage from the initial coverage limit (under paragraph (3) of section 1860D–2(b)) for expenditures incurred through the total amount of expenditures at which benefits are available under paragraph (4) of such section, subject to the reduced coinsurance described in subparagraph (D).

''(D) REDUCTION IN COST-SHARING BELOW OUT-OF-POCKET THRESHOLD.—The substitution for the beneficiary coinsurance described in section 1860D–2(b)(2) (for all amounts above the deductible under subparagraph (B) through the total amount of expenditures at which benefits are available under section 1860D–2(b)(4)) of coinsurance of '15 percent' instead of coinsurance of '25 percent' in section 1860D–2(b)(2).

''(E) REDUCTION OF COST-SHARING ABOVE ANNUAL OUT-OF-POCKET THRESHOLD.—Subject to subsection (c), the substitution for the cost-sharing imposed under section 1860D–2(b)(4)(A) of a copayment or coinsurance not to exceed the copayment or coinsurance amount specified under section 1860D–2(b)(4)(A)(i)(I) for the drug and year involved.

''(3) DETERMINATION OF ELIGIBILITY.—

''(A) SUBSIDY ELIGIBLE INDIVIDUAL DEFINED.—For purposes of this part, subject to subparagraph (F), the term 'subsidy eligible individual' means a part D eligible individual who—

''(i) is enrolled in a prescription drug plan or MA–PD plan;

''(ii) has income below 150 percent of the poverty line applicable to a family of the size involved; and

''(iii) meets the resources requirement described in subparagraph (D) or (E).

''(B) DETERMINATIONS.—

''(i) IN GENERAL.—The determination of whether a part D eligible individual residing in a State is a subsidy eligible individual and whether the individual is described in paragraph (1) shall be determined under the State plan under title XIX for the State under section 1935(a) or by the Commissioner of Social Security. There are authorized to be appropriated to the Social Security Administration such sums as may be necessary for the determination of eligibility under this subparagraph.

''(ii) EFFECTIVE PERIOD.—Determinations under this subparagraph shall be effective beginning with the month in which the individual applies for a determination that the individual is a subsidy eligible individual and shall remain in effect for a period specified by the Secretary, but not to exceed 1 year.

''(iii) REDETERMINATIONS AND APPEALS THROUGH MEDICAID.—Redeterminations and appeals, with respect to eligibility determinations under clause (i) made under a State plan under title XIX, shall be made in accordance with the frequency of, and manner in which, redeterminations and appeals of eligibility are made under such plan for purposes of medical assistance under such title.

''(iv) REDETERMINATIONS AND APPEALS THROUGH COMMISSIONER.—With respect to eligibility determinations under clause (i) made by the Commissioner of Social Security—

''(I) redeterminations shall be made at such time or times as may be provided by the Commissioner; and

''(II) the Commissioner shall establish procedures for appeals of such determinations that are similar to the procedures described in the third sentence of section 1631(c)(1)(A).

''(v) TREATMENT OF MEDICAID BENEFICIARIES.—Subject to subparagraph (F), the Secretary—

''(I) shall provide that part D eligible individuals who are full-benefit dual eligible individuals (as defined in section 1935(c)(6)) or who are recipients of supplemental security income benefits under title XVI shall be treated as subsidy eligible individuals described in paragraph (1); and

''(II) may provide that part D eligible individuals not described in subclause (I) who are determined for purposes of the State plan under title XIX to be eligible for medical assistance under clause (i), (iii), or (iv) of section 1902(a)(10)(E) are treated as being determined to be subsidy eligible individuals described in paragraph (1).

Insofar as the Secretary determines that the eligibility requirements under the State plan for medical assistance referred to in subclause (II) are substantially the same as the requirements for being treated as a subsidy eligible individual described in paragraph (1), the Secretary shall provide for the treatment described in such subclause.

''(C) INCOME DETERMINATIONS.—For purposes of applying this section—

''(i) in the case of a part D eligible individual who is not treated as a subsidy eligible individual under subparagraph (B)(v), income shall be determined in the manner described in section 1905(p)(1)(B), without regard to the application of section 1902(r)(2); and

''(ii) the term 'poverty line' has the meaning given such term in section 673(2) of the Community Services Block Grant Act (42 U.S.C. 9902(2)), including any revision required by such section.

Nothing in clause (i) shall be construed to affect the application of section 1902(r)(2) for the determination of eligibility for medical assistance under title XIX.

''(D) RESOURCE STANDARD APPLIED TO FULL LOW-INCOME SUBSIDY TO BE BASED ON THREE TIMES SSI RESOURCE STANDARD.—The resources requirement of this subparagraph is that an individual's resources (as determined under section 1613 for purposes of the supplemental security income program) do not exceed—

''(i) for 2006 three times the maximum amount of resources that an individual may have and obtain benefits under that program; and

''(ii) for a subsequent year the resource limitation established under this clause for the previous year increased by the annual percentage increase in the consumer price index (all items; U.S. city average) as of September of such previous year.

Any resource limitation established under clause (ii) that is not a multiple of $10 shall be rounded to the nearest multiple of $10.

''(E) ALTERNATIVE RESOURCE STANDARD.—

''(i) IN GENERAL.—The resources requirement of this subparagraph is that an individual's resources (as determined under section 1613 for purposes of the supplemental security income program) do not exceed—

''(I) for 2006, $10,000 (or $20,000 in the case of the combined value of the individual's assets or resources and the assets or resources of the individual's spouse); and

''(II) for a subsequent year the dollar amounts specified in this subclause (or subclause (I)) for the previous year increased by the annual percentage increase in the consumer price index (all items; U.S. city average) as of September of such previous year.

Any dollar amount established under subclause (II) that is not a multiple of $10 shall be rounded to the nearest multiple of $10.

''(ii) USE OF SIMPLIFIED APPLICATION FORM AND PROCESS.—The Secretary, jointly with the Commissioner of Social Security, shall—

''(I) develop a model, simplified application form and process consistent with clause (iii) for the determination and verification of a part D eligible individual's assets or resources under this subparagraph; and

''(II) provide such form to States.

''(iii) DOCUMENTATION AND SAFEGUARDS.—Under such process—

''(I) the application form shall consist of an attestation under penalty of perjury regarding the level of assets or resources (or combined assets and resources in the case of a married part D eligible individual) and valuations of general classes of assets or resources;

''(II) such form shall be accompanied by copies of recent statements (if any) from financial institutions in support of the application; and

''(III) matters attested to in the application shall be subject to appropriate methods of verification.

''(iv) METHODOLOGY FLEXIBILITY.—The Secretary may permit a State in making eligibility determinations for premium and cost-sharing subsidies under this section to use the same asset or resource methodologies that are used with respect to eligibility for medical assistance for medicare cost-sharing described in section 1905(p) so long as the Secretary determines that the use of such methodologies will not result in any significant differences in the number of individuals determined to be subsidy eligible individuals.

''(F) TREATMENT OF TERRITORIAL RESIDENTS.—In the case of a part D eligible individual who is not a resident of the 50 States or the District of Columbia, the individual is not eligible to be a subsidy eligible individual under

this section but may be eligible for financial assistance with prescription drug expenses under section 1935(e).

''(4) INDEXING DOLLAR AMOUNTS.—

''(A) COPAYMENT FOR LOWEST INCOME DUAL ELIGIBLE INDIVIDUALS.—The dollar amounts applied under paragraph (1)(D)(ii)—

''(i) for 2007 shall be the dollar amounts specified in such paragraph increased by the annual percentage increase in the consumer price index (all items; U.S. city average) as of September of such previous year; or

''(ii) for a subsequent year shall be the dollar amounts specified in this clause (or clause (i)) for the previous year increased by the annual percentage increase in the consumer price index (all items; U.S. city average) as of September of such previous year.

Any amount established under clause (i) or (ii), that is based on an increase of $1 or $3, that is not a multiple of 5 cents or 10 cents, respectively, shall be rounded to the nearest multiple of 5 cents or 10 cents, respectively.

''(B) REDUCED DEDUCTIBLE.—The dollar amount applied under paragraph (2)(B)—

''(i) for 2007 shall be the dollar amount specified in such paragraph increased by the annual percentage increase described in section 1860D–2(b)(6) for 2007; or

''(ii) for a subsequent year shall be the dollar amount specified in this clause (or clause (i)) for the previous year increased by the annual percentage increase described in section 1860D–2(b)(6) for the year involved.

Any amount established under clause (i) or (ii) that is not a multiple of $1 shall be rounded to the nearest multiple of $1.

''(b) PREMIUM SUBSIDY AMOUNT.—

''(1) IN GENERAL.—The premium subsidy amount described in this subsection for a subsidy eligible individual residing in a PDP region and enrolled in a prescription drug plan or MA–PD plan is the low-income benchmark premium amount (as defined in paragraph (2)) for the PDP region in which the individual resides or, if greater, the amount specified in paragraph (3).

''(2) LOW-INCOME BENCHMARK PREMIUM AMOUNT DEFINED.—

''(A) IN GENERAL.—For purposes of this subsection, the term 'low-income benchmark premium amount' means, with respect to a PDP region in which—

''(i) all prescription drug plans are offered by the same PDP sponsor, the weighted average of the amounts described in subparagraph (B)(i) for such plans; or

''(ii) there are prescription drug plans offered by more than one PDP sponsor, the weighted average of amounts described in subparagraph (B) for prescription drug plans and MA–PD plans described in section 1851(a)(2)(A)(i) offered in such region.

''(B) PREMIUM AMOUNTS DESCRIBED.—The premium amounts described in this subparagraph are, in the case of—

''(i) a prescription drug plan that is a basic prescription drug plan, the monthly beneficiary premium for such plan;

''(ii) a prescription drug plan that provides alternative prescription drug coverage the actuarial value of which is greater than that of standard prescription drug coverage, the portion of the monthly beneficiary premium that is attributable to basic prescription drug coverage; and

''(iii) an MA–PD plan, the portion of the MA monthly prescription drug beneficiary premium that is attributable to basic prescription drug benefits (described in section 1852(a)(6)(B)(ii)).

The premium amounts described in this subparagraph do not include any amounts attributable to late enrollment penalties under section 1860D–13(b).

''(3) ACCESS TO 0 PREMIUM PLAN.—In no case shall the premium subsidy amount under this subsection for a PDP region be less than the lowest monthly beneficiary premium for a prescription drug plan that offers basic prescription drug coverage in the region.

''(c) ADMINISTRATION OF SUBSIDY PROGRAM.—

''(1) IN GENERAL.—The Secretary shall provide a process whereby, in the case of a part D eligible individual who is determined to be a subsidy eligible individual and who is enrolled in a prescription drug plan or is enrolled in an MA–PD plan—

''(A) the Secretary provides for a notification of the PDP sponsor or the MA organization offering the plan involved that the individual is eligible for a subsidy and the amount of the subsidy under subsection (a);

''(B) the sponsor or organization involved reduces the premiums or cost-sharing otherwise imposed by the amount of the applicable subsidy and submits to the Secretary information on the amount of such reduction;

''(C) the Secretary periodically and on a timely basis reimburses the sponsor or organization for the amount of such reductions; and

''(D) the Secretary ensures the confidentiality of individually identifiable information.

In applying subparagraph (C), the Secretary shall compute reductions based upon imposition under subsections (a)(1)(D) and (a)(2)(E) of unreduced copayment amounts applied under such subsections.

''(2) USE OF CAPITATED FORM OF PAYMENT.—The reimbursement under this section with respect to cost-sharing subsidies may be computed on a capitated basis, taking into account the actuarial value of the subsidies and with appropriate adjustments to reflect differences in the risks actually involved.

''(d) RELATION TO MEDICAID PROGRAM.—For special provisions under the medicaid program relating to medicare prescription drug benefits, see section 1935.

''SUBSIDIES FOR PART D ELIGIBLE INDIVIDUALS FOR QUALIFIED PRESCRIPTION DRUG COVERAGE

''SEC. 1860D–15. (a) SUBSIDY PAYMENT.—In order to reduce premium levels applicable to qualified prescription drug coverage for part D eligible individuals consistent with an overall subsidy level of 74.5 percent for basic prescription drug coverage, to reduce adverse selection among prescription drug plans and MA–PD plans, and to promote the participation of PDP sponsors under this part and MA organizations under part C, the Secretary shall provide for payment to a PDP sponsor that offers a prescription drug plan and an MA organization that offers an MA–PD plan of the following subsidies in accordance with this section:

''(1) DIRECT SUBSIDY.—A direct subsidy for each part D eligible individual enrolled in a prescription drug plan or MA–PD plan for a month equal to—

''(A) the amount of the plan's standardized bid amount (as defined in section 1860D–13(a)(5)), adjusted under subsection (c)(1), reduced by

''(B) the base beneficiary premium (as computed under paragraph (2) of section 1860D–13(a) and as adjusted under paragraph (1)(B) of such section).

''(2) SUBSIDY THROUGH REINSURANCE.—The reinsurance payment amount (as defined in subsection (b)).

This section constitutes budget authority in advance of appropriations Acts and represents the obligation of the Secretary to provide for the payment of amounts provided under this section.

''(b) REINSURANCE PAYMENT AMOUNT.—

''(1) IN GENERAL.—The reinsurance payment amount under this subsection for a part D eligible individual enrolled in a prescription drug plan or MA–PD plan for a coverage year is an amount equal to 80 percent of the allowable reinsurance costs (as specified in paragraph (2)) attributable to that portion of gross covered prescription drug costs as specified in paragraph (3) incurred in the coverage year after such individual has incurred costs that exceed the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B).

''(2) ALLOWABLE REINSURANCE COSTS.—For purposes of this section, the term 'allowable reinsurance costs' means, with respect to gross covered prescription drug costs under a prescription drug plan offered by a PDP sponsor or an MA–PD plan offered by an MA organization, the part of such costs that are actually paid (net of discounts, chargebacks, and average percentage rebates) by the sponsor or organization or by (or on behalf of) an enrollee under the plan, but in no case more than the part of such costs that would have been paid under the plan if the prescription drug coverage under the plan were basic prescription drug coverage, or, in the case of a plan providing supplemental prescription drug coverage, if such coverage were standard prescription drug coverage.

''(3) GROSS COVERED PRESCRIPTION DRUG COSTS.—For purposes of this section, the term 'gross covered prescription drug costs' means, with respect to a part D eligible individual enrolled in a prescription drug plan or MA–PD plan during a coverage year, the costs incurred under the plan, not including administrative costs, but including costs directly related to the dispensing of covered part D drugs during the year and costs relating to the deductible. Such costs shall be determined whether they are paid by the individual or under the plan, regardless of whether the coverage under the plan exceeds basic prescription drug coverage.

''(4) COVERAGE YEAR DEFINED.—For purposes of this section, the term 'coverage year' means a calendar year in which covered part D drugs are dispensed if the claim for such drugs (and payment on such claim) is made not later than such period after the end of such year as the Secretary specifies.

''(c) ADJUSTMENTS RELATING TO BIDS.—

''(1) HEALTH STATUS RISK ADJUSTMENT.—

''(A) ESTABLISHMENT OF RISK ADJUSTORS.—The Secretary shall establish an appropriate methodology for adjusting the standardized bid amount under subsection (a)(1)(A) to take into account variation in costs for basic prescription drug coverage among prescription drug plans and MA–PD plans based on the differences in actuarial risk of different enrollees being served. Any such risk adjustment shall be designed in a manner so as not to result in a change in the aggregate amounts payable to such plans under subsection (a)(1) and through that portion of the monthly beneficiary prescription drug premiums described in subsection (a)(1)(B) and MA monthly prescription drug beneficiary premiums.

''(B) CONSIDERATIONS.—In establishing the methodology under subparagraph (A), the Secretary may take into account the similar methodologies used under section 1853(a)(3) to adjust payments to MA organizations for benefits under the original medicare fee-for-service program option.

''(C) DATA COLLECTION.—In order to carry out this paragraph, the Secretary shall require—

''(i) PDP sponsors to submit data regarding drug claims that can be linked at the individual level to part A and part B data and such other information as the Secretary determines necessary; and

''(ii) MA organizations that offer MA–PD plans to submit data regarding drug claims that can be linked at the individual level to other data that such organizations are required to submit to the Secretary and such other information as the Secretary determines necessary.

''(D) PUBLICATION.—At the time of publication of risk adjustment factors under section 1853(b)(1)(B)(i)(II), the Secretary shall publish the risk adjusters established under this paragraph for the succeeding year.

''(2) GEOGRAPHIC ADJUSTMENT.—

''(A) IN GENERAL.—Subject to subparagraph (B), for purposes of section 1860D–13(a)(1)(B)(iii), the Secretary shall establish an

appropriate methodology for adjusting the national average monthly bid amount (computed under section 1860D–13(a)(4)) to take into account differences in prices for covered part D drugs among PDP regions.

''(B) DE MINIMIS RULE.—If the Secretary determines that the price variations described in subparagraph (A) among PDP regions are de minimis, the Secretary shall not provide for adjustment under this paragraph.

''(C) BUDGET NEUTRAL ADJUSTMENT.—Any adjustment under this paragraph shall be applied in a manner so as to not result in a change in the aggregate payments made under this part that would have been made if the Secretary had not applied such adjustment.

''(d) PAYMENT METHODS.—

''(1) IN GENERAL.—Payments under this section shall be based on such a method as the Secretary determines. The Secretary may establish a payment method by which interim payments of amounts under this section are made during a year based on the Secretary's best estimate of amounts that will be payable after obtaining all of the information.

''(2) REQUIREMENT FOR PROVISION OF INFORMATION.—

''(A) REQUIREMENT.—Payments under this section to a PDP sponsor or MA organization are conditioned upon the furnishing to the Secretary, in a form and manner specified by the Secretary, of such information as may be required to carry out this section.

''(B) RESTRICTION ON USE OF INFORMATION.—Information disclosed or obtained pursuant to subparagraph (A) may be used by officers, employees, and contractors of the Department of Health and Human Services only for the purposes of, and to the extent necessary in, carrying out this section.

''(3) SOURCE OF PAYMENTS.—Payments under this section shall be made from the Medicare Prescription Drug Account.

''(4) APPLICATION OF ENROLLEE ADJUSTMENT.—The provisions of section 1853(a)(2) shall apply to payments to PDP sponsors under this section in the same manner as they apply to payments to MA organizations under section 1853(a).

''(e) PORTION OF TOTAL PAYMENTS TO A SPONSOR OR ORGANIZATION SUBJECT TO RISK (APPLICATION OF RISK CORRIDORS).—

''(1) COMPUTATION OF ADJUSTED ALLOWABLE RISK CORRIDOR COSTS.—

''(A) IN GENERAL.—For purposes of this subsection, the term 'adjusted allowable risk corridor costs' means, for a plan for a coverage year (as defined in subsection (b)(4))—

''(i) the allowable risk corridor costs (as defined in subparagraph (B)) for the plan for the year, reduced by

''(ii) the sum of (I) the total reinsurance payments made under subsection (b) to the sponsor of the plan for the year, and (II) the total subsidy payments made under section 1860D–14 to the sponsor of the plan for the year.

''(B) ALLOWABLE RISK CORRIDOR COSTS.—For purposes of this subsection, the term 'allowable risk corridor costs' means, with respect to a prescription drug plan offered by a PDP sponsor or an MA–PD plan offered by an MA organization, the part of costs (not including administrative costs, but including costs directly related to the dispensing of covered part D drugs during the year) incurred by the sponsor or organization under the plan that are actually paid (net of discounts, chargebacks, and average percentage rebates) by the sponsor or organization under the plan, but in no case more than the part of such costs that would have been paid under the plan if the prescription drug coverage under the plan were basic prescription drug coverage, or, in the case of a plan providing supplemental prescription drug coverage, if such coverage were basic prescription drug coverage taking into account the adjustment under section 1860D–11(c)(2). In computing allowable costs under this paragraph, the Secretary shall compute such costs based upon imposition under paragraphs (1)(D) and (2)(E) of section 1860D–14(a) of the maximum amount of copayments permitted under such paragraphs.

''(2) ADJUSTMENT OF PAYMENT.—

''(A) NO ADJUSTMENT IF ADJUSTED ALLOWABLE RISK CORRIDOR COSTS WITHIN RISK CORRIDOR.—If the adjusted allowable risk corridor costs (as defined in paragraph (1)) for the plan for the year are at least equal to the first threshold lower limit of the risk corridor (specified in paragraph (3)(A)(i)), but not greater than the first threshold upper limit of the risk corridor (specified in paragraph (3)(A)(iii)) for the plan for the year, then no payment adjustment shall be made under this subsection.

''(B) INCREASE IN PAYMENT IF ADJUSTED ALLOWABLE RISK CORRIDOR COSTS ABOVE UPPER LIMIT OF RISK CORRIDOR.—

''(i) COSTS BETWEEN FIRST AND SECOND THRESHOLD UPPER LIMITS.—If the adjusted allowable risk corridor costs for the plan for the year are greater than the first threshold upper limit, but not greater than the second threshold upper limit, of the risk corridor for the plan for the year, the Secretary shall increase the total of the payments made to the sponsor or organization offering the plan for the year under this section by an amount equal to 50 percent (or, for 2006 and 2007, 75 percent or 90 percent if the conditions described in clause (iii) are met for the year) of the difference between such adjusted allowable risk corridor costs and the first threshold upper limit of the risk corridor.

''(ii) COSTS ABOVE SECOND THRESHOLD UPPER LIMITS.—If the adjusted allowable risk corridor costs for the plan for the year are greater than the second threshold upper limit of the risk corridor for the plan for the year, the Secretary shall increase the total of the payments made to the sponsor or organization offering the plan for the year under this section by an amount equal to the sum of—

''(I) 50 percent (or, for 2006 and 2007, 75 percent or 90 percent if the conditions described in clause (iii) are met for the year) of the difference between the second threshold upper limit and the first threshold upper limit; and

''(II) 80 percent of the difference between such adjusted allowable risk corridor costs and the second threshold upper limit of the risk corridor.

''(iii) CONDITIONS FOR APPLICATION OF HIGHER PERCENTAGE FOR 2006 AND 2007.—The conditions described in this clause are met for 2006 or 2007 if the Secretary determines with respect to such year that—

''(I) at least 60 percent of prescription drug plans and MA–PD plans to which this subsection applies have adjusted allowable risk corridor costs for the plan for the year that are more than the first threshold upper limit of the risk corridor for the plan for the year; and

''(II) such plans represent at least 60 percent of part D eligible individuals enrolled in any prescription drug plan or MA–PD plan.

''(C) REDUCTION IN PAYMENT IF ADJUSTED ALLOWABLE RISK CORRIDOR COSTS BELOW LOWER LIMIT OF RISK CORRIDOR.—

''(i) COSTS BETWEEN FIRST AND SECOND THRESHOLD LOWER LIMITS.—If the adjusted allowable risk corridor costs for the plan for the year are less than the first threshold lower limit, but not less than the second threshold lower limit, of the risk corridor for the plan for the year, the Secretary shall reduce the total of the payments made to the sponsor or organization offering the plan for the year under this section by an amount (or otherwise recover from the sponsor or organization an amount) equal to 50 percent (or, for 2006 and 2007, 75 percent) of the difference between the first threshold lower limit of the risk corridor and such adjusted allowable risk corridor costs.

''(ii) COSTS BELOW SECOND THRESHOLD LOWER LIMIT.—If the adjusted allowable risk corridor costs for the plan for the year are less the second threshold lower limit of the risk corridor for the plan for the year, the Secretary shall reduce the total of the payments made to the sponsor or organization offering the plan for the year under this section by an amount (or otherwise recover from the sponsor or organization an amount) equal to the sum of—

''(I) 50 percent (or, for 2006 and 2007, 75 percent) of the difference between the first threshold lower limit and the second threshold lower limit; and

''(II) 80 percent of the difference between the second threshold upper limit of the risk corridor and such adjusted allowable risk corridor costs.

''(3) ESTABLISHMENT OF RISK CORRIDORS.—

''(A) IN GENERAL.—For each plan year the Secretary shall establish a risk corridor for each prescription drug plan and each MA–PD plan. The risk corridor for a plan for a year shall be equal to a range as follows:

''(i) FIRST THRESHOLD LOWER LIMIT.—The first threshold lower limit of such corridor shall be equal to—

''(I) the target amount described in subparagraph (B) for the plan; minus

''(II) an amount equal to the first threshold risk percentage for the plan (as determined under subparagraph (C)(i)) of such target amount.

''(ii) SECOND THRESHOLD LOWER LIMIT.—The second threshold lower limit of such corridor shall be equal to—

''(I) the target amount described in subparagraph (B) for the plan; minus

''(II) an amount equal to the second threshold risk percentage for the plan (as determined under subparagraph (C)(ii)) of such target amount.

''(iii) FIRST THRESHOLD UPPER LIMIT.—The first threshold upper limit of such corridor shall be equal to the sum of—

''(I) such target amount; and

''(II) the amount described in clause (i)(II).

''(iv) SECOND THRESHOLD UPPER LIMIT.—The second threshold upper limit of such corridor shall be equal to the sum of—

''(I) such target amount; and

''(II) the amount described in clause (ii)(II).

''(B) TARGET AMOUNT DESCRIBED.—The target amount described in this paragraph is, with respect to a prescription drug plan or an MA–PD plan in a year, the total amount of payments paid to the PDP sponsor or MA–PD organization for the plan for the year, taking into account amounts paid by the Secretary and enrollees, based upon the standardized bid amount (as defined in section 1860D–13(a)(5) and as risk adjusted under subsection (c)(1)), reduced by the total amount of administrative expenses for the year assumed in such standardized bid.

''(C) FIRST AND SECOND THRESHOLD RISK PERCENTAGE DEFINED.—

''(i) FIRST THRESHOLD RISK PERCENTAGE.—Subject to clause (iii), for purposes of this section, the first threshold risk percentage is—

''(I) for 2006 and 2007, and 2.5 percent;

''(II) for 2008 through 2011, 5 percent; and

''(III) for 2012 and subsequent years, a percentage established by the Secretary, but in no case less than 5 percent.

''(ii) SECOND THRESHOLD RISK PERCENTAGE.—Subject to clause (iii), for purposes of this section, the second threshold risk percentage is—

''(I) for 2006 and 2007, 5 percent;

''(II) for 2008 through 2011, 10 percent; and

''(III) for 2012 and subsequent years, a percentage established by the Secretary that is greater than the percent established for the year under clause (i)(III), but in no case less than 10 percent.

''(iii) REDUCTION OF RISK PERCENTAGE TO ENSURE 2 PLANS IN AN AREA.—Pursuant to section 1860D–11(b)(2)(E)(ii), a PDP sponsor may submit a bid that requests a decrease in the applicable first or second threshold risk percentages or an increase in the percents applied under paragraph (2).

''(4) PLANS AT RISK FOR ENTIRE AMOUNT OF SUPPLEMENTAL PRESCRIPTION DRUG COVERAGE.—A PDP sponsor and MA organization that offers

a plan that provides supplemental prescription drug benefits shall be at full financial risk for the provision of such supplemental benefits.

''(5) NO EFFECT ON MONTHLY PREMIUM.—No adjustment in payments made by reason of this subsection shall affect the monthly beneficiary premium or the MA monthly prescription drug beneficiary premium.

''(f) DISCLOSURE OF INFORMATION.—

''(1) IN GENERAL.—Each contract under this part and under part C shall provide that—

''(A) the PDP sponsor offering a prescription drug plan or an MA organization offering an MA–PD plan shall provide the Secretary with such information as the Secretary determines is necessary to carry out this section; and

''(B) the Secretary shall have the right in accordance with section 1857(d)(2)(B) (as applied under section 1860D–12(b)(3)(C)) to inspect and audit any books and records of a PDP sponsor or MA organization that pertain to the information regarding costs provided to the Secretary under subparagraph (A).

''(2) RESTRICTION ON USE OF INFORMATION.—Information disclosed or obtained pursuant to the provisions of this section may be used by officers, employees, and contractors of the Department of Health and Human Services only for the purposes of, and to the extent necessary in, carrying out this section.

''(g) PAYMENT FOR FALLBACK PRESCRIPTION DRUG PLANS.—In lieu of the amounts otherwise payable under this section to a PDP sponsor offering a fallback prescription drug plan (as defined in section 1860D–3(c)(4)), the amount payable shall be the amounts determined under the contract for such plan pursuant to section 1860D–11(g)(5).

''MEDICARE PRESCRIPTION DRUG ACCOUNT IN THE FEDERAL SUPPLEMENTARY MEDICAL INSURANCE TRUST FUND

''SEC. 1860D–16. (a) ESTABLISHMENT AND OPERATION OF ACCOUNT.—

''(1) ESTABLISHMENT.—There is created within the Federal Supplementary Medical Insurance Trust Fund established by section 1841 an account to be known as the 'Medicare Prescription Drug Account' (in this section referred to as the 'Account').

''(2) FUNDING.—The Account shall consist of such gifts and bequests as may be made as provided in section 201(i)(1), accrued interest on balances in the Account, and such amounts as may be deposited in, or appropriated to, such Account as provided in this part.

''(3) SEPARATE FROM REST OF TRUST FUND.—Funds provided under this part to the Account shall be kept separate from all other funds within the Federal Supplementary Medical Insurance Trust Fund, but shall be invested, and such investments redeemed, in the same manner as all other funds and investments within such Trust Fund.

''(b) PAYMENTS FROM ACCOUNT.—

''(1) IN GENERAL.—The Managing Trustee shall pay from time to time from the Account such amounts as the Secretary certifies are necessary to make payments to operate the program under this part, including—

''(A) payments under section 1860D–14 (relating to low-income subsidy payments);

''(B) payments under section 1860D–15 (relating to subsidy payments and payments for fallback plans);

''(C) payments to sponsors of qualified retiree prescription drug plans under section 1860D–22(a); and

''(D) payments with respect to administrative expenses under this part in accordance with section 201(g).

''(2) TRANSFERS TO MEDICAID ACCOUNT FOR INCREASED ADMINISTRATIVE COSTS.—The Managing Trustee shall transfer from time to time from the Account to the Grants to States for Medicaid account amounts the Secretary certifies are attributable to increases in payment resulting from the application of section 1935(b).

''(3) PAYMENTS OF PREMIUMS WITHHELD.—The Managing Trustee shall make payment to the PDP sponsor or MA organization involved of the premiums (and the portion of late enrollment penalties) that are collected in the manner described in section 1854(d)(2)(A) and that are payable under a prescription drug plan or MA–PD plan offered by such sponsor or organization.

''(4) TREATMENT IN RELATION TO PART B PREMIUM.—Amounts payable from the Account shall not be taken into account in computing actuarial rates or premium amounts under section 1839.

''(c) DEPOSITS INTO ACCOUNT.—

''(1) LOW-INCOME TRANSFER.—Amounts paid under section 1935(c) (and any amounts collected or offset under paragraph (1)(C) of such section) are deposited into the Account.

''(2) AMOUNTS WITHHELD.—Pursuant to sections 1860D–13(c) and 1854(d) (as applied under this part), amounts that are withheld (and allocated) to the Account are deposited into the Account.

''(3) APPROPRIATIONS TO COVER GOVERNMENT CONTRIBUTIONS.—There are authorized to be appropriated from time to time, out of any moneys in the Treasury not otherwise appropriated, to the Account, an amount equivalent to the amount of payments made from the Account under subsection (b) plus such amounts as the Managing Trustee certifies is necessary to maintain an appropriate contingency margin, reduced by the amounts deposited under paragraph (1) or subsection (a)(2).

''(4) INITIAL FUNDING AND RESERVE.—In order to assure prompt payment of benefits provided under this part and the administrative expenses thereunder during the early months of the program established by this part and to provide an initial contingency reserve, there are authorized to be appropriated to the Account, out of any moneys in the Treasury not otherwise appropriated, such amount as the Secretary certifies are required, but not to exceed 10 percent of the estimated total expenditures from such Account in 2006.

''(5) TRANSFER OF ANY REMAINING BALANCE FROM TRANSITIONAL ASSISTANCE ACCOUNT.—Any balance in the Transitional Assistance Account that is transferred under section 1860D–31(k)(5) shall be deposited into the Account.

''Subpart 3—Application to Medicare Advantage Program and Treatment of Employer-Sponsored Programs and Other Prescription Drug Plans

''APPLICATION TO MEDICARE ADVANTAGE PROGRAM AND RELATED MANAGED CARE PROGRAMS

''SEC. 1860D–21. (a) SPECIAL RULES RELATING TO OFFERING OF QUALIFIED PRESCRIPTION DRUG COVERAGE.—

''(1) IN GENERAL.—An MA organization on and after January 1, 2006—

''(A) may not offer an MA plan described in section 1851(a)(2)(A) in an area unless either that plan (or another MA plan offered by the organization in that same service area) includes required prescription drug coverage (as defined in paragraph (2)); and

''(B) may not offer prescription drug coverage (other than that required under parts A and B) to an enrollee—

''(i) under an MSA plan; or

''(ii) under another MA plan unless such drug coverage under such other plan provides qualified prescription drug coverage and unless the requirements of this section with respect to such coverage are met.

''(2) QUALIFYING COVERAGE.—For purposes of paragraph (1)(A), the term 'required coverage' means with respect to an MA–PD plan—

''(A) basic prescription drug coverage; or

''(B) qualified prescription drug coverage that provides supplemental prescription drug coverage, so long as there is no MA monthly supplemental beneficiary premium applied under the plan (due to the application of a credit against such premium of a rebate under section 1854(b)(1)(C)).

''(b) APPLICATION OF DEFAULT ENROLLMENT RULES.—

''(1) SEAMLESS CONTINUATION.—In applying section 1851(c)(3)(A)(ii), an individual who is enrolled in a health benefits plan shall not be considered to have been deemed to make an election into an MA–PD plan unless such health benefits plan provides any prescription drug coverage.

''(2) MA CONTINUATION.—In applying section 1851(c)(3)(B), an individual who is enrolled in an MA plan shall not be considered to have been deemed to make an election into an MA–PD plan unless—

''(A) for purposes of the election as of January 1, 2006, the MA plan provided as of December 31, 2005, any prescription drug coverage; or

''(B) for periods after January 1, 2006, such MA plan is an MA–PD plan.

''(3) DISCONTINUANCE OF MA–PD ELECTION DURING FIRST YEAR OF ELIGIBILITY.—In applying the second sentence of section 1851(e)(4) in the case of an individual who is electing to discontinue enrollment in an MA–PD plan, the individual shall be permitted to enroll in a prescription drug plan under part D at the time of the election of coverage under the original medicare fee-for-service program.

''(4) RULES REGARDING ENROLLEES IN MA PLANS NOT PROVIDING QUALIFIED PRESCRIPTION DRUG COVERAGE.—In the case of an individual who is enrolled in an MA plan (other than an MSA plan) that does not provide qualified prescription drug coverage, if the organization offering such coverage discontinues the offering with respect to the individual of all MA plans that do not provide such coverage—

''(i) the individual is deemed to have elected the original medicare fee-for-service program option, unless the individual affirmatively elects to enroll in an MA–PD plan; and

''(ii) in the case of such a deemed election, the disenrollment shall be treated as an involuntary termination of the MA plan described in subparagraph (B)(ii) of section 1882(s)(3) for purposes of applying such section.

The information disclosed under section 1852(c)(1) for individuals who are enrolled in such an MA plan shall include information regarding such rules.

''(c) APPLICATION OF PART D RULES FOR PRESCRIPTION DRUG COVERAGE.—With respect to the offering of qualified prescription drug coverage by an MA organization under this part on and after January 1, 2006—

''(1) IN GENERAL.—Except as otherwise provided, the provisions of this part shall apply under part C with respect to prescription drug coverage provided under MA–PD plans in lieu of the other provisions of part C that would apply to such coverage under such plans.

''(2) WAIVER.—The Secretary shall waive the provisions referred to in paragraph (1) to the extent the Secretary determines that such provisions duplicate, or are in conflict with, provisions otherwise applicable to the organization or plan under part C or as may be necessary in order to improve coordination of this part with the benefits under this part.

''(3) TREATMENT OF MA OWNED AND OPERATED PHARMACIES.—The Secretary may waive the requirement of section 1860D–4(b)(1)(C) in the case of an MA–PD plan that provides access (other than mail order) to qualified prescription drug coverage through pharmacies owned and operated by the MA organization, if the Secretary determines that the organization's pharmacy network is sufficient to provide comparable access for enrollees under the plan.

''(d) SPECIAL RULES FOR PRIVATE FEE-FOR-SERVICE PLANS THAT OFFER PRESCRIPTION DRUG COVERAGE.—With respect to an MA plan described in section 1851(a)(2)(C) that offers qualified prescription drug coverage, on and after January 1, 2006, the following rules apply:

''(1) REQUIREMENTS REGARDING NEGOTIATED PRICES.—Subsections (a)(1) and (d)(1) of section

1860D–2 and section 1860D–4(b)(2)(A) shall not be construed to require the plan to provide negotiated prices (described in subsection (d)(1)(B) of such section), but shall apply to the extent the plan does so.

''(2) MODIFICATION OF PHARMACY ACCESS STANDARD AND DISCLOSURE REQUIREMENT.—If the plan provides coverage for drugs purchased from all pharmacies, without charging additional cost-sharing, and without regard to whether they are participating pharmacies in a network or have entered into contracts or agreements with pharmacies to provide drugs to enrollees covered by the plan, subsections (b)(1)(C) and (k) of section 1860D–4 shall not apply to the plan.

''(3) DRUG UTILIZATION MANAGEMENT PROGRAM AND MEDICATION THERAPY MANAGEMENT PROGRAM NOT REQUIRED.—The requirements of subparagraphs (A) and (C) of section 1860D–4(c)(1) shall not apply to the plan.

''(4) APPLICATION OF REINSURANCE.—The Secretary shall determine the amount of reinsurance payments under section 1860D–15(b) using a methodology that—

''(A) bases such amount on the Secretary's estimate of the amount of such payments that would be payable if the plan were an MA–PD plan described in section 1851(a)(2)(A)(i) and the previous provisions of this subsection did not apply; and

''(B) takes into account the average reinsurance payments made under section 1860D–15(b) for populations of similar risk under MA–PD plans described in such section.

''(5) EXEMPTION FROM RISK CORRIDOR PROVISIONS.—The provisions of section 1860D–15(e) shall not apply.

''(6) EXEMPTION FROM NEGOTIATIONS.—Subsections (d) and (e)(2)(C) of section 1860D–11 shall not apply and the provisions of section 1854(a)(5)(B) prohibiting the review, approval, or disapproval of amounts described in such section shall apply to the proposed bid and terms and conditions described in section 1860D–11(d).

''(7) TREATMENT OF INCURRED COSTS WITHOUT REGARD TO FORMULARY.—The exclusion of costs incurred for covered part D drugs which are not included (or treated as being included) in a plan's formulary under section 1860D–2(b)(4)(B)(i) shall not apply insofar as the plan does not utilize a formulary.

''(e) APPLICATION TO REASONABLE COST REIMBURSEMENT CONTRACTORS.—

''(1) IN GENERAL.—Subject to paragraphs (2) and (3) and rules established by the Secretary, in the case of an organization that is providing benefits under a reasonable cost reimbursement contract under section 1876(h) and that elects to provide qualified prescription drug coverage to a part D eligible individual who is enrolled under such a contract, the provisions of this part (and related provisions of part C) shall apply to the provision of such coverage to such enrollee in the same manner as such provisions apply to the provision of such coverage under an MA–PD local plan described in section 1851(a)(2)(A)(i) and coverage under such a contract that so provides qualified prescription drug coverage shall be deemed to be an MA–PD local plan.

''(2) LIMITATION ON ENROLLMENT.—In applying paragraph (1), the organization may not enroll part D eligible individuals who are not enrolled under the reasonable cost reimbursement contract involved.

''(3) BIDS NOT INCLUDED IN DETERMINING NATIONAL AVERAGE MONTHLY BID AMOUNT.—The bid of an organization offering prescription drug coverage under this subsection shall not be taken into account in computing the national average monthly bid amount and low-income benchmark premium amount under this part.

''(f) APPLICATION TO PACE.—

''(1) IN GENERAL.—Subject to paragraphs (2) and (3) and rules established by the Secretary, in the case of a PACE program under section 1894 that elects to provide qualified prescription drug coverage to a part D eligible individual who is enrolled under such program, the provisions of this part (and related provisions of part C) shall apply to the provision of such coverage to such enrollee in a manner that is similar to the manner in which such provisions apply to the provision of such coverage under an MA–PD local plan described in section 1851(a)(2)(A)(ii) and a PACE program that so provides such coverage may be deemed to be an MA–PD local plan.

''(2) LIMITATION ON ENROLLMENT.—In applying paragraph (1), the organization may not enroll part D eligible individuals who are not enrolled under the PACE program involved.

''(3) BIDS NOT INCLUDED IN DETERMINING STANDARDIZED BID AMOUNT.—The bid of an organization offering prescription drug coverage under this subsection is not be taken into account in computing any average benchmark bid amount and low-income benchmark premium amount under this part.

''SPECIAL RULES FOR EMPLOYER-SPONSORED PROGRAMS

''SEC. 1860D–22. (a) SUBSIDY PAYMENT.—

''(1) IN GENERAL.—The Secretary shall provide in accordance with this subsection for payment to the sponsor of a qualified retiree prescription drug plan (as defined in paragraph (2)) of a special subsidy payment equal to the amount specified in paragraph (3) for each qualified covered retiree under the plan (as defined in paragraph (4)). This subsection constitutes budget authority in advance of appropriations Acts and represents the obligation of the Secretary to provide for the payment of amounts provided under this section.

''(2) QUALIFIED RETIREE PRESCRIPTION DRUG PLAN DEFINED.—For purposes of this subsection, the term 'qualified retiree prescription drug plan' means employment-based retiree health coverage (as defined in subsection (c)(1)) if, with respect to a part D eligible individual who is a participant or beneficiary under such coverage, the following requirements are met:

''(A) ATTESTATION OF ACTUARIAL EQUIVALENCE TO STANDARD COVERAGE.—The sponsor of the plan provides the Secretary, annually or at such other time as the Secretary may require, with an attestation that the actuarial value of prescription drug coverage under the plan (as determined using the processes and methods described in section 1860D–11(c)) is at least equal to the actuarial value of standard prescription drug coverage.

''(B) AUDITS.—The sponsor of the plan, or an administrator of the plan designated by the sponsor, shall maintain (and afford the Secretary access to) such records as the Secretary may require for purposes of audits and other oversight activities necessary to ensure the adequacy of prescription drug coverage and the accuracy of payments made under this section. The provisions of section 1860D–2(d)(3) shall apply to such information under this section (including such actuarial value and attestation) in a manner similar to the manner in which they apply to financial records of PDP sponsors and MA organizations.

''(C) PROVISION OF DISCLOSURE REGARDING PRESCRIPTION DRUG COVERAGE.—The sponsor of the plan shall provide for disclosure of information regarding prescription drug coverage in accordance with section 1860D–13(b)(6)(B).

''(3) EMPLOYER AND UNION SPECIAL SUBSIDY AMOUNTS.—

''(A) IN GENERAL.—For purposes of this subsection, the special subsidy payment amount under this paragraph for a qualifying covered retiree for a coverage year enrolled with the sponsor of a qualified retiree prescription drug plan is, for the portion of the retiree's gross covered retiree plan-related prescription drug costs (as defined in subparagraph (C)(ii)) for such year that exceeds the cost threshold amount specified in subparagraph (B) and does not exceed the cost limit under such subparagraph, an amount equal to 28 percent of the allowable retiree costs (as defined in subparagraph (C)(i)) attributable to such gross covered prescription drug costs.

''(B) COST THRESHOLD AND COST LIMIT APPLICABLE.—

''(i) IN GENERAL.—Subject to clause (ii)—

''(I) the cost threshold under this subparagraph is equal to $250 for plan years that end in 2006; and

''(II) the cost limit under this subparagraph is equal to $5,000 for plan years that end in 2006.

''(ii) INDEXING.—The cost threshold and cost limit amounts specified in subclauses (I) and (II) of clause (i) for a plan year that ends after 2006 shall be adjusted in the same manner as the annual deductible and the annual out-of-pocket threshold, respectively, are annually adjusted under paragraphs (1) and (4)(B) of section 1860D–2(b).

''(C) DEFINITIONS.—For purposes of this paragraph:

''(i) ALLOWABLE RETIREE COSTS.—The term 'allowable retiree costs' means, with respect to gross covered prescription drug costs under a qualified retiree prescription drug plan by a plan sponsor, the part of such costs that are actually paid (net of discounts, chargebacks, and average percentage rebates) by the sponsor or by or on behalf of a qualifying covered retiree under the plan.

''(ii) GROSS COVERED RETIREE PLAN-RELATED PRESCRIPTION DRUG COSTS.—For purposes of this section, the term 'gross covered retiree plan-related prescription drug costs' means, with respect to a qualifying covered retiree enrolled in a qualified retiree prescription drug plan during a coverage year, the costs incurred under the plan, not including administrative costs, but including costs directly related to the dispensing of covered part D drugs during the year. Such costs shall be determined whether they are paid by the retiree or under the plan.

''(iii) COVERAGE YEAR.—The term 'coverage year' has the meaning given such term in section 1860D–15(b)(4).

''(4) QUALIFYING COVERED RETIREE DEFINED.—For purposes of this subsection, the term 'qualifying covered retiree' means a part D eligible individual who is not enrolled in a prescription drug plan or an MA–PD plan but is covered under a qualified retiree prescription drug plan.

''(5) PAYMENT METHODS, INCLUDING PROVISION OF NECESSARY INFORMATION.—The provisions of section 1860D–15(d) (including paragraph (2), relating to requirement for provision of information) shall apply to payments under this subsection in a manner similar to the manner in which they apply to payment under section 1860D–15(b).

''(6) CONSTRUCTION.—Nothing in this subsection shall be construed as—

''(A) precluding a part D eligible individual who is covered under employment-based retiree health coverage from enrolling in a prescription drug plan or in an MA–PD plan;

''(B) precluding such employment-based retiree health coverage or an employer or other person from paying all or any portion of any premium required for coverage under a prescription drug plan or MA–PD plan on behalf of such an individual;

''(C) preventing such employment-based retiree health coverage from providing coverage—

''(i) that is better than standard prescription drug coverage to retirees who are covered under a qualified retiree prescription drug plan; or

''(ii) that is supplemental to the benefits provided under a prescription drug plan or an MA–PD plan, including benefits to retirees who are not covered under a qualified retiree prescription drug plan but who are enrolled in such a prescription drug plan or MA–PD plan; or

''(D) preventing employers to provide for flexibility in benefit design and pharmacy access provisions, without regard to the requirements for basic prescription drug coverage, so long as the actuarial equivalence requirement of paragraph (2)(A) is met.

''(b) APPLICATION OF MA WAIVER AUTHORITY.—The provisions of section 1857(i) shall apply with respect to prescription drug plans in relation to employment-based retiree health coverage in a manner similar to the manner in which they apply to an MA plan in relation to employers, including authorizing the establishment of separate premium amounts for enrollees in a prescription drug plan by reason of such coverage and limitations on enrollment to part D eligible individuals enrolled under such coverage.

''(c) DEFINITIONS.—For purposes of this section:

''(1) EMPLOYMENT-BASED RETIREE HEALTH COVERAGE.—The term 'employment-based retiree health coverage' means health insurance or other coverage of health care costs (whether provided by voluntary insurance coverage or pursuant to statutory or contractual obligation) for part D eligible individuals (or for such individuals and their spouses and dependents) under a group health plan based on their status as retired participants in such plan.

''(2) SPONSOR.—The term 'sponsor' means a plan sponsor, as defined in section 3(16)(B) of the Employee Retirement Income Security Act of 1974, in relation to a group health plan, except that, in the case of a plan maintained jointly by one employer and an employee organization and with respect to which the employer is the primary source of financing, such term means such employer.

''(3) GROUP HEALTH PLAN.—The term 'group health plan' includes such a plan as defined in section 607(1) of the Employee Retirement Income Security Act of 1974 and also includes the following:

''(A) FEDERAL AND STATE GOVERNMENTAL PLANS.—Such a plan established or maintained for its employees by the Government of the United States, by the government of any State or political subdivision thereof, or by any agency or instrumentality of any of the foregoing, including a health benefits plan offered under chapter 89 of title 5, United States Code.

''(B) COLLECTIVELY BARGAINED PLANS.—Such a plan established or maintained under or pursuant to one or more collective bargaining agreements.

''(C) CHURCH PLANS.—Such a plan established and maintained for its employees (or their beneficiaries) by a church or by a convention or association of churches which is exempt from tax under section 501 of the Internal Revenue Code of 1986.

''STATE PHARMACEUTICAL ASSISTANCE PROGRAMS

''SEC. 1860D–23. (a) REQUIREMENTS FOR BENEFIT COORDINATION.—

''(1) IN GENERAL.—Before July 1, 2005, the Secretary shall establish consistent with this section requirements for prescription drug plans to ensure the effective coordination between a part D plan (as defined in paragraph (5)) and a State Pharmaceutical Assistance Program (as defined in subsection (b)) with respect to—

''(A) payment of premiums and coverage; and

''(B) payment for supplemental prescription drug benefits,

for part D eligible individuals enrolled under both types of plans.

''(2) COORDINATION ELEMENTS.—The requirements under paragraph (1) shall include requirements relating to coordination of each of the following:

''(A) Enrollment file sharing.

''(B) The processing of claims, including electronic processing.

''(C) Claims payment.

''(D) Claims reconciliation reports.

''(E) Application of the protection against high out-of-pocket expenditures under section 1860D–2(b)(4).

''(F) Other administrative processes specified by the Secretary.

Such requirements shall be consistent with applicable law to safeguard the privacy of any individually identifiable beneficiary information.

''(3) USE OF LUMP SUM PER CAPITA METHOD.—Such requirements shall include a method for the application by a part D plan of specified funding amounts from a State Pharmaceutical Assistance Program for enrolled individuals for supplemental prescription drug benefits.

''(4) CONSULTATION.—In establishing requirements under this subsection, the Secretary shall consult with State Pharmaceutical Assistance Programs, MA organizations, States, pharmaceutical benefit managers, employers, representatives of part D eligible individuals, the data processing experts, pharmacists, pharmaceutical manufacturers, and other experts.

''(5) PART D PLAN DEFINED.—For purposes of this section and section 1860D–24, the term 'part D plan' means a prescription drug plan and an MA–PD plan.

''(b) STATE PHARMACEUTICAL ASSISTANCE PROGRAM.—For purposes of this part, the term 'State Pharmaceutical Assistance Program' means a State program—

''(1) which provides financial assistance for the purchase or provision of supplemental prescription drug coverage or benefits on behalf of part D eligible individuals;

''(2) which, in determining eligibility and the amount of assistance to part D eligible individuals under the Program, provides assistance to such individuals in all part D plans and does not discriminate based upon the part D plan in which the individual is enrolled; and

''(3) which satisfies the requirements of subsections (a) and (c).

''(c) RELATION TO OTHER PROVISIONS.—

''(1) MEDICARE AS PRIMARY PAYOR.—The requirements of this section shall not change or affect the primary payor status of a part D plan.

''(2) USE OF A SINGLE CARD.—A card that is issued under section 1860D–4(b)(2)(A) for use under a part D plan may also be used in connection with coverage of benefits provided under a State Pharmaceutical Assistance Program and, in such case, may contain an emblem or symbol indicating such connection.

''(3) OTHER PROVISIONS.—The provisions of section 1860D–24(c) shall apply to the requirements under this section.

''(4) SPECIAL TREATMENT UNDER OUT-OF-POCKET RULE.—In applying section 1860D–2(b)(4)(C)(ii), expenses incurred under a State Pharmaceutical Assistance Program may be counted toward the annual out-of-pocket threshold.

''(5) CONSTRUCTION.—Nothing in this section shall be construed as requiring a State Pharmaceutical Assistance Program to coordinate or provide financial assistance with respect to any part D plan.

''(d) FACILITATION OF TRANSITION AND COORDINATION WITH STATE PHARMACEUTICAL ASSISTANCE PROGRAMS.—

''(1) TRANSITIONAL GRANT PROGRAM.—The Secretary shall provide payments to State Pharmaceutical Assistance Programs with an application approved under this subsection.

''(2) USE OF FUNDS.—Payments under this section may be used by a Program for any of the following:

''(A) Educating part D eligible individuals enrolled in the Program about the prescription drug coverage available through part D plans under this part.

''(B) Providing technical assistance, phone support, and counseling for such enrollees to facilitate selection and enrollment in such plans.

''(C) Other activities designed to promote the effective coordination of enrollment, coverage, and payment between such Program and such plans.

''(3) ALLOCATION OF FUNDS.—Of the amount appropriated to carry out this subsection for a fiscal year, the Secretary shall allocate payments among Programs that have applications approved under paragraph (4) for such fiscal year in proportion to the number of enrollees enrolled in each such Program as of October 1, 2003.

''(4) APPLICATION.—No payments may be made under this subsection except pursuant to an application that is submitted and approved in a time, manner, and form specified by the Secretary.

''(5) FUNDING.—Out of any funds in the Treasury not otherwise appropriated, there are appropriated for each of fiscal years 2005 and 2006, $62,500,000 to carry out this subsection.

''COORDINATION REQUIREMENTS FOR PLANS PROVIDING PRESCRIPTION DRUG COVERAGE

''SEC. 1860D–24. (a) APPLICATION OF BENEFIT COORDINATION REQUIREMENTS TO ADDITIONAL PLANS.—

''(1) IN GENERAL.—The Secretary shall apply the coordination requirements established under section 1860D–23(a) to Rx plans described in subsection (b) in the same manner as such requirements apply to a State Pharmaceutical Assistance Program.

''(2) APPLICATION TO TREATMENT OF CERTAIN OUT-OF-POCKET EXPENDITURES.—To the extent specified by the Secretary, the requirements referred to in paragraph (1) shall apply to procedures established under section 1860D–2(b)(4)(D).

''(3) USER FEES.—

''(A) IN GENERAL.—The Secretary may impose user fees for the transmittal of information necessary for benefit coordination under section 1860D–2(b)(4)(D) in a manner similar to the manner in which user fees are imposed under section 1842(h)(3)(B), except that the Secretary may retain a portion of such fees to defray the Secretary's costs in carrying out procedures under section 1860D–2(b)(4)(D).

''(B) APPLICATION.—A user fee may not be imposed under subparagraph (A) with respect to a State Pharmaceutical Assistance Program.

''(b) RX PLAN.—An Rx plan described in this subsection is any of the following:

''(1) MEDICAID PROGRAMS.—A State plan under title XIX, including such a plan operating under a waiver under section 1115, if it meets the requirements of section 1860D–23(b)(2).

''(2) GROUP HEALTH PLANS.—An employer group health plan.

''(3) FEHBP.—The Federal employees health benefits plan under chapter 89 of title 5, United States Code.

''(4) MILITARY COVERAGE (INCLUDING TRICARE).—Coverage under chapter 55 of title 10, United States Code.

''(5) OTHER PRESCRIPTION DRUG COVERAGE.—Such other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of part D eligible individuals as the Secretary may specify.

''(c) RELATION TO OTHER PROVISIONS.—

''(1) USE OF COST MANAGEMENT TOOLS.—The requirements of this section shall not impair or prevent a PDP sponsor or MA organization from applying cost management tools (including differential payments) under all methods of operation.

''(2) NO AFFECT ON TREATMENT OF CERTAIN OUT-OF-POCKET EXPENDITURES.—The requirements of this section shall not affect the application of the procedures established under section 1860D–2(b)(4)(D).

''Subpart 4—Medicare Prescription Drug Discount Card and Transitional Assistance Program

''MEDICARE PRESCRIPTION DRUG DISCOUNT CARD AND TRANSITIONAL ASSISTANCE PROGRAM

''SEC. 1860D–31. (a) ESTABLISHMENT OF PROGRAM.—

''(1) IN GENERAL.—The Secretary shall establish a program under this section—

''(A) to endorse prescription drug discount card programs that meet the requirements of this section in order to provide access to prescription drug discounts through prescription drug card sponsors for discount card eligible individuals throughout the United States; and

''(B) to provide for transitional assistance for transitional assistance eligible individuals enrolled in such endorsed programs.

''(2) PERIOD OF OPERATION.—

''(A) IMPLEMENTATION DEADLINE.—The Secretary shall implement the program under this section so that discount cards and transitional assistance are first available by not later than 6 months after the date of the enactment of this section.

''(B) EXPEDITING IMPLEMENTATION.—The Secretary shall promulgate regulations to carry out the program under this section which may be effective and final immediately on an interim basis as of the date of publication of the interim final regulation. If the Secretary provides for an interim final regulation, the Secretary shall provide for a period of public comments on such regulation after the date of publication. The Secretary may change or revise such regulation after completion of the period of public comment.

''(C) TERMINATION AND TRANSITION.—

''(i) IN GENERAL.—Subject to clause (ii)—

''(I) the program under this section shall not apply to covered discount card drugs dispensed after December 31, 2005; and

''(II) transitional assistance shall be available after such date to the extent the assistance relates to drugs dispensed on or before such date.

''(ii) TRANSITION.—In the case of an individual who is enrolled in an endorsed discount card program as of December 31, 2005, during the individual's transition period (if any) under clause (iii), in accordance with transition rules specified by the Secretary—

''(I) such endorsed program may continue to apply to covered discount card drugs dispensed to the individual under the program during such transition period;

''(II) no annual enrollment fee shall be applicable during the transition period;

''(III) during such period the individual may not change the endorsed program plan in which the individual is enrolled; and

''(IV) the balance of any transitional assistance remaining on January 1, 2006, shall remain available for drugs dispensed during the individual's transition period.

''(iii) TRANSITION PERIOD.—The transition period under this clause for an individual is the period beginning on January 1, 2006, and ending in the case of an individual who—

''(I) is enrolled in a prescription drug plan or an MA–PD plan before the last date of the initial enrollment period under section 1860D–1(b)(2)(A), on the effective date of the individual's coverage under such part; or

''(II) is not so enrolled, on the last day of such initial period.

''(3) VOLUNTARY NATURE OF PROGRAM.—Nothing in this section shall be construed as requiring a discount card eligible individual to enroll in an endorsed discount card program under this section.

''(4) GLOSSARY AND DEFINITIONS OF TERMS.—For purposes of this section:

''(A) COVERED DISCOUNT CARD DRUG.—The term 'covered discount card drug' has the meaning given the term 'covered part D drug' in section 1860D–2(e).

''(B) DISCOUNT CARD ELIGIBLE INDIVIDUAL.—The term 'discount card eligible individual' is defined in subsection (b)(1)(A).

''(C) ENDORSED DISCOUNT CARD PROGRAM; ENDORSED PROGRAM.—The terms 'endorsed discount card program' and 'endorsed program' mean a prescription drug discount card program that is endorsed (and for which the sponsor has a contract with the Secretary) under this section.

''(D) NEGOTIATED PRICE.—Negotiated prices are described in subsection (e)(1)(A)(ii).

''(E) PRESCRIPTION DRUG CARD SPONSOR; SPONSOR.—The terms 'prescription drug card sponsor' and 'sponsor' are defined in subsection (h)(1)(A).

''(F) STATE.—The term 'State' has the meaning given such term for purposes of title XIX.

''(G) TRANSITIONAL ASSISTANCE ELIGIBLE INDIVIDUAL.—The term 'transitional assistance eligible individual' is defined in subsection (b)(2).

''(b) ELIGIBILITY FOR DISCOUNT CARD AND FOR TRANSITIONAL ASSISTANCE.—For purposes of this section:

''(1) DISCOUNT CARD ELIGIBLE INDIVIDUAL.—

''(A) IN GENERAL.—The term 'discount card eligible individual' means an individual who—

''(i) is entitled to benefits, or enrolled, under part A or enrolled under part B; and

''(ii) subject to paragraph (4), is not an individual described in subparagraph (B).

''(B) INDIVIDUAL DESCRIBED.—An individual described in this subparagraph is an individual described in subparagraph (A)(i) who is enrolled under title XIX (or under a waiver under section 1115 of the requirements of such title) and is entitled to any medical assistance for outpatient prescribed drugs described in section 1905(a)(12).

''(2) TRANSITIONAL ASSISTANCE ELIGIBLE INDIVIDUAL.—

''(A) IN GENERAL.—Subject to subparagraph (B), the term 'transitional assistance eligible individual' means a discount card eligible individual who resides in one of the 50 States or the District of Columbia and whose income (as determined under subsection (f)(1)(B)) is not more than 135 percent of the poverty line (as defined in section 673(2) of the Community Services Block Grant Act, 42 U.S.C. 9902(2), including any revision required by such section) applicable to the family size involved (as determined under subsection (f)(1)(B)).

''(B) EXCLUSION OF INDIVIDUALS WITH CERTAIN PRESCRIPTION DRUG COVERAGE.—Such term does not include an individual who has coverage of, or assistance for, covered discount card drugs under any of the following:

''(i) A group health plan or health insurance coverage (as such terms are defined in section 2791 of the Public Health Service Act), other than coverage under a plan under part C and other than coverage consisting only of excepted benefits (as defined in such section).

''(ii) Chapter 55 of title 10, United States Code (relating to medical and dental care for members of the uniformed services).

''(iii) A plan under chapter 89 of title 5, United States Code (relating to the Federal employees' health benefits program).

''(3) SPECIAL TRANSITIONAL ASSISTANCE ELIGIBLE INDIVIDUAL.—The term 'special transitional assistance eligible individual' means a transitional assistance eligible individual whose income (as determined under subsection (f)(1)(B)) is not more than 100 percent of the poverty line (as defined in section 673(2) of the Community Services Block Grant Act, 42 U.S.C. 9902(2), including any revision required by such section) applicable to the family size involved (as determined under subsection (f)(1)(B)).

''(4) TREATMENT OF MEDICAID MEDICALLY NEEDY.—For purposes of this section, the Secretary shall provide for appropriate rules for the treatment of medically needy individuals described in section 1902(a)(10)(C) as discount card eligible individuals and as transitional assistance eligible individuals.

''(c) ENROLLMENT AND ENROLLMENT FEES.—

''(1) ENROLLMENT PROCESS.—The Secretary shall establish a process through which a discount card eligible individual is enrolled and disenrolled in an endorsed discount card program under this section consistent with the following:

''(A) CONTINUOUS OPEN ENROLLMENT.—Subject to the succeeding provisions of this paragraph and subsection (h)(9), a discount card eligible individual who is not enrolled in an endorsed discount card program and is residing in a State may enroll in any such endorsed program—

''(i) that serves residents of the State; and

''(ii) at any time beginning on the initial enrollment date, specified by the Secretary, and before January 1, 2006.

''(B) USE OF STANDARD ENROLLMENT FORM.—An enrollment in an endorsed program shall only be effected through completion of a standard enrollment form specified by the Secretary. Each sponsor of an endorsed program shall transmit to the Secretary (in a form and manner specified by the Secretary) information on individuals who complete such enrollment forms and, to the extent provided under subsection (f), information regarding certification as a transitional assistance eligible individual.

''(C) ENROLLMENT ONLY IN ONE PROGRAM.—

''(i) IN GENERAL.—Subject to clauses (ii) and (iii), a discount card eligible individual may be enrolled in only one endorsed discount card program under this section.

''(ii) CHANGE IN ENDORSED PROGRAM PERMITTED FOR 2005.—The Secretary shall establish a process, similar to (and coordinated with) the process for annual, coordinated elections under section 1851(e)(3) during 2004, under which an individual enrolled in an endorsed discount card program may change the endorsed program in which the individual is enrolled for 2005.

''(iii) ADDITIONAL EXCEPTIONS.—The Secretary shall permit an individual to change the endorsed discount card program in which the individual is enrolled in the case of an individual who changes residence to be outside the service area of such program and in such other exceptional cases as the Secretary may provide (taking into account the circumstances for special election periods under section 1851(e)(4)). Under the previous sentence, the Secretary may consider a change in residential setting (such as placement in a nursing facility) or enrollment in or disenrollment from a plan under part C through which the individual was enrolled in an endorsed program to be an exceptional circumstance.

''(D) DISENROLLMENT.—

''(i) VOLUNTARY.—An individual may voluntarily disenroll from an endorsed discount card program at any time. In the case of such a voluntary disenrollment, the individual may not enroll in another endorsed program, except under such exceptional circumstances as the Secretary may recognize under subparagraph (C)(iii) or during the annual coordinated enrollment period provided under subparagraph (C)(ii).

''(ii) INVOLUNTARY.—An individual who is enrolled in an endorsed discount card program and not a transitional assistance eligible individual may be disenrolled by the sponsor of the program if the individual fails to pay any annual enrollment fee required under the program.

''(E) APPLICATION TO CERTAIN ENROLLEES.—In the case of a discount card eligible individual who is enrolled in a plan described in section 1851(a)(2)(A) or under a reasonable cost reimbursement contract under section 1876(h) that is offered by an organization that also is a prescription discount card sponsor that offers an endorsed discount card program under which the individual may be enrolled and that has made an election to apply the special rules under subsection (h)(9)(B) for such an endorsed program, the individual may only enroll in such an endorsed discount card program offered by that sponsor.

''(2) ENROLLMENT FEES.—

''(A) IN GENERAL.—Subject to the succeeding provisions of this paragraph, a prescription drug card sponsor may charge an annual enrollment fee for each discount card eligible individual enrolled in an endorsed discount card program offered by such sponsor. The annual enrollment fee for either 2004 or 2005 shall not be prorated for portions of a year. There shall be no annual enrollment fee for a year after 2005.

''(B) AMOUNT.—No annual enrollment fee charged under subparagraph (A) may exceed $30.

''(C) UNIFORM ENROLLMENT FEE.—A prescription drug card sponsor shall ensure that the annual enrollment fee (if any) for an endorsed discount card program is the same for all discount card eligible individuals enrolled in the program and residing in the State.

''(D) COLLECTION.—The annual enrollment fee (if any) charged for enrollment in an endorsed

program shall be collected by the sponsor of the program.

''(E) PAYMENT OF FEE FOR TRANSITIONAL ASSISTANCE ELIGIBLE INDIVIDUALS.—Under subsection (g)(1)(A), the annual enrollment fee (if any) otherwise charged under this paragraph with respect to a transitional assistance eligible individual shall be paid by the Secretary on behalf of such individual.

''(F) OPTIONAL PAYMENT OF FEE BY STATE.—

''(i) IN GENERAL.—The Secretary shall establish an arrangement under which a State may provide for payment of some or all of the enrollment fee for some or all enrollees who are not transitional assistance eligible individuals in the State, as specified by the State under the arrangement. Insofar as such a payment arrangement is made with respect to an enrollee, the amount of the enrollment fee shall be paid directly by the State to the sponsor.

''(ii) NO FEDERAL MATCHING AVAILABLE UNDER MEDICAID OR SCHIP.—Expenditures made by a State for enrollment fees described in clause (i) shall not be treated as State expenditures for purposes of Federal matching payments under title XIX or XXI.

''(G) RULES IN CASE OF CHANGES IN PROGRAM ENROLLMENT DURING A YEAR.—The Secretary shall provide special rules in the case of payment of an annual enrollment fee for a discount card eligible individual who changes the endorsed program in which the individual is enrolled during a year.

''(3) ISSUANCE OF DISCOUNT CARD.—Each prescription drug card sponsor of an endorsed discount card program shall issue, in a standard format specified by the Secretary, to each discount card eligible individual enrolled in such program a card that establishes proof of enrollment and that can be used in a coordinated manner to identify the sponsor, program, and individual for purposes of the program under this section.

''(4) PERIOD OF ACCESS.—In the case of a discount card eligible individual who enrolls in an endorsed program, access to negotiated prices and transitional assistance, if any, under such endorsed program shall take effect on such date as the Secretary shall specify.

''(d) PROVISION OF INFORMATION ON ENROLLMENT AND PROGRAM FEATURES.—

''(1) SECRETARIAL RESPONSIBILITIES.—

''(A) IN GENERAL.—The Secretary shall provide for activities under this subsection to broadly disseminate information to discount card eligible individuals (and prospective eligible individuals) regarding—

''(i) enrollment in endorsed discount card programs; and

''(ii) the features of the program under this section, including the availability of transitional assistance.

''(B) PROMOTION OF INFORMED CHOICE.—In order to promote informed choice among endorsed prescription drug discount card programs, the Secretary shall provide for the dissemination of information which—

''(i) compares the annual enrollment fee and other features of such programs, which may include comparative prices for covered discount card drugs; and

''(ii) includes educational materials on the variability of discounts on prices of covered discount card drugs under an endorsed program.

The dissemination of information under clause (i) shall, to the extent practicable, be coordinated with the dissemination of educational information on other medicare options.

''(C) SPECIAL RULE FOR INITIAL ENROLLMENT DATE UNDER THE PROGRAM.—To the extent practicable, the Secretary shall ensure, through the activities described in subparagraphs (A) and (B), that discount card eligible individuals are provided with such information at least 30 days prior to the initial enrollment date specified under subsection (c)(1)(A)(ii).

''(D) USE OF MEDICARE TOLL-FREE NUMBER.—The Secretary shall provide through the toll-free telephone number 1–800–MEDICARE for the receipt and response to inquiries and complaints concerning the program under this section and endorsed programs.

''(2) PRESCRIPTION DRUG CARD SPONSOR RESPONSIBILITIES.—

''(A) IN GENERAL.—Each prescription drug card sponsor that offers an endorsed discount card program shall make available to discount card eligible individuals (through the Internet and otherwise) information that the Secretary identifies as being necessary to promote informed choice among endorsed discount card programs by such individuals, including information on enrollment fees and negotiated prices for covered discount card drugs charged to such individuals.

''(B) RESPONSE TO ENROLLEE QUESTIONS.—Each sponsor offering an endorsed discount card program shall have a mechanism (including a toll-free telephone number) for providing upon request specific information (such as negotiated prices and the amount of transitional assistance remaining available through the program) to discount card eligible individuals enrolled in the program. The sponsor shall inform transitional assistance eligible individuals enrolled in the program of the availability of such toll-free telephone number to provide information on the amount of available transitional assistance.

''(C) INFORMATION ON BALANCE OF TRANSITIONAL ASSISTANCE AVAILABLE AT POINT-OF-SALE.—Each sponsor offering an endorsed discount card program shall have a mechanism so that information on the amount of transitional assistance remaining under subsection (g)(1)(B) is available (electronically or by telephone) at the point-of-sale of covered discount card drugs.

''(3) PUBLIC DISCLOSURE OF PHARMACEUTICAL PRICES FOR EQUIVALENT DRUGS.—

''(A) IN GENERAL.—A prescription drug card sponsor offering an endorsed discount card program shall provide that each pharmacy that dispenses a covered discount card drug shall inform a discount card eligible individual enrolled in the program of any differential between the price of the drug to the enrollee and the price of the lowest priced generic covered discount card drug under the program that is therapeutically equivalent and bioequivalent and available at such pharmacy.

''(B) TIMING OF NOTICE.—

''(i) IN GENERAL.—Subject to clause (ii), the information under subparagraph (A) shall be provided at the time of purchase of the drug involved, or, in the case of dispensing by mail order, at the time of delivery of such drug.

''(ii) WAIVER.—The Secretary may waive clause (i) in such circumstances as the Secretary may specify.

''(e) DISCOUNT CARD FEATURES.—

''(1) SAVINGS TO ENROLLEES THROUGH NEGOTIATED PRICES.—

''(A) ACCESS TO NEGOTIATED PRICES.—

''(i) IN GENERAL.—Each prescription drug card sponsor that offers an endorsed discount card program shall provide each discount card eligible individual enrolled in the program with access to negotiated prices.

''(ii) NEGOTIATED PRICES.—For purposes of this section, negotiated prices shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered discount card drugs, and include any dispensing fees for such drugs.

''(B) ENSURING PHARMACY ACCESS.—Each prescription drug card sponsor offering an endorsed discount card program shall secure the participation in its network of a sufficient number of pharmacies that dispense (other than solely by mail order) drugs directly to enrollees to ensure convenient access to covered discount card drugs at negotiated prices (consistent with rules established by the Secretary). The Secretary shall establish convenient access rules under this clause that are no less favorable to enrollees than the standards for convenient access to pharmacies included in the statement of work of solicitation (#MDA906–03–R–0002) of the Department of Defense under the TRICARE Retail Pharmacy (TRRx) as of March 13, 2003.

''(C) PROHIBITION ON CHARGES FOR REQUIRED SERVICES.—

''(i) IN GENERAL.—Subject to clause (ii), a prescription drug card sponsor (and any pharmacy contracting with such sponsor for the provision of covered discount card drugs to individuals enrolled in such sponsor's endorsed discount card program) may not charge an enrollee any amount for any items and services required to be provided by the sponsor under this section.

''(ii) CONSTRUCTION.—Nothing in clause (i) shall be construed to prevent—

''(I) the sponsor from charging the annual enrollment fee (except in the case of a transitional assistance eligible individual); and

''(II) the pharmacy dispensing the covered discount card drug, from imposing a charge (consistent with the negotiated price) for the covered discount card drug dispensed, reduced by the amount of any transitional assistance made available.

''(D) INAPPLICABILITY OF MEDICAID BEST PRICE RULES.—The prices negotiated from drug manufacturers for covered discount card drugs under an endorsed discount card program under this section shall (notwithstanding any other provision of law) not be taken into account for the purposes of establishing the best price under section 1927(c)(1)(C).

''(2) REDUCTION OF MEDICATION ERRORS AND ADVERSE DRUG INTERACTIONS.—Each endorsed discount card program shall implement a system to reduce the likelihood of medication errors and adverse drug interactions and to improve medication use.

''(f) ELIGIBILITY PROCEDURES FOR ENDORSED PROGRAMS AND TRANSITIONAL ASSISTANCE.—

''(1) DETERMINATIONS.—

''(A) PROCEDURES.—The determination of whether an individual is a discount card eligible individual or a transitional assistance eligible individual or a special transitional assistance eligible individual (as defined in subsection (b)) shall be determined under procedures specified by the Secretary consistent with this subsection.

''(B) INCOME AND FAMILY SIZE DETERMINATIONS.—For purposes of this section, the Secretary shall define the terms 'income' and 'family size' and shall specify the methods and period for which they are determined. If under such methods income or family size is determined based on the income or family size for prior periods of time, the Secretary shall permit (whether through a process of reconsideration or otherwise) an individual whose income or family size has changed to elect to have eligibility for transitional assistance determined based on income or family size for a more recent period.

''(2) USE OF SELF-CERTIFICATION FOR TRANSITIONAL ASSISTANCE.—

''(A) IN GENERAL.—Under the procedures specified under paragraph (1)(A) an individual who wishes to be treated as a transitional assistance eligible individual or a special transitional assistance eligible individual under this section (or another qualified person on such individual's behalf) shall certify on the enrollment form under subsection (c)(1)(B) (or similar form specified by the Secretary), through a simplified means specified by the Secretary and under penalty of perjury or similar sanction for false statements, as to the amount of the individual's income, family size, and individual's prescription drug coverage (if any) insofar as they relate to eligibility to be a transitional assistance eligible individual or a special transitional assistance eligible individual. Such certification shall be deemed as consent to verification of respective eligibility under paragraph (3). A certification under this paragraph may be provided before, on, or after the time of enrollment under an endorsed program.

''(B) TREATMENT OF SELF-CERTIFICATION.—The Secretary shall treat a certification under subparagraph (A) that is verified under paragraph (3) as a determination that the individual involved is a transitional assistance eligible individual or special transitional assistance eligible individual (as the case may be) for the entire period of the enrollment of the individual in any endorsed program.

''(3) VERIFICATION.—

''(A) IN GENERAL.—The Secretary shall establish methods (which may include the use of sampling and the use of information described in subparagraph (B)) to verify eligibility for individuals who seek to enroll in an endorsed program and for individuals who provide a certification under paragraph (2).

''(B) INFORMATION DESCRIBED.—The information described in this subparagraph is as follows:

''(i) MEDICAID-RELATED INFORMATION.—Information on eligibility under title XIX and provided to the Secretary under arrangements between the Secretary and States in order to verify the eligibility of individuals who seek to enroll in an endorsed program and of individuals who provide certification under paragraph (2).

''(ii) SOCIAL SECURITY INFORMATION.—Financial information made available to the Secretary under arrangements between the Secretary and the Commissioner of Social Security in order to verify the eligibility of individuals who provide such certification.

''(iii) INFORMATION FROM SECRETARY OF THE TREASURY.—Financial information made available to the Secretary under section 6103(l)(19) of the Internal Revenue Code of 1986 in order to verify the eligibility of individuals who provide such certification.

''(C) VERIFICATION IN CASES OF MEDICAID ENROLLEES.—

''(i) IN GENERAL.—Nothing in this section shall be construed as preventing the Secretary from finding that a discount card eligible individual meets the income requirements under subsection (b)(2)(A) if the individual is within a category of discount card eligible individuals who are enrolled under title XIX (such as qualified medicare beneficiaries (QMBs), specified low-income medicare beneficiaries (SLMBs), and certain qualified individuals (QI–1s)).

''(ii) AVAILABILITY OF INFORMATION FOR VERIFICATION PURPOSES.—As a condition of provision of Federal financial participation to a State that is one of the 50 States or the District of Columbia under title XIX, for purposes of carrying out this section, the State shall provide the information it submits to the Secretary relating to such title in a manner specified by the Secretary that permits the Secretary to identify individuals who are described in subsection (b)(1)(B) or are transitional assistance eligible individuals or special transitional assistance eligible individuals.

''(4) RECONSIDERATION.—

''(A) IN GENERAL.—The Secretary shall establish a process under which a discount card eligible individual, who is determined through the certification and verification methods under paragraphs (2) and (3) not to be a transitional assistance eligible individual or a special transitional assistance eligible individual, may request a reconsideration of the determination.

''(B) CONTRACT AUTHORITY.—The Secretary may enter into a contract to perform the reconsiderations requested under subparagraph (A).

''(C) COMMUNICATION OF RESULTS.—Under the process under subparagraph (A) the results of such reconsideration shall be communicated to the individual and the prescription drug card sponsor involved.

''(g) TRANSITIONAL ASSISTANCE.—

''(1) PROVISION OF TRANSITIONAL ASSISTANCE.—An individual who is a transitional assistance eligible individual (as determined under this section) and who is enrolled with an endorsed program is entitled—

''(A) to have payment made of any annual enrollment fee charged under subsection (c)(2) for enrollment under the program; and

''(B) to have payment made, up to the amount specified in paragraph (2), under such endorsed program of 90 percent (or 95 percent in the case of a special transitional assistance eligible individual) of the costs incurred for covered discount card drugs obtained through the program taking into account the negotiated price (if any) for the drug under the program.

''(2) LIMITATION ON DOLLAR AMOUNT.—

''(A) IN GENERAL.—Subject to subparagraph (B), the amount specified in this paragraph for a transitional assistance eligible individual—

''(i) for costs incurred during 2004, is $600; or

''(ii) for costs incurred during 2005, is—

''(I) $600, plus

''(II) except as provided in subparagraph (E), the amount by which the amount available under this paragraph for 2004 for that individual exceeds the amount of payment made under paragraph (1)(B) for that individual for costs incurred during 2004.

''(B) PRORATION.—

''(i) IN GENERAL.—In the case of an individual not described in clause (ii) with respect to a year, the Secretary may prorate the amount specified in subparagraph (A) for the balance of the year involved in a manner specified by the Secretary.

''(ii) INDIVIDUAL DESCRIBED.—An individual described in this clause is a transitional assistance eligible individual who—

''(I) with respect to 2004, enrolls in an endorsed program, and provides a certification under subsection (f)(2), before the initial implementation date of the program under this section; and

''(II) with respect to 2005, is enrolled in an endorsed program, and has provided such a certification, before February 1, 2005.

''(C) ACCOUNTING FOR AVAILABLE BALANCES IN CASES OF CHANGES IN PROGRAM ENROLLMENT.—In the case of a transitional assistance eligible individual who changes the endorsed discount card program in which the individual is enrolled under this section, the Secretary shall provide a process under which the Secretary provides to the sponsor of the endorsed program in which the individual enrolls information concerning the balance of amounts available on behalf of the individual under this paragraph.

''(D) LIMITATION ON USE OF FUNDS.—Pursuant to subsection (a)(2)(C), no assistance shall be provided under paragraph (1)(B) with respect to covered discount card drugs dispensed after December 31, 2005.

''(E) NO ROLLOVER PERMITTED IN CASE OF VOLUNTARY DISENROLLMENT.—Except in such exceptional cases as the Secretary may provide, in the case of a transitional assistance eligible individual who voluntarily disenrolls from an endorsed plan, the provisions of subclause (II) of subparagraph (A)(ii) shall not apply.

''(3) PAYMENT.—The Secretary shall provide a method for the reimbursement of prescription drug card sponsors for assistance provided under this subsection.

''(4) COVERAGE OF COINSURANCE.—

''(A) WAIVER PERMITTED BY PHARMACY.—Nothing in this section shall be construed as precluding a pharmacy from reducing or waiving the application of coinsurance imposed under paragraph (1)(B) in accordance with section 1128B(b)(3)(G).

''(B) OPTIONAL PAYMENT OF COINSURANCE BY STATE.—

''(i) IN GENERAL.—The Secretary shall establish an arrangement under which a State may provide for payment of some or all of the coinsurance under paragraph (1)(B) for some or all enrollees in the State, as specified by the State under the arrangement. Insofar as such a payment arrangement is made with respect to an enrollee, the amount of the coinsurance shall be paid directly by the State to the pharmacy involved.

''(ii) NO FEDERAL MATCHING AVAILABLE UNDER MEDICAID OR SCHIP.—Expenditures made by a State for coinsurance described in clause (i) shall not be treated as State expenditures for purposes of Federal matching payments under title XIX or XXI.

''(iii) NOT TREATED AS MEDICARE COST-SHARING.—Coinsurance described in paragraph (1)(B) shall not be treated as coinsurance under this title for purposes of section 1905(p)(3)(B).

''(C) TREATMENT OF COINSURANCE.—The amount of any coinsurance imposed under paragraph (1)(B), whether paid or waived under this paragraph, shall not be taken into account in applying the limitation in dollar amount under paragraph (2).

''(5) ENSURING ACCESS TO TRANSITIONAL ASSISTANCE FOR QUALIFIED RESIDENTS OF LONG-TERM CARE FACILITIES AND AMERICAN INDIANS.—

''(A) RESIDENTS OF LONG-TERM CARE FACILITIES.—The Secretary shall establish procedures and may waive requirements of this section as necessary to negotiate arrangements with sponsors to provide arrangements with pharmacies that support long-term care facilities in order to ensure access to transitional assistance for transitional assistance eligible individuals who reside in long-term care facilities.

''(B) AMERICAN INDIANS.—The Secretary shall establish procedures and may waive requirements of this section to ensure that, for purposes of providing transitional assistance, pharmacies operated by the Indian Health Service, Indian tribes and tribal organizations, and urban Indian organizations (as defined in section 4 of the Indian Health Care Improvement Act) have the opportunity to participate in the pharmacy networks of at least two endorsed programs in each of the 50 States and the District of Columbia where such a pharmacy operates.

''(6) NO IMPACT ON BENEFITS UNDER OTHER PROGRAMS.—The availability of negotiated prices or transitional assistance under this section shall not be treated as benefits or otherwise taken into account in determining an individual's eligibility for, or the amount of benefits under, any other Federal program.

''(7) DISREGARD FOR PURPOSES OF PART C.—Nonuniformity of benefits resulting from the implementation of this section (including the provision or nonprovision of transitional assistance and the payment or waiver of any enrollment fee under this section) shall not be taken into account in applying section 1854(f).

''(h) QUALIFICATION OF PRESCRIPTION DRUG CARD SPONSORS AND ENDORSEMENT OF DISCOUNT CARD PROGRAMS; BENEFICIARY PROTECTIONS.—

''(1) PRESCRIPTION DRUG CARD SPONSOR AND QUALIFICATIONS.—

''(A) PRESCRIPTION DRUG CARD SPONSOR AND SPONSOR DEFINED.—For purposes of this section, the terms 'prescription drug card sponsor' and 'sponsor' mean any nongovernmental entity that the Secretary determines to be appropriate to offer an endorsed discount card program under this section, which may include—

''(i) a pharmaceutical benefit management company;

''(ii) a wholesale or retail pharmacy delivery system;

''(iii) an insurer (including an insurer that offers medicare supplemental policies under section 1882);

''(iv) an organization offering a plan under part C; or

''(v) any combination of the entities described in clauses (i) through (iv).

''(B) ADMINISTRATIVE QUALIFICATIONS.—Each endorsed discount card program shall be operated directly, or through arrangements with an affiliated organization (or organizations), by one or more entities that have demonstrated experience and expertise in operating such a program or a similar program and that meets such business stability and integrity requirements as the Secretary may specify.

''(C) ACCOUNTING FOR TRANSITIONAL ASSISTANCE.—The sponsor of an endorsed discount

card program shall have arrangements satisfactory to the Secretary to account for the assistance provided under subsection (g) on behalf of transitional assistance eligible individuals.

''(2) APPLICATIONS FOR PROGRAM ENDORSEMENT.—

''(A) SUBMISSION.—Each prescription drug card sponsor that seeks endorsement of a prescription drug discount card program under this section shall submit to the Secretary, at such time and in such manner as the Secretary may specify, an application containing such information as the Secretary may require.

''(B) APPROVAL; COMPLIANCE WITH APPLICABLE REQUIREMENTS.—The Secretary shall review the application submitted under subparagraph (A) and shall determine whether to endorse the prescription drug discount card program. The Secretary may not endorse such a program unless—

''(i) the program and prescription drug card sponsor offering the program comply with the applicable requirements under this section; and

''(ii) the sponsor has entered into a contract with the Secretary to carry out such requirements.

''(C) TERMINATION OF ENDORSEMENT AND CONTRACTS.—An endorsement of an endorsed program and a contract under subparagraph (B) shall be for the duration of the program under this section (including any transition applicable under subsection (a)(2)(C)(ii)), except that the Secretary may, with notice and for cause (as defined by the Secretary), terminate such endorsement and contract.

''(D) ENSURING CHOICE OF PROGRAMS.—

''(i) IN GENERAL.—The Secretary shall ensure that there is available to each discount card eligible individual a choice of at least 2 endorsed programs (each offered by a different sponsor).

''(ii) LIMITATION ON NUMBER.—The Secretary may limit (but not below 2) the number of sponsors in a State that are awarded contracts under this paragraph.

''(3) SERVICE AREA ENCOMPASSING ENTIRE STATES.—Except as provided in paragraph (9), if a prescription drug card sponsor that offers an endorsed program enrolls in the program individuals residing in any part of a State, the sponsor must permit any discount card eligible individual residing in any portion of the State to enroll in the program.

''(4) SAVINGS TO MEDICARE BENEFICIARIES.—Each prescription drug card sponsor that offers an endorsed discount card program shall pass on to discount card eligible individuals enrolled in the program negotiated prices on covered discount card drugs, including discounts negotiated with pharmacies and manufacturers, to the extent disclosed under subsection (i)(1).

''(5) GRIEVANCE MECHANISM.—Each prescription drug card sponsor shall provide meaningful procedures for hearing and resolving grievances between the sponsor (including any entity or individual through which the sponsor carries out the endorsed discount card program) and enrollees in endorsed discount card programs of the sponsor under this section in a manner similar to that required under section 1852(f).

''(6) CONFIDENTIALITY OF ENROLLEE RECORDS.—

''(A) IN GENERAL.—For purposes of the program under this section, the operations of an endorsed program are covered functions and a prescription drug card sponsor is a covered entity for purposes of applying part C of title XI and all regulatory provisions promulgated thereunder, including regulations (relating to privacy) adopted pursuant to the authority of the Secretary under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note).

''(B) WAIVER AUTHORITY.—In order to promote participation of sponsors in the program under this section, the Secretary may waive such relevant portions of regulations relating to privacy referred to in subparagraph (A), for such appropriate, limited period of time, as the Secretary specifies.

''(7) LIMITATION ON PROVISION AND MARKETING OF PRODUCTS AND SERVICES.—The sponsor of an endorsed discount card program—

''(A) may provide under the program—

''(i) a product or service only if the product or service is directly related to a covered discount card drug; or

''(ii) a discount price for nonprescription drugs; and

''(B) may, to the extent otherwise permitted under paragraph (6) (relating to application of HIPAA requirements), market a product or service under the program only if the product or service is directly related to—

''(i) a covered discount card drug; or

''(ii) a drug described in subparagraph (A)(ii) and the marketing consists of information on the discounted price made available for the drug involved.

''(8) ADDITIONAL PROTECTIONS.—Each endorsed discount card program shall meet such additional requirements as the Secretary identifies to protect and promote the interest of discount card eligible individuals, including requirements that ensure that discount card eligible individuals enrolled in endorsed discount card programs are not charged more than the lower of the price based on negotiated prices or the usual and customary price.

''(9) SPECIAL RULES FOR CERTAIN ORGANIZATIONS.—

''(A) IN GENERAL.—In the case of an organization that is offering a plan under part C or enrollment under a reasonable cost reimbursement contract under section 1876(h) that is seeking to be a prescription drug card sponsor under this section, the organization may elect to apply the special rules under subparagraph (B) with respect to enrollees in any plan described in section 1851(a)(2)(A) that it offers or under such contract and an endorsed discount card program it offers, but only if it limits enrollment under such program to individuals enrolled in such plan or under such contract.

''(B) SPECIAL RULES.—The special rules under this subparagraph are as follows:

''(i) LIMITATION ON ENROLLMENT.—The sponsor limits enrollment under this section under the endorsed discount card program to discount card eligible individuals who are enrolled in the part C plan involved or under the reasonable cost reimbursement contract involved and is not required nor permitted to enroll other individuals under such program.

''(ii) PHARMACY ACCESS.—Pharmacy access requirements under subsection (e)(1)(B) are deemed to be met if the access is made available through a pharmacy network (and not only through mail order) and the network used by the sponsor is approved by the Secretary.

''(iii) SPONSOR REQUIREMENTS.—The Secretary may waive the application of such requirements for a sponsor as the Secretary determines to be duplicative or to conflict with a requirement of the organization under part C or section 1876 (as the case may be) or to be necessary in order to improve coordination of this section with the benefits under such part or section.

''(i) DISCLOSURE AND OVERSIGHT.—

''(1) DISCLOSURE.—Each prescription drug card sponsor offering an endorsed discount card program shall disclose to the Secretary (in a manner specified by the Secretary) information relating to program performance, use of prescription drugs by discount card eligible individuals enrolled in the program, the extent to which negotiated price concessions described in subsection (e)(1)(A)(ii) made available to the entity by a manufacturer are passed through to enrollees through pharmacies or otherwise, and such other information as the Secretary may specify. The provisions of section 1927(b)(3)(D) shall apply to drug pricing data reported under the previous sentence (other than data in aggregate form).

''(2) OVERSIGHT; AUDIT AND INSPECTION AUTHORITY.—The Secretary shall provide appropriate oversight to ensure compliance of endorsed discount card programs and their sponsors with the requirements of this section. The Secretary shall have the right to audit and inspect any books and records of a prescription discount card sponsor (and of any affiliated organization referred to in subsection (h)(1)(B)) that pertain to the endorsed discount card program under this section, including amounts payable to the sponsor under this section.

''(3) SANCTIONS FOR ABUSIVE PRACTICES.—The Secretary may implement intermediate sanctions or may revoke the endorsement of a program offered by a sponsor under this section if the Secretary determines that the sponsor or the program no longer meets the applicable requirements of this section or that the sponsor has engaged in false or misleading marketing practices. The Secretary may impose a civil money penalty in an amount not to exceed $10,000 for conduct that a party knows or should know is a violation of this section. The provisions of section 1128A (other than subsections (a) and (b) and the second sentence of subsection (f)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

''(j) TREATMENT OF TERRITORIES.—

''(1) IN GENERAL.—The Secretary may waive any provision of this section (including subsection (h)(2)(D)) in the case of a resident of a State (other than the 50 States and the District of Columbia) insofar as the Secretary determines it is necessary to secure access to negotiated prices for discount card eligible individuals (or, at the option of the Secretary, individuals described in subsection (b)(1)(A)(i)).

''(2) TRANSITIONAL ASSISTANCE.—

''(A) IN GENERAL.—In the case of a State, other than the 50 States and the District of Columbia, if the State establishes a plan described in subparagraph (B) (for providing transitional assistance with respect to the provision of prescription drugs to some or all individuals residing in the State who are described in subparagraph (B)(i)), the Secretary shall pay to the State for the entire period of the operation of this section an amount equal to the amount allotted to the State under subparagraph (C).

''(B) PLAN.—The plan described in this subparagraph is a plan that—

''(i) provides transitional assistance with respect to the provision of covered discount card drugs to some or all individuals who are entitled to benefits under part A or enrolled under part B, who reside in the State, and who have income below 135 percent of the poverty line; and

''(ii) assures that amounts received by the State under this paragraph are used only for such assistance.

''(C) ALLOTMENT LIMIT.—The amount described in this subparagraph for a State is equal to $35,000,000 multiplied by the ratio (as estimated by the Secretary) of—

''(i) the number of individuals who are entitled to benefits under part A or enrolled under part B and who reside in the State (as determined by the Secretary as of July 1, 2003), to

''(ii) the sum of such numbers for all States to which this paragraph applies.

''(D) CONTINUED AVAILABILITY OF FUNDS.—Amounts made available to a State under this paragraph which are not used under this paragraph shall be added to the amount available to that State for purposes of carrying out section 1935(e).

''(k) FUNDING.—

''(1) ESTABLISHMENT OF TRANSITIONAL ASSISTANCE ACCOUNT.—

''(A) IN GENERAL.—There is created within the Federal Supplementary Medical Insurance Trust Fund established by section 1841 an account to be known as the 'Transitional Assistance Account' (in this subsection referred to as the 'Account').

''(B) FUNDS.—The Account shall consist of such gifts and bequests as may be made as provided in section 201(i)(1), accrued interest on

balances in the Account, and such amounts as may be deposited in, or appropriated to, the Account as provided in this subsection.

''(C) SEPARATE FROM REST OF TRUST FUND.—Funds provided under this subsection to the Account shall be kept separate from all other funds within the Federal Supplementary Medical Insurance Trust Fund, but shall be invested, and such investments redeemed, in the same manner as all other funds and investments within such Trust Fund.

''(2) PAYMENTS FROM ACCOUNT.—

''(A) IN GENERAL.—The Managing Trustee shall pay from time to time from the Account such amounts as the Secretary certifies are necessary to make payments for transitional assistance provided under subsections (g) and (j)(2).

''(B) TREATMENT IN RELATION TO PART B PREMIUM.—Amounts payable from the Account shall not be taken into account in computing actuarial rates or premium amounts under section 1839.

''(3) APPROPRIATIONS TO COVER BENEFITS.—There are appropriated to the Account in a fiscal year, out of any moneys in the Treasury not otherwise appropriated, an amount equal to the payments made from the Account in the year.

''(4) FOR ADMINISTRATIVE EXPENSES.—There are authorized to be appropriated to the Secretary such sums as may be necessary to carry out the Secretary's responsibilities under this section.

''(5) TRANSFER OF ANY REMAINING BALANCE TO MEDICARE PRESCRIPTION DRUG ACCOUNT.—Any balance remaining in the Account after the Secretary determines that funds in the Account are no longer necessary to carry out the program under this section shall be transferred and deposited into the Medicare Prescription Drug Account under section 1860D–16.

''(6) CONSTRUCTION.—Nothing in this section shall be construed as authorizing the Secretary to provide for payment (other than payment of an enrollment fee on behalf of a transitional assistance eligible individual under subsection (g)(1)(A)) to a sponsor for administrative expenses incurred by the sponsor in carrying out this section (including in administering the transitional assistance provisions of subsections (f) and (g)).

''Subpart 5—Definitions and Miscellaneous Provisions

''DEFINITIONS; TREATMENT OF REFERENCES TO PROVISIONS IN PART C

''SEC. 1860D–41. (a) DEFINITIONS.—For purposes of this part:

''(1) BASIC PRESCRIPTION DRUG COVERAGE.—The term 'basic prescription drug coverage' is defined in section 1860D–2(a)(3).

''(2) COVERED PART D DRUG.—The term 'covered part D drug' is defined in section 1860D–2(e).

''(3) CREDITABLE PRESCRIPTION DRUG COVERAGE.—The term 'creditable prescription drug coverage' has the meaning given such term in section 1860D–13(b)(4).

''(4) PART D ELIGIBLE INDIVIDUAL.—The term 'part D eligible individual' has the meaning given such term in section 1860D–1(a)(4)(A).

''(5) FALLBACK PRESCRIPTION DRUG PLAN.—The term 'fallback prescription drug plan' has the meaning given such term in section 1860D–11(g)(4).

''(6) INITIAL COVERAGE LIMIT.—The term 'initial coverage limit' means such limit as established under section 1860D–2(b)(3), or, in the case of coverage that is not standard prescription drug coverage, the comparable limit (if any) established under the coverage.

''(7) INSURANCE RISK.—The term 'insurance risk' means, with respect to a participating pharmacy, risk of the type commonly assumed only by insurers licensed by a State and does not include payment variations designed to reflect performance-based measures of activities within the control of the pharmacy, such as formulary compliance and generic drug substitution.

''(8) MA PLAN.—The term 'MA plan' has the meaning given such term in section 1860D–1(a)(4)(B).

''(9) MA–PD PLAN.—The term 'MA–PD plan' has the meaning given such term in section 1860D–1(a)(4)(C).

''(10) MEDICARE PRESCRIPTION DRUG ACCOUNT.—The term 'Medicare Prescription Drug Account' means the Account created under section 1860D–16(a).

''(11) PDP APPROVED BID.—The term 'PDP approved bid' has the meaning given such term in section 1860D–13(a)(6).

''(12) PDP REGION.—The term 'PDP region' means such a region as provided under section 1860D–11(a)(2).

''(13) PDP SPONSOR.—The term 'PDP sponsor' means a nongovernmental entity that is certified under this part as meeting the requirements and standards of this part for such a sponsor.

''(14) PRESCRIPTION DRUG PLAN.—The term 'prescription drug plan' means prescription drug coverage that is offered—

''(A) under a policy, contract, or plan that has been approved under section 1860D–11(e); and

''(B) by a PDP sponsor pursuant to, and in accordance with, a contract between the Secretary and the sponsor under section 1860D–12(b).

''(15) QUALIFIED PRESCRIPTION DRUG COVERAGE.—The term 'qualified prescription drug coverage' is defined in section 1860D–2(a)(1).

''(16) STANDARD PRESCRIPTION DRUG COVERAGE.—The term 'standard prescription drug coverage' is defined in section 1860D–2(b).

''(17) STATE PHARMACEUTICAL ASSISTANCE PROGRAM.—The term 'State Pharmaceutical Assistance Program' has the meaning given such term in section 1860D–23(b).

''(18) SUBSIDY ELIGIBLE INDIVIDUAL.—The term 'subsidy eligible individual' has the meaning given such term in section 1860D–14(a)(3)(A).

''(b) APPLICATION OF PART C PROVISIONS UNDER THIS PART.—For purposes of applying provisions of part C under this part with respect to a prescription drug plan and a PDP sponsor, unless otherwise provided in this part such provisions shall be applied as if—

''(1) any reference to an MA plan included a reference to a prescription drug plan;

''(2) any reference to an MA organization or a provider-sponsored organization included a reference to a PDP sponsor;

''(3) any reference to a contract under section 1857 included a reference to a contract under section 1860D–12(b);

''(4) any reference to part C included a reference to this part; and

''(5) any reference to an election period under section 1851 were a reference to an enrollment period under section 1860D–1.

''MISCELLANEOUS PROVISIONS

''SEC. 1860D–42. (a) ACCESS TO COVERAGE IN TERRITORIES.—The Secretary may waive such requirements of this part, including section 1860D–3(a)(1), insofar as the Secretary determines it is necessary to secure access to qualified prescription drug coverage for part D eligible individuals residing in a State (other than the 50 States and the District of Columbia).

''(b) APPLICATION OF DEMONSTRATION AUTHORITY.—The provisions of section 402 of the Social Security Amendments of 1967 (Public Law 90–248) shall apply with respect to this part and part C in the same manner it applies with respect to parts A and B, except that any reference with respect to a Trust Fund in relation to an experiment or demonstration project relating to prescription drug coverage under this part shall be deemed a reference to the Medicare Prescription Drug Account within the Federal Supplementary Medical Insurance Trust Fund.''.

(b) SUBMISSION OF LEGISLATIVE PROPOSAL.—Not later than 6 months after the date of the enactment of this Act, the Secretary shall submit to the appropriate committees of Congress a legislative proposal providing for such technical and conforming amendments in the law as are required by the provisions of this title and title II.

(c) STUDY ON TRANSITIONING PART B PRESCRIPTION DRUG COVERAGE.—Not later than January 1, 2005, the Secretary shall submit a report to Congress that makes recommendations regarding methods for providing benefits under subpart 1 of part D of title XVIII of the Social Security Act for outpatient prescription drugs for which benefits are provided under part B of such title.

(d) REPORT ON PROGRESS IN IMPLEMENTATION OF PRESCRIPTION DRUG BENEFIT.—Not later than March 1, 2005, the Secretary shall submit a report to Congress on the progress that has been made in implementing the prescription drug benefit under this title. The Secretary shall include in the report specific steps that have been taken, and that need to be taken, to ensure a timely start of the program on January 1, 2006. The report shall include recommendations regarding an appropriate transition from the program under section 1860D–31 of the Social Security Act to prescription drug benefits under subpart 1 of part D of title XVIII of such Act.

(e) ADDITIONAL CONFORMING CHANGES.—

(1) CONFORMING REFERENCES TO PREVIOUS PART D.—Any reference in law (in effect before the date of the enactment of this Act) to part D of title XVIII of the Social Security Act is deemed a reference to part E of such title (as in effect after such date).

(2) CONFORMING AMENDMENT PERMITTING WAIVER OF COST-SHARING.—Section 1128B(b)(3) (42 U.S.C. 1320a–7b(b)(3)) is amended—

(A) by striking ''and'' at the end of subparagraph (E);

(B) by striking the period at the end of subparagraph (F) and inserting ''; and''; and

(C) by adding at the end the following new subparagraph:

''(G) the waiver or reduction by pharmacies (including pharmacies of the Indian Health Service, Indian tribes, tribal organizations, and urban Indian organizations) of any cost-sharing imposed under part D of title XVIII, if the conditions described in clauses (i) through (iii) of section 1128A(i)(6)(A) are met with respect to the waiver or reduction (except that, in the case of such a waiver or reduction on behalf of a subsidy eligible individual (as defined in section 1860D–14(a)(3)), section 1128A(i)(6)(A) shall be applied without regard to clauses (ii) and (iii) of that section).''.

(3) MEDICARE PRESCRIPTION DRUG ACCOUNT.—

(A) Section 201(g) (42 U.S.C. 401(g)) is amended—

(i) in paragraph (1)(B)(i)(V), by inserting ''(and, of such portion, the portion of such costs which should have been borne by the Medicare Prescription Drug Account in such Trust Fund)'' after ''Trust Fund''; and

(ii) in paragraph (1)(B)(ii)(III), by inserting ''(and, of such portion, the portion of such costs which should have been borne by the Medicare Prescription Drug Account in such Trust Fund)'' after ''Trust Fund''.

(B) Section 201(i)(1) (42 U.S.C. 401(i)(1)) is amended by inserting ''(and for the Medicare Prescription Drug Account and the Transitional Assistance Account in such Trust Fund)'' after ''Federal Supplementary Medical Insurance Trust Fund''.

(C) Section 1841 (42 U.S.C. 1395t) is amended—

(i) in the last sentence of subsection (a)—

(I) by striking ''and'' before ''such amounts''; and

(II) by inserting before the period the following: '', and such amounts as may be deposited in, or appropriated to, the Medicare Prescription Drug Account established by section 1860D–16'';

(ii) in subsection (g), by adding at the end the following: ''The payments provided for under part D, other than under section 1860D–31(k)(2),

shall be made from the Medicare Prescription Drug Account in the Trust Fund.'';

(iii) in subsection (h), by inserting ''or pursuant to section 1860D–13(c)(1) or 1854(d)(2)(A) (in which case payments shall be made in appropriate part from the Medicare Prescription Drug Account in the Trust Fund)'' after ''1840(d)''; and

(iv) in subsection (i), by inserting after ''and section 1842(g)'' the following: ''and pursuant to sections 1860D–13(c)(1) and 1854(d)(2)(A) (in which case payments shall be made in appropriate part from the Medicare Prescription Drug Account in the Trust Fund)''.

(D) Section 1853(f) (42 U.S.C. 1395w–23(f)) is amended—

(i) in the heading by striking ''TRUST FUND'' and inserting ''TRUST FUNDS''; and

(ii) by inserting after the first sentence the following: ''Payments to MA organizations for statutory drug benefits provided under this title are made from the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.''.

(4) APPLICATION OF CONFIDENTIALITY FOR DRUG PRICING DATA.—Section 1927(b)(3)(D) (42 U.S.C. 1396r–8(b)(3)(D)) is amended by adding after and below clause (iii) the following:

''The previous sentence shall also apply to information disclosed under section 1860D–2(d)(2) or 1860D–4(c)(2)(E).''.

(5) CLARIFICATION OF TREATMENT OF PART A ENROLLEES.—Section 1818(a) (42 U.S.C. 1395i–2(a)) is amended by adding at the end the following: ''Except as otherwise provided, any reference to an individual entitled to benefits under this part includes an individual entitled to benefits under this part pursuant to an enrollment under this section or section 1818A.''.

(6) DISCLOSURE.—Section 6103(l)(7)(D)(ii) of the Internal Revenue Code of 1986 is amended by inserting ''or subsidies provided under section 1860D–14 of such Act'' after ''Social Security Act''.

(7) EXTENSION OF STUDY AUTHORITY.—Section 1875(b) (42 U.S.C. 1395ll(b)) is amended by striking ''the insurance programs under parts A and B'' and inserting ''this title''.

(8) CONFORMING AMENDMENTS RELATING TO FACILITATION OF ELECTRONIC PRESCRIBING.—

(A) Section 1128B(b)(3)(C) (42 U.S.C. 1320a–7b(b)(3)(C)) is amended by inserting ''or in regulations under section 1860D–3(e)(6)'' after ''1987''.

(B) Section 1877(b) (42 U.S.C. 1395nn(b)) is amended by adding at the end the following new paragraph:

''(5) ELECTRONIC PRESCRIBING.—An exception established by regulation under section 1860D–3(e)(6).''.

(9) OTHER CHANGES.—Section 1927(g)(1)(B)(i) (42 U.S.C. 1396r–8(g)(1)(B)(i)) is amended—

(A) by adding ''and'' at the end of subclause (II); and

(B) by striking subclause (IV).

SEC. 102. MEDICARE ADVANTAGE CONFORMING AMENDMENTS.

(a) CONFORMING AMENDMENTS TO ENROLLMENT PROCESS.—

(1) EXTENDING OPEN ENROLLMENT PERIODS.—Section 1851(e) (42 U.S.C. 1395w–21(e)) is amended—

(A) in paragraph (2), by striking ''2004'' and ''2005'' and inserting ''2005'' and ''2006'' each place it appears; and

(B) in paragraph (4), by striking ''2005'' and inserting ''2006'' each place it appears.

(2) ESTABLISHMENT OF SPECIAL ANNUAL, COORDINATED ELECTION PERIOD FOR 6 MONTHS BEGINNING NOVEMBER 15, 2005.—Section 1851(e)(3)(B) (42 U.S.C. 1395w–21(e)(3)(B)) is amended to read as follows:

''(B) ANNUAL, COORDINATED ELECTION PERIOD.—For purposes of this section, the term 'annual, coordinated election period' means—

''(i) with respect to a year before 2002, the month of November before such year;

''(ii) with respect to 2002, 2003, 2004, and 2005, the period beginning on November 15 and ending on December 31 of the year before such year;

''(iii) with respect to 2006, the period beginning on November 15, 2005, and ending on May 15, 2006; and

''(iv) with respect to 2007 and succeeding years, the period beginning on November 15 and ending on December 31 of the year before such year.''.

(3) SPECIAL INFORMATION CAMPAIGN.—Section 1851(e)(3) (42 U.S.C. 1395w–21(e)(3)) is amended—

(A) in subparagraph (C), by inserting ''and during the period described in subparagraph (B)(iii)'' after ''(beginning with 1999)''; and

(B) in subparagraph (D)—

(i) in the heading by striking ''CAMPAIGN IN 1998'' and inserting ''CAMPAIGNS''; and

(ii) by adding at the end the following: ''During the period described in subparagraph (B)(iii), the Secretary shall provide for an educational and publicity campaign to inform MA eligible individuals about the availability of MA plans (including MA–PD plans) offered in different areas and the election process provided under this section.''.

(4) COORDINATING INITIAL ENROLLMENT PERIODS.—Section 1851(e)(1) (42 U.S.C. 1395w–21(e)(1)) is amended by adding at the end the following new sentence: ''If any portion of an individual's initial enrollment period under part B occurs after the end of the annual, coordinated election period described in paragraph (3)(B)(iii), the initial enrollment period under this part shall further extend through the end of the individual's initial enrollment period under part B.''.

(5) COORDINATION OF EFFECTIVENESS OF ELECTIONS DURING ANNUAL COORDINATED ELECTION PERIOD FOR 2006.—Section 1851(f)(3) (42 U.S.C. 1395w–21(f)(3)) is amended by inserting '', other than the period described in clause (iii) of such subsection'' after ''subsection (e)(3)(B)''.

(6) LIMITATION ON ONE-CHANGE RULE TO SAME TYPE OF PLAN.—Section 1851(e)(2) (42 U.S.C. 1395w–21(e)(2)) is amended—

(A) in subparagraph (B)(i), by inserting '', subparagraph (C)(iii),'' after ''clause (ii)'';

(B) in subparagraph (C)(i), by striking ''clause (ii)'' and inserting ''clauses (ii) and (iii)''; and

(C) by adding at the end of subparagraph (C) the following new clause:

''(iii) LIMITATION ON EXERCISE OF RIGHT WITH RESPECT TO PRESCRIPTION DRUG COVERAGE.—Effective for plan years beginning on or after January 1, 2006, in applying clause (i) (and clause (i) of subparagraph (B)) in the case of an individual who—

''(I) is enrolled in an MA plan that does provide qualified prescription drug coverage, the individual may exercise the right under such clause only with respect to coverage under the original fee-for-service plan or coverage under another MA plan that does not provide such coverage and may not exercise such right to obtain coverage under an MA–PD plan or under a prescription drug plan under part D; or

''(II) is enrolled in an MA–PD plan, the individual may exercise the right under such clause only with respect to coverage under another MA–PD plan (and not an MA plan that does not provide qualified prescription drug coverage) or under the original fee-for-service plan and coverage under a prescription drug plan under part D.''.

(b) PROMOTION OF E-PRESCRIBING BY MA PLANS.—Section 1852(j) (42 U.S.C. 1395w–22(j)) is amended by adding at the end the following new paragraph:

''(7) PROMOTION OF E-PRESCRIBING BY MA PLANS.—

''(A) IN GENERAL.—An MA–PD plan may provide for a separate payment or otherwise provide for a differential payment for a participating physician that prescribes covered part D drugs in accordance with an electronic prescription drug program that meets standards established under section 1860D–4(e).

''(B) CONSIDERATIONS.—Such payment may take into consideration the costs of the physician in implementing such a program and may also be increased for those participating physicians who significantly increase—

''(i) formulary compliance;

''(ii) lower cost, therapeutically equivalent alternatives;

''(iii) reductions in adverse drug interactions; and

''(iv) efficiencies in filing prescriptions through reduced administrative costs.

''(C) STRUCTURE.—Additional or increased payments under this subsection may be structured in the same manner as medication therapy management fees are structured under section 1860D–4(c)(2)(E).''.

(c) OTHER CONFORMING AMENDMENTS.—

(1) Section 1851(a)(1) (42 U.S.C. 1395w–21(a)(1)) is amended—

(A) by inserting ''(other than qualified prescription drug benefits)'' after ''benefits'';

(B) by striking the period at the end of subparagraph (B) and inserting a comma; and

(C) by adding after and below subparagraph (B) the following:

''and may elect qualified prescription drug coverage in accordance with section 1860D–1.''.

(2) EFFECTIVE DATE.—The amendments made by this subsection shall apply on and after January 1, 2006.

SEC. 103. MEDICAID AMENDMENTS.

(a) DETERMINATIONS OF ELIGIBILITY FOR LOW-INCOME SUBSIDIES.—

(1) REQUIREMENT.—Section 1902(a) (42 U.S.C. 1396a(a)) is amended—

(A) by striking ''and'' at the end of paragraph (64);

(B) by striking the period at the end of paragraph (65) and inserting ''; and''; and

(C) by inserting after paragraph (65) the following new paragraph:

''(66) provide for making eligibility determinations under section 1935(a).''.

(2) NEW SECTION.—Title XIX is further amended—

(A) by redesignating section 1935 as section 1936; and

(B) by inserting after section 1934 the following new section:

''SPECIAL PROVISIONS RELATING TO MEDICARE PRESCRIPTION DRUG BENEFIT

''SEC. 1935. (a) REQUIREMENTS RELATING TO MEDICARE PRESCRIPTION DRUG LOW-INCOME SUBSIDIES AND MEDICARE TRANSITIONAL PRESCRIPTION DRUG ASSISTANCE.—As a condition of its State plan under this title under section 1902(a)(66) and receipt of any Federal financial assistance under section 1903(a), a State shall do the following:

''(1) INFORMATION FOR TRANSITIONAL PRESCRIPTION DRUG ASSISTANCE VERIFICATION.—The State shall provide the Secretary with information to carry out section 1860D–31(f)(3)(B)(i).

''(2) ELIGIBILITY DETERMINATIONS FOR LOW-INCOME SUBSIDIES.—The State shall—

''(A) make determinations of eligibility for premium and cost-sharing subsidies under and in accordance with section 1860D–14;

''(B) inform the Secretary of such determinations in cases in which such eligibility is established; and

''(C) otherwise provide the Secretary with such information as may be required to carry out part D, other than subpart 4, of title XVIII (including section 1860D–14).

''(3) SCREENING FOR ELIGIBILITY, AND ENROLLMENT OF, BENEFICIARIES FOR MEDICARE COST-SHARING.—As part of making an eligibility determination required under paragraph (2) for an individual, the State shall make a determination of the individual's eligibility for medical assistance for any medicare cost-sharing described in section 1905(p)(3) and, if the individual is eligible for any such medicare cost-sharing, offer enrollment to the individual under the State plan (or under a waiver of such plan).

''(b) REGULAR FEDERAL SUBSIDY OF ADMINISTRATIVE COSTS.—The amounts expended by a State in carrying out subsection (a) are expenditures reimbursable under the appropriate paragraph of section 1903(a).

(b) PHASED-IN FEDERAL ASSUMPTION OF MEDICAID RESPONSIBILITY FOR PREMIUM AND COST-SHARING SUBSIDIES FOR DUALLY ELIGIBLE INDIVIDUALS.—Section 1935, as inserted by subsection (a)(2), is amended by adding at the end the following new subsection:

''(c) FEDERAL ASSUMPTION OF MEDICAID PRESCRIPTION DRUG COSTS FOR DUALLY ELIGIBLE INDIVIDUALS.—

''(1) PHASED-DOWN STATE CONTRIBUTION.—

''(A) IN GENERAL.—Each of the 50 States and the District of Columbia for each month beginning with January 2006 shall provide for payment under this subsection to the Secretary of the product of—

''(i) the amount computed under paragraph (2)(A) for the State and month;

''(ii) the total number of full-benefit dual eligible individuals (as defined in paragraph (6)) for such State and month; and

''(iii) the factor for the month specified in paragraph (5).

''(B) FORM AND MANNER OF PAYMENT.—Payment under subparagraph (A) shall be made in a manner specified by the Secretary that is similar to the manner in which State payments are made under an agreement entered into under section 1843, except that all such payments shall be deposited into the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.

''(C) COMPLIANCE.—If a State fails to pay to the Secretary an amount required under subparagraph (A), interest shall accrue on such amount at the rate provided under section 1903(d)(5). The amount so owed and applicable interest shall be immediately offset against amounts otherwise payable to the State under section 1903(a), in accordance with the Federal Claims Collection Act of 1996 and applicable regulations.

''(D) DATA MATCH.—The Secretary shall perform such periodic data matches as may be necessary to identify and compute the number of full-benefit dual eligible individuals for purposes of computing the amount under subparagraph (A).

''(2) AMOUNT.—

''(A) IN GENERAL.—The amount computed under this paragraph for a State described in paragraph (1) and for a month in a year is equal to—

''(i) 1/12 of the product of—

''(I) the base year state medicaid per capita expenditures for covered part D drugs for full-benefit dual eligible individuals (as computed under paragraph (3)); and

''(II) a proportion equal to 100 percent minus the Federal medical assistance percentage (as defined in section 1905(b)) applicable to the State for the fiscal year in which the month occurs; and

''(ii) increased for each year (beginning with 2004 up to and including the year involved) by the applicable growth factor specified in paragraph (4) for that year.

''(B) NOTICE.—The Secretary shall notify each State described in paragraph (1) not later than October 15 before the beginning of each year (beginning with 2006) of the amount computed under subparagraph (A) for the State for that year.

''(3) BASE YEAR STATE MEDICAID PER CAPITA EXPENDITURES FOR COVERED PART D DRUGS FOR FULL-BENEFIT DUAL ELIGIBLE INDIVIDUALS.—

''(A) IN GENERAL.—For purposes of paragraph (2)(A), the 'base year State medicaid per capita expenditures for covered part D drugs for full-benefit dual eligible individuals' for a State is equal to the weighted average (as weighted under subparagraph (C)) of—

''(i) the gross per capita medicaid expenditures for prescription drugs for 2003, determined under subparagraph (B); and

''(ii) the estimated actuarial value of prescription drug benefits provided under a capitated managed care plan per full-benefit dual eligible individual for 2003, as determined using such data as the Secretary determines appropriate.

''(B) GROSS PER CAPITA MEDICAID EXPENDITURES FOR PRESCRIPTION DRUGS.—

''(i) IN GENERAL.—The gross per capita medicaid expenditures for prescription drugs for 2003 under this subparagraph is equal to the expenditures, including dispensing fees, for the State under this title during 2003 for covered outpatient drugs, determined per full-benefit-dual-eligible-individual for such individuals not receiving medical assistance for such drugs through a medicaid managed care plan.

''(ii) DETERMINATION.—In determining the amount under clause (i), the Secretary shall—

''(I) use data from the Medicaid Statistical Information System (MSIS) and other available data;

''(II) exclude expenditures attributable to covered outpatient prescription drugs that are not covered part D drugs (as defined in section 1860D–2(e)); and

''(III) reduce such expenditures by the product of such portion and the adjustment factor (described in clause (iii)).

''(iii) ADJUSTMENT FACTOR.—The adjustment factor described in this clause for a State is equal to the ratio for the State for 2003 of—

''(I) aggregate payments under agreements under section 1927; to

''(II) the gross expenditures under this title for covered outpatient drugs referred to in clause (i).

Such factor shall be determined based on information reported by the State in the medicaid financial management reports (form CMS–64) for the 4 quarters of calendar year 2003 and such other data as the Secretary may require.

''(C) WEIGHTED AVERAGE.—The weighted average under subparagraph (A) shall be determined taking into account—

''(i) with respect to subparagraph (A)(i), the average number of full-benefit dual eligible individuals in 2003 who are not described in clause (ii); and

''(ii) with respect to subparagraph (A)(ii), the average number of full-benefit dual eligible individuals in such year who received in 2003 medical assistance for covered outpatient drugs through a medicaid managed care plan.

''(4) APPLICABLE GROWTH FACTOR.—The applicable growth factor under this paragraph for—

''(A) each of 2004, 2005, and 2006, is the average annual percent change (to that year from the previous year) of the per capita amount of prescription drug expenditures (as determined based on the most recent National Health Expenditure projections for the years involved); and

''(B) a succeeding year, is the annual percentage increase specified in section 1860D–2(b)(6) for the year.

''(5) FACTOR.—The factor under this paragraph for a month—

''(A) in 2006 is 90 percent;

''(B) in 2007 is 88-1/3 percent;

''(C) in 2008 is 86-2/3 percent;

''(D) in 2009 is 85 percent;

''(E) in 2010 is 83-1/3 percent;

''(F) in 2011 is 81-2/3 percent;

''(G) in 2012 is 80 percent;

''(H) in 2013 is 78-1/3 percent;

''(I) in 2014 is 76-2/3 percent; or

''(J) after December 2014, is 75 percent.

''(6) FULL-BENEFIT DUAL ELIGIBLE INDIVIDUAL DEFINED.—

''(A) IN GENERAL.—For purposes of this section, the term 'full-benefit dual eligible individual' means for a State for a month an individual who—

''(i) has coverage for the month for covered part D drugs under a prescription drug plan under part D of title XVIII, or under an MA–PD plan under part C of such title; and

''(ii) is determined eligible by the State for medical assistance for full benefits under this title for such month under section 1902(a)(10)(A) or 1902(a)(10)(C), by reason of section 1902(f), or under any other category of eligibility for medical assistance for full benefits under this title, as determined by the Secretary.

''(B) TREATMENT OF MEDICALLY NEEDY AND OTHER INDIVIDUALS REQUIRED TO SPEND DOWN.—In applying subparagraph (A) in the case of an individual determined to be eligible by the State for medical assistance under section 1902(a)(10)(C) or by reason of section 1902(f), the individual shall be treated as meeting the requirement of subparagraph (A)(ii) for any month if such medical assistance is provided for in any part of the month.''.

(c) MEDICAID COORDINATION WITH MEDICARE PRESCRIPTION DRUG BENEFITS.—Section 1935, as so inserted and amended, is further amended by adding at the end the following new subsection:

''(d) COORDINATION OF PRESCRIPTION DRUG BENEFITS.—

''(1) MEDICARE AS PRIMARY PAYOR.—In the case of a part D eligible individual (as defined in section 1860D–1(a)(3)(A)) who is described in subsection (c)(6)(A)(ii), notwithstanding any other provision of this title, medical assistance is not available under this title for such drugs (or for any cost-sharing respecting such drugs), and the rules under this title relating to the provision of medical assistance for such drugs shall not apply. The provision of benefits with respect to such drugs shall not be considered as the provision of care or services under the plan under this title. No payment may be made under section 1903(a) for prescribed drugs for which medical assistance is not available pursuant to this paragraph.

''(2) COVERAGE OF CERTAIN EXCLUDABLE DRUGS.—In the case of medical assistance under this title with respect to a covered outpatient drug (other than a covered part D drug) furnished to an individual who is enrolled in a prescription drug plan under part D of title XVIII or an MA–PD plan under part C of such title, the State may elect to provide such medical assistance in the manner otherwise provided in the case of individuals who are not full-benefit dual eligible individuals or through an arrangement with such plan.''.

(d) TREATMENT OF TERRITORIES.—

(1) IN GENERAL.—Section 1935, as so inserted and amended, is further amended—

(A) in subsection (a) in the matter preceding paragraph (1), by inserting ''subject to subsection (e)'' after ''section 1903(a)'';

(B) in subsection (c)(1), by inserting ''subject to subsection (e)'' after ''1903(a)(1)''; and

(C) by adding at the end the following new subsection:

''(e) TREATMENT OF TERRITORIES.—

''(1) IN GENERAL.—In the case of a State, other than the 50 States and the District of Columbia—

''(A) the previous provisions of this section shall not apply to residents of such State; and

''(B) if the State establishes and submits to the Secretary a plan described in paragraph (2) (for providing medical assistance with respect to the provision of prescription drugs to part D eligible individuals), the amount otherwise determined under section 1108(f) (as increased under section 1108(g)) for the State shall be increased by the amount for the fiscal period specified in paragraph (3).

''(2) PLAN.—The Secretary shall determine that a plan is described in this paragraph if the plan—

''(A) provides medical assistance with respect to the provision of covered part D drugs (as defined in section 1860D–2(e)) to low-income part D eligible individuals;

''(B) provides assurances that additional amounts received by the State that are attributable to the operation of this subsection shall be used only for such assistance and related administrative expenses and that no more than 10

percent of the amount specified in paragraph (3)(A) for the State for any fiscal period shall be used for such administrative expenses; and

''(C) meets such other criteria as the Secretary may establish.

''(3) INCREASED AMOUNT.—

''(A) IN GENERAL.—The amount specified in this paragraph for a State for a year is equal to the product of—

''(i) the aggregate amount specified in subparagraph (B); and

''(ii) the ratio (as estimated by the Secretary) of—

''(I) the number of individuals who are entitled to benefits under part A or enrolled under part B and who reside in the State (as determined by the Secretary based on the most recent available data before the beginning of the year); to

''(II) the sum of such numbers for all States that submit a plan described in paragraph (2).

''(B) AGGREGATE AMOUNT.—The aggregate amount specified in this subparagraph for—

''(i) the last 3 quarters of fiscal year 2006, is equal to $28,125,000;

''(ii) fiscal year 2007, is equal to $37,500,000; or

''(iii) a subsequent year, is equal to the aggregate amount specified in this subparagraph for the previous year increased by annual percentage increase specified in section 1860D–2(b)(6) for the year involved.

''(4) REPORT.—The Secretary shall submit to Congress a report on the application of this subsection and may include in the report such recommendations as the Secretary deems appropriate.''.

(2) CONFORMING AMENDMENT.—Section 1108(f) (42 U.S.C. 1308(f)) is amended by inserting ''and section 1935(e)(1)(B)'' after ''Subject to subsection (g)''.

(e) AMENDMENT TO BEST PRICE.—

(1) IN GENERAL.—Section 1927(c)(1)(C)(i) (42 U.S.C. 1396r–8(c)(1)(C)(i)) is amended—

(A) by striking ''and'' at the end of subclause (III);

(B) by striking the period at the end of subclause (IV) and inserting a semicolon; and

(C) by adding at the end the following new subclauses:

''(V) the prices negotiated from drug manufacturers for covered discount card drugs under an endorsed discount card program under section 1860D–31; and

''(VI) any prices charged which are negotiated by a prescription drug plan under part D of title XVIII, by an MA–PD plan under part C of such title with respect to covered part D drugs or by a qualified retiree prescription drug plan (as defined in section 1860D–22(a)(2)) with respect to such drugs on behalf of individuals entitled to benefits under part A or enrolled under part B of such title.''.

(2) IN GENERAL.—Section 1927(c)(1)(C)(i)(VI) of the Social Security Act, as added by paragraph (1), shall apply to prices charged for drugs dispensed on or after January 1, 2006.

(f) EXTENSION OF MEDICARE COST-SHARING FOR PART B PREMIUM FOR QUALIFYING INDIVIDUALS THROUGH SEPTEMBER 2004.—

(1) IN GENERAL.—Section 1902(a)(10)(E)(iv) (42 U.S.C. 1396a(a)(10)(E)(iv)), as amended by section 401(a) of Public Law 108–89, is amended by striking ''ending with March 2004'' and inserting ''ending with September 2004''.

(2) TOTAL AMOUNT AVAILABLE FOR ALLOCATION.—Section 1933(g) (42 U.S.C. 1396u–3(g)), as added by section 401(c) of Public Law 108–89, is amended—

(A) in the matter preceding paragraph (1), by striking ''March 31, 2004'' and inserting ''September 30, 2004''; and

(B) in paragraph (2), by striking ''$100,000,000'' and inserting ''$300,000,000''.

(3) EFFECTIVE DATE.—The amendments made by this subsection shall apply to calendar quarters beginning on or after April 1, 2004.

(g) OUTREACH BY THE COMMISSIONER OF SOCIAL SECURITY.—Section 1144 (42 U.S.C. 1320b–14) is amended—

(1) in the section heading, by inserting ''AND SUBSIDIES FOR LOW-INCOME INDIVIDUALS UNDER TITLE XVIII'' after ''COST-SHARING'';

(2) in subsection (a)—

(A) in paragraph (1)—

(i) in subparagraph (A), by inserting ''for the transitional assistance under section 1860D–31(f), or for premium and cost-sharing subsidies under section 1860D–14'' before the semicolon; and

(ii) in subparagraph (B), by inserting '', program, and subsidies'' after ''medical assistance''; and

(B) in paragraph (2)—

(i) in the matter preceding subparagraph (A), by inserting '', the transitional assistance under section 1860D–31(f), or premium and cost-sharing subsidies under section 1860D–14'' after ''assistance''; and

(ii) in subparagraph (A), by striking ''such eligibility'' and inserting ''eligibility for medicare cost-sharing under the medicaid program''; and

(3) in subsection (b)—

(A) in paragraph (1)(A), by inserting '', for transitional assistance under section 1860D–31(f), or for premium and cost-sharing subsidies for low-income individuals under section 1860D–14'' after ''1933''; and

(B) in paragraph (2), by inserting '', program, and subsidies'' after ''medical assistance''.

SEC. 104. MEDIGAP AMENDMENTS.

(a) RULES RELATING TO MEDIGAP POLICIES THAT PROVIDE PRESCRIPTION DRUG COVERAGE.—

(1) IN GENERAL.—Section 1882 (42 U.S.C. 1395ss) is amended by adding at the end the following new subsection:

''(v) RULES RELATING TO MEDIGAP POLICIES THAT PROVIDE PRESCRIPTION DRUG COVERAGE.—

''(1) PROHIBITION ON SALE, ISSUANCE, AND RENEWAL OF NEW POLICIES THAT PROVIDE PRESCRIPTION DRUG COVERAGE.—

''(A) IN GENERAL.—Notwithstanding any other provision of law, on or after January 1, 2006, a medigap Rx policy (as defined in paragraph (6)(A)) may not be sold, issued, or renewed under this section—

''(i) to an individual who is a part D enrollee (as defined in paragraph (6)(B)); or

''(ii) except as provided in subparagraph (B), to an individual who is not a part D enrollee.

''(B) CONTINUATION PERMITTED FOR NON-PART D ENROLLEES.—Subparagraph (A)(ii) shall not apply to the renewal of a medigap Rx policy that was issued before January 1, 2006.

''(C) CONSTRUCTION.—Nothing in this subsection shall be construed as preventing the offering on and after January 1, 2006, of 'H', 'I', and 'J' policies described in paragraph (2)(D)(i) if the benefit packages are modified in accordance with paragraph (2)(C).

''(2) ELIMINATION OF DUPLICATIVE COVERAGE UPON PART D ENROLLMENT.—

''(A) IN GENERAL.—In the case of an individual who is covered under a medigap Rx policy and enrolls under a part D plan—

''(i) before the end of the initial part D enrollment period, the individual may—

''(I) enroll in a medicare supplemental policy without prescription drug coverage under paragraph (3); or

''(II) continue the policy in effect subject to the modification described in subparagraph (C)(i); or

''(ii) after the end of such period, the individual may continue the policy in effect subject to such modification.

''(B) NOTICE REQUIRED TO BE PROVIDED TO CURRENT POLICYHOLDERS WITH MEDIGAP RX POLICY.—No medicare supplemental policy of an issuer shall be deemed to meet the standards in subsection (c) unless the issuer provides written notice (in accordance with standards of the Secretary established in consultation with the National Association of Insurance Commissioners) during the 60-day period immediately preceding the initial part D enrollment period, to each individual who is a policyholder or certificate holder of a medigap Rx policy (at the most recent available address of that individual) of the following:

''(i) If the individual enrolls in a plan under part D during the initial enrollment period under section 1860D–1(b)(2)(A), the individual has the option of—

''(I) continuing enrollment in the individual's current plan, but the plan's coverage of prescription drugs will be modified under subparagraph (C)(i); or

''(II) enrolling in another medicare supplemental policy pursuant to paragraph (3).

''(ii) If the individual does not enroll in a plan under part D during such period, the individual may continue enrollment in the individual's current plan without change, but—

''(I) the individual will not be guaranteed the option of enrollment in another medicare supplemental policy pursuant to paragraph (3); and

''(II) if the current plan does not provide creditable prescription drug coverage (as defined in section 1860D–13(b)(4)), notice of such fact and that there are limitations on the periods in a year in which the individual may enroll under a part D plan and any such enrollment is subject to a late enrollment penalty.

''(iii) Such other information as the Secretary may specify (in consultation with the National Association of Insurance Commissioners), including the potential impact of such election on premiums for medicare supplemental policies.

''(C) MODIFICATION.—

''(i) IN GENERAL.—The policy modification described in this subparagraph is the elimination of prescription coverage for expenses of prescription drugs incurred after the effective date of the individual's coverage under a part D plan and the appropriate adjustment of premiums to reflect such elimination of coverage.

''(ii) CONTINUATION OF RENEWABILITY AND APPLICATION OF MODIFICATION.—No medicare supplemental policy of an issuer shall be deemed to meet the standards in subsection (c) unless the issuer—

''(I) continues renewability of medigap Rx policies that it has issued, subject to subclause (II); and

''(II) applies the policy modification described in clause (i) in the cases described in clauses (i)(II) and (ii) of subparagraph (A).

''(D) REFERENCES TO RX POLICIES.—

''(i) H, I, AND J POLICIES.—Any reference to a benefit package classified as 'H', 'I', or 'J' (including the benefit package classified as 'J' with a high deductible feature, as described in subsection (p)(11)) under the standards established under subsection (p)(2) shall be construed as including a reference to such a package as modified under subparagraph (C) and such packages as modified shall not be counted as a separate benefit package under such subsection.

''(ii) APPLICATION IN WAIVERED STATES.—Except for the modification provided under subparagraph (C), the waivers previously in effect under subsection (p)(2) shall continue in effect.

''(3) AVAILABILITY OF SUBSTITUTE POLICIES WITH GUARANTEED ISSUE.—

''(A) IN GENERAL.—The issuer of a medicare supplemental policy—

''(i) may not deny or condition the issuance or effectiveness of a medicare supplemental policy that has a benefit package classified as 'A', 'B', 'C', or 'F' (including the benefit package classified as 'F' with a high deductible feature, as described in subsection (p)(11)), under the standards established under subsection (p)(2), or a benefit package described in subparagraph (A) or (B) of subsection (w)(2) and that is offered and is available for issuance to new enrollees by such issuer;

''(ii) may not discriminate in the pricing of such policy, because of health status, claims experience, receipt of health care, or medical condition; and

''(iii) may not impose an exclusion of benefits based on a pre-existing condition under such policy, in the case of an individual described in subparagraph (B) who seeks to enroll under the policy not later than 63 days after the effective date of the individual's coverage under a part D plan.

''(B) INDIVIDUAL COVERED.—An individual described in this subparagraph with respect to the issuer of a medicare supplemental policy is an individual who—

''(i) enrolls in a part D plan during the initial part D enrollment period;

''(ii) at the time of such enrollment was enrolled in a medigap Rx policy issued by such issuer; and

''(iii) terminates enrollment in such policy and submits evidence of such termination along with the application for the policy under subparagraph (A).

''(C) SPECIAL RULE FOR WAIVERED STATES.—For purposes of applying this paragraph in the case of a State that provides for offering of benefit packages other than under the classification referred to in subparagraph (A)(i), the references to benefit packages in such subparagraph are deemed references to comparable benefit packages offered in such State.

''(4) ENFORCEMENT.—

''(A) PENALTIES FOR DUPLICATION.—The penalties described in subsection (d)(3)(A)(ii) shall apply with respect to a violation of paragraph (1)(A).

''(B) GUARANTEED ISSUE.—The provisions of paragraph (4) of subsection (s) shall apply with respect to the requirements of paragraph (3) in the same manner as they apply to the requirements of such subsection.

''(5) CONSTRUCTION.—Any provision in this section or in a medicare supplemental policy relating to guaranteed renewability of coverage shall be deemed to have been met with respect to a part D enrollee through the continuation of the policy subject to modification under paragraph (2)(C) or the offering of a substitute policy under paragraph (3). The previous sentence shall not be construed to affect the guaranteed renewability of such a modified or substitute policy.

''(6) DEFINITIONS.—For purposes of this subsection:

''(A) MEDIGAP RX POLICY.—The term 'medigap Rx policy' means a medicare supplemental policy—

''(i) which has a benefit package classified as 'H', 'I', or 'J' (including the benefit package classified as 'J' with a high deductible feature, as described in subsection (p)(11)) under the standards established under subsection (p)(2), without regard to this subsection; and

''(ii) to which such standards do not apply (or to which such standards have been waived under subsection (p)(6)) but which provides benefits for prescription drugs.

Such term does not include a policy with a benefit package as classified under clause (i) which has been modified under paragraph (2)(C)(i).

''(B) PART D ENROLLEE.—The term 'part D enrollee' means an individual who is enrolled in a part D plan.

''(C) PART D PLAN.—The term 'part D plan' means a prescription drug plan or an MA–PD plan (as defined for purposes of part D).

''(D) INITIAL PART D ENROLLMENT PERIOD.—The term 'initial part D enrollment period' means the initial enrollment period described in section 1860D–1(b)(2)(A).''.

(2) CONFORMING CURRENT GUARANTEED ISSUE PROVISIONS.—

(A) EXTENDING GUARANTEED ISSUE POLICY FOR INDIVIDUALS ENROLLED IN MEDIGAP RX POLICIES WHO TRY MEDICARE ADVANTAGE.—Subsection (s)(3)(C)(ii) of such section is amended—

(i) by striking ''(ii) Only'' and inserting ''(ii)(I) Subject to subclause (II), only''; and

(ii) by adding at the end the following new subclause:

''(II) If the medicare supplemental policy referred to in subparagraph (B)(v) was a medigap Rx policy (as defined in subsection (v)(6)(A)), a medicare supplemental policy described in this subparagraph is such policy in which the individual was most recently enrolled as modified under subsection (v)(2)(C)(i) or, at the election of the individual, a policy referred to in subsection (v)(3)(A)(i).''.

(B) CONFORMING AMENDMENT.—Section 1882(s)(3)(C)(iii) is amended by inserting ''and subject to subsection (v)(1)'' after ''subparagraph (B)(vi)''.

(b) DEVELOPMENT OF NEW STANDARDS FOR MEDIGAP POLICIES.—

(1) IN GENERAL.—Section 1882 (42 U.S.C. 1395ss) is further amended by adding at the end the following new subsection:

''(w) DEVELOPMENT OF NEW STANDARDS FOR MEDICARE SUPPLEMENTAL POLICIES.—

''(1) IN GENERAL.—The Secretary shall request the National Association of Insurance Commissioners to review and revise the standards for benefit packages under subsection (p)(1), taking into account the changes in benefits resulting from enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and to otherwise update standards to reflect other changes in law included in such Act. Such revision shall incorporate the inclusion of the 2 benefit packages described in paragraph (2). Such revisions shall be made consistent with the rules applicable under subsection (p)(1)(E) with the reference to the '1991 NAIC Model Regulation' deemed a reference to the NAIC Model Regulation as published in the Federal Register on December 4, 1998, and as subsequently updated by the National Association of Insurance Commissioners to reflect previous changes in law (and subsection (v)) and the reference to 'date of enactment of this subsection' deemed a reference to the date of enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. To the extent practicable, such revision shall provide for the implementation of revised standards for benefit packages as of January 1, 2006.

''(2) NEW BENEFIT PACKAGES.—The benefit packages described in this paragraph are the following (notwithstanding any other provision of this section relating to a core benefit package):

''(A) FIRST NEW BENEFIT PACKAGE.—A benefit package consisting of the following:

''(i) Subject to clause (ii), coverage of 50 percent of the cost-sharing otherwise applicable under parts A and B, except there shall be no coverage of the part B deductible and coverage of 100 percent of any cost-sharing otherwise applicable for preventive benefits.

''(ii) Coverage for all hospital inpatient coinsurance and 365 extra lifetime days of coverage of inpatient hospital services (as in the current core benefit package).

''(iii) A limitation on annual out-of-pocket expenditures under parts A and B to $4,000 in 2006 (or, in a subsequent year, to such limitation for the previous year increased by an appropriate inflation adjustment specified by the Secretary).

''(B) SECOND NEW BENEFIT PACKAGE.—A benefit package consisting of the benefit package described in subparagraph (A), except as follows:

''(i) Substitute '75 percent' for '50 percent' in clause (i) of such subparagraph.

''(ii) Substitute '$2,000' for '$4,000' in clause (iii) of such subparagraph.''.

(2) CONFORMING AMENDMENTS.—Section 1882 (42 U.S.C. 1395ss) is amended—

(A) in subsection (g)(1), by inserting ''a prescription drug plan under part D or'' after ''but does not include''; and

(B) in subsection (o)(1), by striking ''subsection (p)'' and inserting ''subsections (p), (v), and (w)''.

(c) RULE OF CONSTRUCTION.—

(1) IN GENERAL.—Nothing in this Act shall be construed to require an issuer of a medicare supplemental policy under section 1882 of the Social Security Act (42 U.S.C. 1395rr) to participate as a PDP sponsor under part D of title XVIII of such Act, as added by section 101, as a condition for issuing such policy.

(2) PROHIBITION ON STATE REQUIREMENT.—A State may not require an issuer of a medicare supplemental policy under section 1882 of the Social Security Act (42 U.S.C. 1395rr) to participate as a PDP sponsor under such part D as a condition for issuing such policy.

SEC. 105. ADDITIONAL PROVISIONS RELATING TO MEDICARE PRESCRIPTION DRUG DISCOUNT CARD AND TRANSITIONAL ASSISTANCE PROGRAM.

(a) EXCLUSION OF COSTS FROM DETERMINATION OF PART B MONTHLY PREMIUM.—Section 1839(g) (42 U.S.C. 1395r(g)) is amended—

(1) by striking ''attributable to the application of section'' and inserting ''attributable to—

''(1) the application of section'';

(2) by striking the period and inserting ''; and''; and

(3) by adding at the end the following new paragraph:

''(2) the medicare prescription drug discount card and transitional assistance program under section 1860D–31.''.

(b) APPLICATION OF CONFIDENTIALITY FOR DRUG PRICING DATA.—The last sentence of section 1927(b)(3)(D) (42 U.S.C. 1396r–8(b)(3)(D)), as added by section 101(e)(4), is amended by inserting ''and drug pricing data reported under the first sentence of section 1860D–31(i)(1)'' after ''section 1860D–4(c)(2)(E)''.

(c) RULES FOR IMPLEMENTATION.—The following rules shall apply to the medicare prescription drug discount card and transitional assistance program under section 1860D–31 of the Social Security Act, as added by section 101(a):

(1) In promulgating regulations pursuant to subsection (a)(2)(B) of such section 1860D–31—

(A) section 1871(a)(3) of the Social Security Act (42 U.S.C. 1395hh(a)(3)), as added by section 902(a)(1), shall not apply;

(B) chapter 35 of title 44, United States Code, shall not apply; and

(C) sections 553(d) and 801(a)(3)(A) of title 5, United States Code, shall not apply.

(2) Section 1857(c)(5) of the Social Security Act (42 U.S.C. 1395w–27(c)(5)) shall apply with respect to section 1860D–31 of such Act, as added by section 101(a), in the same manner as it applies to part C of title XVIII of such Act.

(3) The administration of such program shall be made without regard to chapter 35 of title 44, United States Code.

(4)(A) There shall be no judicial review of a determination not to endorse, or enter into a contract, with a prescription drug card sponsor under section 1860D–31 of the Social Security Act.

(B) In the case of any order issued to enjoin any provision of section 1860D–31 of the Social Security Act (or of any provision of this section), such order shall not affect any other provision of such section (or of this section) and all such provisions shall be treated as severable.

(d) CONFORMING AMENDMENTS TO FEDERAL SMI TRUST FUND FOR TRANSITIONAL ASSISTANCE ACCOUNT.—Section 1841 (42 U.S.C. 1395t), as amended by section 101(e)(3)(C), is amended—

(1) in the last sentence of subsection (a), by inserting after ''section 1860D–16'' the following: ''or the Transitional Assistance Account established by section 1860D–31(k)(1)''; and

(2) in subsection (g), by adding at the end the following: ''The payments provided for under section 1860D–31(k)(2) shall be made from the Transitional Assistance Account in the Trust Fund.''.

(e) DISCLOSURE OF RETURN INFORMATION FOR PURPOSES OF PROVIDING TRANSITIONAL ASSISTANCE UNDER MEDICARE DISCOUNT CARD PROGRAM.—

(1) IN GENERAL.—Subsection (l) of section 6103 of the Internal Revenue Code of 1986 (relating to

disclosure of returns and return information for purposes other than tax administration) is amended by adding at the end the following new paragraph:

''(19) DISCLOSURE OF RETURN INFORMATION FOR PURPOSES OF PROVIDING TRANSITIONAL ASSISTANCE UNDER MEDICARE DISCOUNT CARD PROGRAM.—

''(A) IN GENERAL.—The Secretary, upon written request from the Secretary of Health and Human Services pursuant to carrying out section 1860D–31 of the Social Security Act, shall disclose to officers, employees, and contractors of the Department of Health and Human Services with respect to a taxpayer for the applicable year—

''(i)(I) whether the adjusted gross income, as modified in accordance with specifications of the Secretary of Health and Human Services for purposes of carrying out such section, of such taxpayer and, if applicable, such taxpayer's spouse, for the applicable year, exceeds the amounts specified by the Secretary of Health and Human Services in order to apply the 100 and 135 percent of the poverty lines under such section, (II) whether the return was a joint return, and (III) the applicable year, or

''(ii) if applicable, the fact that there is no return filed for such taxpayer for the applicable year.

''(B) DEFINITION OF APPLICABLE YEAR.—For the purposes of this subsection, the term 'applicable year' means the most recent taxable year for which information is available in the Internal Revenue Service's taxpayer data information systems, or, if there is no return filed for such taxpayer for such year, the prior taxable year.

''(C) RESTRICTION ON USE OF DISCLOSED INFORMATION.—Return information disclosed under this paragraph may be used only for the purposes of determining eligibility for and administering transitional assistance under section 1860D–31 of the Social Security Act.''

(2) CONFIDENTIALITY.—Paragraph (3) of section 6103(a) of such Code is amended by striking ''or (16)'' and inserting ''(16), or (19)''.

(3) PROCEDURES AND RECORDKEEPING RELATED TO DISCLOSURES.—Subsection (p)(4) of section 6103 of such Code is amended by striking ''(l)(16) or (17)'' each place it appears and inserting ''(l)(16), (17), or (19)''.

(4) UNAUTHORIZED DISCLOSURE OR INSPECTION.—Paragraph (2) of section 7213(a) of such Code is amended by striking ''or (16)'' and inserting ''(16), or (19)''.

SEC. 106. STATE PHARMACEUTICAL ASSISTANCE TRANSITION COMMISSION.

(a) ESTABLISHMENT.—

(1) IN GENERAL.—There is established, as of the first day of the third month beginning after the date of the enactment of this Act, a State Pharmaceutical Assistance Transition Commission (in this section referred to as the ''Commission'') to develop a proposal for addressing the unique transitional issues facing State pharmaceutical assistance programs, and program participants, due to the implementation of the voluntary prescription drug benefit program under part D of title XVIII of the Social Security Act, as added by section 101.

(2) DEFINITIONS.—For purposes of this section:

(A) STATE PHARMACEUTICAL ASSISTANCE PROGRAM DEFINED.—The term ''State pharmaceutical assistance program'' means a program (other than the medicaid program) operated by a State (or under contract with a State) that provides as of the date of the enactment of this Act financial assistance to medicare beneficiaries for the purchase of prescription drugs.

(B) PROGRAM PARTICIPANT.—The term ''program participant'' means a low-income medicare beneficiary who is a participant in a State pharmaceutical assistance program.

(b) COMPOSITION.—The Commission shall include the following:

(1) A representative of each Governor of each State that the Secretary identifies as operating on a statewide basis a State pharmaceutical assistance program that provides for eligibility and benefits that are comparable or more generous than the low-income assistance eligibility and benefits offered under section 1860D–14 of the Social Security Act.

(2) Representatives from other States that the Secretary identifies have in operation other State pharmaceutical assistance programs, as appointed by the Secretary.

(3) Representatives of organizations that have an inherent interest in program participants or the program itself, as appointed by the Secretary but not to exceed the number of representatives under paragraphs (1) and (2).

(4) Representatives of Medicare Advantage organizations, pharmaceutical benefit managers, and other private health insurance plans, as appointed by the Secretary.

(5) The Secretary (or the Secretary's designee) and such other members as the Secretary may specify. The Secretary shall designate a member to serve as Chair of the Commission and the Commission shall meet at the call of the Chair.

(c) DEVELOPMENT OF PROPOSAL.—The Commission shall develop the proposal described in subsection (a) in a manner consistent with the following principles:

(1) Protection of the interests of program participants in a manner that is the least disruptive to such participants and that includes a single point of contact for enrollment and processing of benefits.

(2) Protection of the financial and flexibility interests of States so that States are not financially worse off as a result of the enactment of this title.

(3) Principles of medicare modernization under this Act.

(d) REPORT.—By not later than January 1, 2005, the Commission shall submit to the President and Congress a report that contains a detailed proposal (including specific legislative or administrative recommendations, if any) and such other recommendations as the Commission deems appropriate.

(e) SUPPORT.—The Secretary shall provide the Commission with the administrative support services necessary for the Commission to carry out its responsibilities under this section.

(f) TERMINATION.—The Commission shall terminate 30 days after the date of submission of the report under subsection (d).

SEC. 107. STUDIES AND REPORTS.

(a) STUDY REGARDING REGIONAL VARIATIONS IN PRESCRIPTION DRUG SPENDING.—

(1) IN GENERAL.—The Secretary shall conduct a study that examines variations in per capita spending for covered part D drugs under part D of title XVIII of the Social Security Act among PDP regions and, with respect to such spending, the amount of such variation that is attributable to—

(A) price variations (described in section 1860D–15(c)(2) of such Act); and

(B) differences in per capita utilization that is not taken into account in the health status risk adjustment provided under section 1860D–15(c)(1) of such Act.

(2) REPORT AND RECOMMENDATIONS.—Not later than January 1, 2009, the Secretary shall submit to Congress a report on the study conducted under paragraph (1). Such report shall include—

(A) information regarding the extent of geographic variation described in paragraph (1)(B);

(B) an analysis of the impact on direct subsidies under section 1860D–15(a)(1) of the Social Security Act in different PDP regions if such subsidies were adjusted to take into account the variation described in subparagraph (A); and

(C) recommendations regarding the appropriateness of applying an additional geographic adjustment factor under section 1860D–15(c)(2) that reflects some or all of the variation described in subparagraph (A).

(b) REVIEW AND REPORT ON CURRENT STANDARDS OF PRACTICE FOR PHARMACY SERVICES PROVIDED TO PATIENTS IN NURSING FACILITIES.—

(1) REVIEW.—

(A) IN GENERAL.—Not later than 12 months after the date of the enactment of this Act, the Secretary shall conduct a thorough review of the current standards of practice for pharmacy services provided to patients in nursing facilities

(B) SPECIFIC MATTERS REVIEWED.—In conducting the review under subparagraph (A), the Secretary shall—

(i) assess the current standards of practice, clinical services, and other service requirements generally used for pharmacy services in long-term care settings; and

(ii) evaluate the impact of those standards with respect to patient safety, reduction of medication errors and quality of care.

(2) REPORT.—

(A) IN GENERAL.—Not later than the date that is 18 months after the date of the enactment of this Act, the Secretary shall submit a report to Congress on the study conducted under paragraph (1)(A).

(B) CONTENTS.—The report submitted under subparagraph (A) shall contain—

(i) a description of the plans of the Secretary to implement the provisions of this Act in a manner consistent with applicable State and Federal laws designed to protect the safety and quality of care of nursing facility patients; and

(ii) recommendations regarding necessary actions and appropriate reimbursement to ensure the provision of prescription drugs to medicare beneficiaries residing in nursing facilities in a manner consistent with existing patient safety and quality of care standards under applicable State and Federal laws.

(c) IOM STUDY ON DRUG SAFETY AND QUALITY.—

(1) IN GENERAL.—The Secretary shall enter into a contract with the Institutes of Medicine of the National Academies of Science (such Institutes referred to in this subsection as the ''IOM'') to carry out a comprehensive study (in this subsection referred to as the ''study'') of drug safety and quality issues in order to provide a blueprint for system-wide change.

(2) OBJECTIVES.—

(A) The study shall develop a full understanding of drug safety and quality issues through an evidence-based review of literature, case studies, and analysis. This review will consider the nature and causes of medication errors, their impact on patients, the differences in causation, impact, and prevention across multiple dimensions of health care delivery-including patient populations, care settings, clinicians, and institutional cultures.

(B) The study shall attempt to develop credible estimates of the incidence, severity, costs of medication errors that can be useful in prioritizing resources for national quality improvement efforts and influencing national health care policy.

(C) The study shall evaluate alternative approaches to reducing medication errors in terms of their efficacy, cost-effectiveness, appropriateness in different settings and circumstances, feasibility, institutional barriers to implementation, associated risks, and the quality of evidence supporting the approach.

(D) The study shall provide guidance to consumers, providers, payers, and other key stakeholders on high-priority strategies to achieve both short-term and long-term drug safety goals, to elucidate the goals and expected results of such initiatives and support the business case for them, and to identify critical success factors and key levers for achieving success.

(E) The study shall assess the opportunities and key impediments to broad nationwide implementation of medication error reductions, and to provide guidance to policy-makers and government agencies (including the Food and Drug Administration, the Centers for Medicare & Medicaid Services, and the National Institutes of Health) in promoting a national agenda for medication error reduction.

(F) The study shall develop an applied research agenda to evaluate the health and cost impacts of alternative interventions, and to assess collaborative public and private strategies for implementing the research agenda through AHRQ and other government agencies.

(3) CONDUCT OF STUDY.—

(A) EXPERT COMMITTEE.—In conducting the study, the IOM shall convene a committee of leading experts and key stakeholders in pharmaceutical management and drug safety, including clinicians, health services researchers, pharmacists, system administrators, payer representatives, and others.

(B) COMPLETION.—The study shall be completed within an 18-month period.

(4) REPORT.—A report on the study shall be submitted to Congress upon the completion of the study.

(5) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary.

(d) STUDY OF MULTI-YEAR CONTRACTS.—

(1) IN GENERAL.—The Secretary shall provide for a study on the feasibility and advisability of providing for contracting with PDP sponsors and MA organizations under parts C and D of title XVIII on a multi-year basis.

(2) REPORT.—Not later than January 1, 2007, the Secretary shall submit to Congress a report on the study under paragraph (1). The report shall include such recommendations as the Secretary deems appropriate.

(e) GAO STUDY REGARDING IMPACT OF ASSETS TEST FOR SUBSIDY ELIGIBLE INDIVIDUALS.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study to determine the extent to which drug utilization and access to covered part D drugs under part D of title XVIII of the Social Security Act by subsidy eligible individuals differs from such utilization and access for individuals who would qualify as such subsidy eligible individuals but for the application of section 1860D–14(a)(3)(A)(iii) of such Act.

(2) REPORT.—Not later than September 30, 2007, the Comptroller General shall submit a report to Congress on the study conducted under paragraph (1) that includes such recommendations for legislation as the Comptroller General determines are appropriate.

(f) STUDY ON MAKING PRESCRIPTION PHARMACEUTICAL INFORMATION ACCESSIBLE FOR BLIND AND VISUALLY-IMPAIRED INDIVIDUALS.—

(1) STUDY.—

(A) IN GENERAL.—The Secretary shall undertake a study of how to make prescription pharmaceutical information, including drug labels and usage instructions, accessible to blind and visually-impaired individuals.

(B) STUDY TO INCLUDE EXISTING AND EMERGING TECHNOLOGIES.—The study under subparagraph (A) shall include a review of existing and emerging technologies, including assistive technology, that makes essential information on the content and prescribed use of pharmaceutical medicines available in a usable format for blind and visually-impaired individuals.

(2) REPORT.—

(A) IN GENERAL.—Not later than 18 months after the date of the enactment of this Act, the Secretary shall submit a report to Congress on the study required under paragraph (1).

(B) CONTENTS OF REPORT.—The report required under paragraph (1) shall include recommendations for the implementation of usable formats for making prescription pharmaceutical information available to blind and visually-impaired individuals and an estimate of the costs associated with the implementation of each format.

SEC. 108. GRANTS TO PHYSICIANS TO IMPLEMENT ELECTRONIC PRESCRIPTION DRUG PROGRAMS.

(a) IN GENERAL.—The Secretary is authorized to make grants to physicians for the purpose of assisting such physicians to implement electronic prescription drug programs that comply with the standards promulgated or modified under section 1860D–4(e) of the Social Security Act, as inserted by section 101(a).

(b) AWARDING OF GRANTS.—

(1) APPLICATION.—No grant may be made under this section except pursuant to a grant application that is submitted and approved in a time, manner, and form specified by the Secretary.

(2) CONSIDERATIONS AND PREFERENCES.—In awarding grants under this section, the Secretary shall—

(A) give special consideration to physicians who serve a disproportionate number of medicare patients; and

(B) give preference to physicians who serve a rural or underserved area.

(3) LIMITATION ON GRANTS.—Only 1 grant may be awarded under this section with respect to any physician or group practice of physicians.

(c) TERMS AND CONDITIONS.—

(1) IN GENERAL.—Grants under this section shall be made under such terms and conditions as the Secretary specifies consistent with this section.

(2) USE OF GRANT FUNDS.—Funds provided under grants under this section may be used for any of the following:

(A) For purchasing, leasing, and installing computer software and hardware, including handheld computer technologies.

(B) Making upgrades and other improvements to existing computer software and hardware to enable e-prescribing.

(C) Providing education and training to eligible physician staff on the use of technology to implement the electronic transmission of prescription and patient information.

(3) PROVISION OF INFORMATION.—As a condition for the awarding of a grant under this section, an applicant shall provide to the Secretary such information as the Secretary may require in order to—

(A) evaluate the project for which the grant is made; and

(B) ensure that funding provided under the grant is expended only for the purposes for which it is made.

(4) AUDIT.—The Secretary shall conduct appropriate audits of grants under this section.

(5) MATCHING REQUIREMENT.—The applicant for a grant under this section shall agree, with respect to the costs to be incurred by the applicant in implementing an electronic prescription drug program, to make available (directly or through donations from public or private entities) non-Federal contributions toward such costs in an amount that is not less than 50 percent of such costs. Non-Federal contributions under the previous sentence may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such contributions.

(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $50,000,000 for fiscal year 2007 and such sums as may be necessary for each of fiscal years 2008 and 2009.

SEC. 109. EXPANDING THE WORK OF MEDICARE QUALITY IMPROVEMENT ORGANIZATIONS TO INCLUDE PARTS C AND D.

(a) APPLICATION TO MEDICARE MANAGED CARE AND PRESCRIPTION DRUG COVERAGE.—Section 1154(a)(1) (42 U.S.C. 1320c–3(a)(1)) is amended by inserting '', to Medicare Advantage organizations pursuant to contracts under part C, and to prescription drug sponsors pursuant to contracts under part D'' after ''under section 1876''.

(b) PRESCRIPTION DRUG THERAPY QUALITY IMPROVEMENT.—Section 1154(a) (42 U.S.C. 1320c–3(a)) is amended by adding at the end the following new paragraph:

''(17) The organization shall execute its responsibilities under subparagraphs (A) and (B) of paragraph (1) by offering to providers, practitioners, Medicare Advantage organizations offering Medicare Advantage plans under part C, and prescription drug sponsors offering prescription drug plans under part D quality improvement assistance pertaining to prescription drug therapy. For purposes of this part and title XVIII, the functions described in this paragraph shall be treated as a review function.''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply on and after January 1, 2004.

(d) IOM STUDY OF QIOS.—

(1) IN GENERAL.—The Secretary shall request the Institute of Medicine of the National Academy of Sciences to conduct an evaluation of the program under part B of title XI of the Social Security Act. The study shall include a review of the following:

(A) An overview of the program under such part.

(B) The duties of organizations with contracts with the Secretary under such part.

(C) The extent to which quality improvement organizations improve the quality of care for medicare beneficiaries.

(D) The extent to which other entities could perform such quality improvement functions as well as, or better than, quality improvement organizations.

(E) The effectiveness of reviews and other actions conducted by such organizations in carrying out those duties.

(F) The source and amount of funding for such organizations.

(G) The conduct of oversight of such organizations.

(2) REPORT TO CONGRESS.—Not later than June 1, 2006, the Secretary shall submit to Congress a report on the results of the study described in paragraph (1), including any recommendations for legislation.

(3) INCREASED COMPETITION.—If the Secretary finds based on the study conducted under paragraph (1) that other entities could improve quality in the medicare program as well as, or better than, the current quality improvement organizations, then the Secretary shall provide for such increased competition through the addition of new types of entities which may perform quality improvement functions.

SEC. 110. CONFLICT OF INTEREST STUDY.

(a) STUDY.—The Federal Trade Commission shall conduct a study of differences in payment amounts for pharmacy services provided to enrollees in group health plans that utilize pharmacy benefit managers. Such study shall include the following:

(1) An assessment of the differences in costs incurred by such enrollees and plans for prescription drugs dispensed by mail-order pharmacies owned by pharmaceutical benefit managers compared to mail-order pharmacies not owned by pharmaceutical benefit managers, and community pharmacies.

(2) Whether such plans are acting in a manner that maximizes competition and results in lower prescription drug prices for enrollees.

(b) REPORT.—Not later than 18 months after the date of the enactment of this Act, the Commission shall submit to Congress a report on the study conducted under subsection (a). Such report shall include recommendations regarding any need for legislation to ensure the fiscal integrity of the voluntary prescription drug benefit program under part D of title XVIII, as added by section 101, that may be appropriated as the result of such study.

(c) EXEMPTION FROM PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code, shall not apply to the collection of information under subsection (a).

SEC. 111. STUDY ON EMPLOYMENT-BASED RETIREE HEALTH COVERAGE.

(a) STUDY.—The Comptroller General of the United States shall conduct an initial and final study under this subsection to examine trends in employment-based retiree health coverage (as

defined in 1860D–22(c)(1) of the Social Security Act, as added by section 101), including coverage under the Federal Employees Health Benefits Program (FEHBP), and the options and incentives available under this Act which may have an effect on the voluntary provision of such coverage.

(b) CONTENT OF INITIAL STUDY.—The initial study under this section shall consider the following:

(1) Trends in employment-based retiree health coverage prior to the date of the enactment of this Act.

(2) The opinions of sponsors of employment-based retiree health coverage concerning which of the options available under this Act they are most likely to utilize for the provision of health coverage to their medicare-eligible retirees, including an assessment of the administrative burdens associated with the available options.

(3) The likelihood of sponsors of employment-based retiree health coverage to maintain or adjust their levels of retiree health benefits beyond coordination with medicare, including for prescription drug coverage, provided to medicare-eligible retirees after the date of the enactment of this Act.

(4) The factors that sponsors of employment-based retiree health coverage expect to consider in making decisions about any changes they may make in the health coverage provided to medicare-eligible retirees.

(5) Whether the prescription drug plan options available, or the health plan options available under the Medicare Advantage program, are likely to cause employers and other entities that did not provide health coverage to retirees prior to the date of the enactment of this Act to provide supplemental coverage or contributions toward premium expenses for medicare-eligible retirees who may enroll in such options in the future.

(c) CONTENTS OF FINAL STUDY.—The final study under this section shall consider the following:

(1) Changes in the trends in employment-based retiree health coverage since the completion of the initial study by the Comptroller General.

(2) Factors contributing to any changes in coverage levels.

(3) The number and characteristics of sponsors of employment-based retiree health coverage who receive the special subsidy payments under section 1860D–22 of the Social Security Act, as added by section 101, for the provision of prescription drug coverage to their medicare-eligible retirees that is the same or greater actuarial value as the prescription drug coverage available to other medicare beneficiaries without employment-based retiree health coverage.

(4) The extent to which sponsors of employment-based retiree health coverage provide supplemental health coverage or contribute to the premiums for medicare-eligible retirees who enroll in a prescription drug plan or an MA–PD plan.

(5) Other coverage options, including tax-preferred retirement or health savings accounts, consumer-directed health plans, or other vehicles that sponsors of employment-based retiree health coverage believe would assist retirees with their future health care needs and their willingness to sponsor such alternative plan designs.

(6) The extent to which employers or other entities that did not provide employment-based retiree health coverage prior to the date of the enactment of this Act provided some form of coverage or financial assistance for retiree health care needs after the date of the enactment of this Act.

(7) Recommendations by employers, benefits experts, academics, and others on ways that the voluntary provision of employment-based retiree health coverage may be improved and expanded.

(d) REPORTS.—The Comptroller General shall submit a report to Congress on—

(1) the initial study under subsection (b) not later than 1 year after the date of the enactment of this Act; and

(2) the final study under subsection (c) not later than January 1, 2007.

(e) CONSULTATION.—The Comptroller General shall consult with sponsors of employment-based retiree health coverage, benefits experts, human resources professionals, employee benefits consultants, and academics with experience in health benefits and survey research in the development and design of the initial and final studies under this section.

TITLE II—MEDICARE ADVANTAGE

Subtitle A—Implementation of Medicare Advantage Program

SEC. 201. IMPLEMENTATION OF MEDICARE ADVANTAGE PROGRAM.

(a) IN GENERAL.—There is hereby established the Medicare Advantage program. The Medicare Advantage program shall consist of the program under part C of title XVIII of the Social Security Act (as amended by this Act).

(b) REFERENCES.—Subject to subsection (c), any reference to the program under part C of title XVIII of the Social Security Act shall be deemed a reference to the Medicare Advantage program and, with respect to such part, any reference to ''Medicare+Choice'' is deemed a reference to ''Medicare Advantage'' and ''MA''.

(c) TRANSITION.—In order to provide for an orderly transition and avoid beneficiary and provider confusion, the Secretary shall provide for an appropriate transition in the use of the terms ''Medicare+Choice'' and ''Medicare Advantage'' (or ''MA'') in reference to the program under part C of title XVIII of the Social Security Act. Such transition shall be fully completed for all materials for plan years beginning not later than January 1, 2006. Before the completion of such transition, any reference to ''Medicare Advantage'' or ''MA'' shall be deemed to include a reference to ''Medicare+Choice''.

Subtitle B—Immediate Improvements

SEC. 211. IMMEDIATE IMPROVEMENTS.

(a) EQUALIZING PAYMENTS WITH FEE-FOR-SERVICE.—

(1) IN GENERAL.—Section 1853(c)(1) (42 U.S.C. 1395w–23(c)(1)) is amended by adding at the end the following:

''(D) 100 PERCENT OF FEE-FOR-SERVICE COSTS.—

''(i) IN GENERAL.—For each year specified in clause (ii), the adjusted average per capita cost for the year involved, determined under section 1876(a)(4) and adjusted as appropriate for the purpose of risk adjustment, for the MA payment area for individuals who are not enrolled in an MA plan under this part for the year, but adjusted to exclude costs attributable to payments under section 1886(h).

''(ii) PERIODIC REBASING.—The provisions of clause (i) shall apply for 2004 and for subsequent years as the Secretary shall specify (but not less than once every 3 years).

''(iii) INCLUSION OF COSTS OF VA AND DOD MILITARY FACILITY SERVICES TO MEDICARE-ELIGIBLE BENEFICIARIES.—In determining the adjusted average per capita cost under clause (i) for a year, such cost shall be adjusted to include the Secretary's estimate, on a per capita basis, of the amount of additional payments that would have been made in the area involved under this title if individuals entitled to benefits under this title had not received services from facilities of the Department of Defense or the Department of Veterans Affairs.''.

(2) CONFORMING AMENDMENT.—Such section is further amended, in the matter before subparagraph (A), by striking ''or (C)'' and inserting ''(C), or (D)''.

(b) CHANGE IN BUDGET NEUTRALITY FOR BLEND.—Section 1853(c) (42 U.S.C. 1395w–23(c)) is amended—

(1) in paragraph (1)(A), by inserting ''(for a year other than 2004)'' after ''multiplied''; and

(2) in paragraph (5), by inserting ''(other than 2004)'' after ''for each year''.

(c) INCREASING MINIMUM PERCENTAGE INCREASE TO NATIONAL GROWTH RATE.—

(1) IN GENERAL.—Section 1853(c)(1) (42 U.S.C. 1395w–23(c)(1)) is amended—

(A) in subparagraph (A), by striking ''The sum'' and inserting ''For a year before 2005, the sum'';

(B) in subparagraph (B)(iv), by striking ''and each succeeding year'' and inserting '', 2003, and 2004'';

(C) in subparagraph (C)(iv), by striking ''and each succeeding year'' and inserting ''and 2003''; and

(D) by adding at the end of subparagraph (C) the following new clause:

''(v) For 2004 and each succeeding year, the greater of—

''(I) 102 percent of the annual MA capitation rate under this paragraph for the area for the previous year; or

''(II) the annual MA capitation rate under this paragraph for the area for the previous year increased by the national per capita MA growth percentage, described in paragraph (6) for that succeeding year, but not taking into account any adjustment under paragraph (6)(C) for a year before 2004.''.

(2) CONFORMING AMENDMENT.—Section 1853(c)(6)(C) (42 U.S.C. 1395w–23(c)(6)(C)) is amended by inserting before the period at the end the following: '', except that for purposes of paragraph (1)(C)(v)(II), no such adjustment shall be made for a year before 2004''.

(d) INCLUSION OF COSTS OF DOD AND VA MILITARY FACILITY SERVICES TO MEDICARE-ELIGIBLE BENEFICIARIES IN CALCULATION OF PAYMENT RATES.—Section 1853(c)(3) (42 U.S.C. 1395w–23(c)(3)) is amended—

(1) in subparagraph (A), by striking ''subparagraph (B)'' and inserting ''subparagraphs (B) and (E)''; and

(2) by adding at the end the following new subparagraph:

''(E) INCLUSION OF COSTS OF DOD AND VA MILITARY FACILITY SERVICES TO MEDICARE-ELIGIBLE BENEFICIARIES.—In determining the area-specific MA capitation rate under subparagraph (A) for a year (beginning with 2004), the annual per capita rate of payment for 1997 determined under section 1876(a)(1)(C) shall be adjusted to include in the rate the Secretary's estimate, on a per capita basis, of the amount of additional payments that would have been made in the area involved under this title if individuals entitled to benefits under this title had not received services from facilities of the Department of Defense or the Department of Veterans Affairs.''.

(e) EXTENDING SPECIAL RULE FOR CERTAIN INPATIENT HOSPITAL STAYS TO REHABILITATION HOSPITALS AND LONG-TERM CARE HOSPITALS.—

(1) IN GENERAL.—Section 1853(g) (42 U.S.C. 1395w–23(g)) is amended—

(A) in the matter preceding paragraph (1), by inserting '', a rehabilitation hospital described in section 1886(d)(1)(B)(ii) or a distinct part rehabilitation unit described in the matter following clause (v) of section 1886(d)(1)(B), or a long-term care hospital (described in section 1886(d)(1)(B)(iv))'' after ''1886(d)(1)(B))''; and

(B) in paragraph (2)(B), by inserting ''or other payment provision under this title for inpatient services for the type of facility, hospital, or unit involved, described in the matter preceding paragraph (1), as the case may be,'' after ''1886(d)''.

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to contract years beginning on or after January 1, 2004.

(f) MEDPAC STUDY OF AAPCC.—

(1) STUDY.—The Medicare Payment Advisory Commission shall conduct a study that assesses the method used for determining the adjusted average per capita cost (AAPCC) under section 1876(a)(4) of the Social Security Act (42 U.S.C. 1395mm(a)(4)) as applied under section 1853(c)(1)(A) of such Act (as amended by subsection (a)). Such study shall include an examination of—

(A) the bases for variation in such costs between different areas, including differences in input prices, utilization, and practice patterns;

(B) the appropriate geographic area for payment of MA local plans under the Medicare Advantage program under part C of title XVIII of such Act; and

(C) the accuracy of risk adjustment methods in reflecting differences in costs of providing care to different groups of beneficiaries served under such program.

(2) REPORT.—Not later than 18 months after the date of the enactment of this Act, the Commission shall submit to Congress a report on the study conducted under paragraph (1).

(g) REPORT ON IMPACT OF INCREASED FINANCIAL ASSISTANCE TO MEDICARE ADVANTAGE PLANS.—Not later than July 1, 2006, the Secretary shall submit to Congress a report that describes the impact of additional financing provided under this Act and other Acts (including the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 and BIPA) on the availability of Medicare Advantage plans in different areas and its impact on lowering premiums and increasing benefits under such plans.

(h) MEDPAC STUDY AND REPORT ON CLARIFICATION OF AUTHORITY REGARDING DISAPPROVAL OF UNREASONABLE BENEFICIARY COST-SHARING.—

(1) STUDY.—The Medicare Payment Advisory Commission, in consultation with beneficiaries, consumer groups, employers, and organizations offering plans under part C of title XVIII of the Social Security Act, shall conduct a study to determine the extent to which the cost-sharing structures under such plans affect access to covered services or select enrollees based on the health status of eligible individuals described in section 1851(a)(3) of the Social Security Act (42 U.S.C. 1395w–21(a)(3)).

(2) REPORT.—Not later than December 31, 2004, the Commission shall submit a report to Congress on the study conducted under paragraph (1) together with recommendations for such legislation and administrative actions as the Commission considers appropriate.

(i) IMPLEMENTATION OF PROVISIONS.—

(1) ANNOUNCEMENT OF REVISED MEDICARE ADVANTAGE PAYMENT RATES.—Within 6 weeks after the date of the enactment of this Act, the Secretary shall determine, and shall announce (in a manner intended to provide notice to interested parties) MA capitation rates under section 1853 of the Social Security Act (42 U.S.C. 1395w–23) for 2004, revised in accordance with the provisions of this section.

(2) TRANSITION TO REVISED PAYMENT RATES.—The provisions of section 604 of BIPA (114 Stat. 2763A–555) (other than subsection (a)) shall apply to the provisions of subsections (a) through (d) of this section for 2004 in the same manner as the provisions of such section 604 applied to the provisions of BIPA for 2001.

(3) SPECIAL RULE FOR PAYMENT RATES IN 2004.—

(A) JANUARY AND FEBRUARY.—Notwithstanding the amendments made by subsections (a) through (d), for purposes of making payments under section 1853 of the Social Security Act (42 U.S.C. 1395w–23) for January and February 2004, the annual capitation rate for a payment area shall be calculated and the excess amount under section 1854(f)(1)(B) of such Act (42 U.S.C. 1395w–24(f)(1)(B)) shall be determined as if such amendments had not been enacted.

(B) MARCH THROUGH DECEMBER.—Notwithstanding the amendments made by subsections (a) through (d), for purposes of making payments under section 1853 of the Social Security Act (42 U.S.C. 1395w–23) for March through December 2004, the annual capitation rate for a payment area shall be calculated and the excess amount under section 1854(f)(1)(B) of such Act (42 U.S.C. 1395w–24(f)(1)(B)) shall be determined, in such manner as the Secretary estimates will ensure that the total of such payments with respect to 2004 is the same as the amounts that would have been if subparagraph (A) had not been enacted.

(C) CONSTRUCTION.—Subparagraphs (A) and (B) shall not be taken into account in computing such capitation rate for 2005 and subsequent years.

(4) PLANS REQUIRED TO PROVIDE NOTICE OF CHANGES IN PLAN BENEFITS.—In the case of an organization offering a plan under part C of title XVIII of the Social Security Act that revises its submission of the information described in section 1854(a)(1) of such Act (42 U.S.C. 1395w–23(a)(1)) for a plan pursuant to the application of paragraph (2), if such revision results in changes in beneficiary premiums, beneficiary cost-sharing, or benefits under the plan, then by not later than 3 weeks after the date the Secretary approves such submission, the organization offering the plan shall provide each beneficiary enrolled in the plan with written notice of such changes.

(5) LIMITATION ON REVIEW.—There shall be no administrative or judicial review under section 1869 or section 1878 of the Social Security Act (42 U.S.C. 1395ff and 1395oo), or otherwise of any determination made by the Secretary under this subsection or the application of the payment rates determined pursuant to this subsection.

(j) ADDITIONAL AMENDMENTS.—Section 1852(d)(4) (42 U.S.C. 1395w–22(d)(4)) is amended—

(1) in subparagraph (B), by inserting ''(other than deemed contracts or agreements under subsection (j)(6))'' after ''the plan has contracts or agreements''; and

(2) in the last sentence, by inserting before the period at the end the following: '', except that, if a plan entirely meets such requirement with respect to a category of health care professional or provider on the basis of subparagraph (B), it may provide for a higher beneficiary copayment in the case of health care professionals and providers of that category who do not have contracts or agreements (other than deemed contracts or agreements under subsection (j)(6)) to provide covered services under the terms of the plan''.

Subtitle C—Offering of Medicare Advantage (MA) Regional Plans; Medicare Advantage Competition

SEC. 221. ESTABLISHMENT OF MA REGIONAL PLANS.

(a) OFFERING OF MA REGIONAL PLANS.—

(1) IN GENERAL.—Section 1851(a)(2)(A) is amended—

(A) by striking ''COORDINATED CARE PLANS.—Coordinated'' and inserting the following: ''COORDINATED CARE PLANS (INCLUDING REGIONAL PLANS).—

''(i) IN GENERAL.—Coordinated'';

(B) by inserting ''regional or local'' before ''preferred provider organization plans''; and

(C) by inserting ''(including MA regional plans)'' after ''preferred provider organization plans''.

(2) MORATORIUM ON NEW LOCAL PREFERRED PROVIDER ORGANIZATION PLANS.—The Secretary shall not permit the offering of a local preferred provider organization plan under part C of title XVIII of the Social Security Act during 2006 or 2007 in a service area unless such plan was offered under such part (including under a demonstration project under such part) in such area as of December 31, 2005.

(b) DEFINITION OF MA REGIONAL PLAN; MA LOCAL PLAN.—

(1) IN GENERAL.—Section 1859(b) (42 U.S.C. 1395w–29(b)) is amended by adding at the end the following new paragraphs:

''(4) MA REGIONAL PLAN.—The term 'MA regional plan' means an MA plan described in section 1851(a)(2)(A)(i)—

''(A) that has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan;

''(B) that provides for reimbursement for all covered benefits regardless of whether such benefits are provided within such network of providers; and

''(C) the service area of which is one or more entire MA regions.

''(5) MA LOCAL PLAN.—The term 'MA local plan' means an MA plan that is not an MA regional plan.''.

(2) CONSTRUCTION.—Nothing in part C of title XVIII of the Social Security Act shall be construed as preventing an MSA plan or MA private fee-for-service plan from having a service area that covers one or more MA regions or the entire nation.

(c) RULES FOR MA REGIONAL PLANS.—Part C of title XVIII (42 U.S.C. 1395w–21 et seq.) is amended by inserting after section 1857 the following new section:

''SPECIAL RULES FOR MA REGIONAL PLANS

''SEC. 1858. (a) REGIONAL SERVICE AREA; ESTABLISHMENT OF MA REGIONS.—

''(1) COVERAGE OF ENTIRE MA REGION.—The service area for an MA regional plan shall consist of an entire MA region established under paragraph (2) and the provisions of section 1854(h) shall not apply to such a plan.

''(2) ESTABLISHMENT OF MA REGIONS.—

''(A) MA REGION.—For purposes of this title, the term 'MA region' means such a region within the 50 States and the District of Columbia as established by the Secretary under this paragraph.

''(B) ESTABLISHMENT.—

''(i) INITIAL ESTABLISHMENT.—Not later than January 1, 2005, the Secretary shall first establish and publish MA regions.

''(ii) PERIODIC REVIEW AND REVISION OF SERVICE AREAS.—The Secretary may periodically review MA regions under this paragraph and, based on such review, may revise such regions if the Secretary determines such revision to be appropriate.

''(C) REQUIREMENTS FOR MA REGIONS.—The Secretary shall establish, and may revise, MA regions under this paragraph in a manner consistent with the following:

''(i) NUMBER OF REGIONS.—There shall be no fewer than 10 regions, and no more than 50 regions.

''(ii) MAXIMIZING AVAILABILITY OF PLANS.—The regions shall maximize the availability of MA regional plans to all MA eligible individuals without regard to health status, especially those residing in rural areas.

''(D) MARKET SURVEY AND ANALYSIS.—Before establishing MA regions, the Secretary shall conduct a market survey and analysis, including an examination of current insurance markets, to determine how the regions should be established.

''(3) NATIONAL PLAN.—Nothing in this subsection shall be construed as preventing an MA regional plan from being offered in more than one MA region (including all regions).

''(b) APPLICATION OF SINGLE DEDUCTIBLE AND CATASTROPHIC LIMIT ON OUT-OF-POCKET EXPENSES.—An MA regional plan shall include the following:

''(1) SINGLE DEDUCTIBLE.—Any deductible for benefits under the original medicare fee-for-service program option shall be a single deductible (instead of a separate inpatient hospital deductible and a part B deductible) and may be applied differentially for in-network services and may be waived for preventive or other items and services.

''(2) CATASTROPHIC LIMIT.—

''(A) IN-NETWORK.—A catastrophic limit on out-of-pocket expenditures for in-network benefits under the original medicare fee-for-service program option.

''(B) TOTAL.—A catastrophic limit on out-of-pocket expenditures for all benefits under the original medicare fee-for-service program option.

''(c) PORTION OF TOTAL PAYMENTS TO AN ORGANIZATION SUBJECT TO RISK FOR 2006 AND 2007.—

''(1) APPLICATION OF RISK CORRIDORS.—

''(A) IN GENERAL.—This subsection shall only apply to MA regional plans offered during 2006 or 2007.

''(B) NOTIFICATION OF ALLOWABLE COSTS UNDER THE PLAN.—In the case of an MA organization that offers an MA regional plan in an MA region in 2006 or 2007, the organization shall notify the Secretary, before such date in the succeeding year as the Secretary specifies, of—

''(i) its total amount of costs that the organization incurred in providing benefits covered under the original medicare fee-for-service program option for all enrollees under the plan in the region in the year and the portion of such costs that is attributable to administrative expenses described in subparagraph (C); and

''(ii) its total amount of costs that the organization incurred in providing rebatable integrated benefits (as defined in subparagraph (D)) and with respect to such benefits the portion of such costs that is attributable to administrative expenses described in subparagraph (C) and not described in clause (i) of this subparagraph.

''(C) ALLOWABLE COSTS DEFINED.—For purposes of this subsection, the term 'allowable costs' means, with respect to an MA regional plan for a year, the total amount of costs described in subparagraph (B) for the plan and year, reduced by the portion of such costs attributable to administrative expenses incurred in providing the benefits described in such subparagraph.

''(D) REBATABLE INTEGRATED BENEFITS.—For purposes of this subsection, the term 'rebatable integrated benefits' means such non-drug supplemental benefits under subclause (I) of section 1854(b)(1)(C)(ii) pursuant to a rebate under such section that the Secretary determines are integrated with the benefits described in subparagraph (B)(i).

''(2) ADJUSTMENT OF PAYMENT.—

''(A) NO ADJUSTMENT IF ALLOWABLE COSTS WITHIN 3 PERCENT OF TARGET AMOUNT.—If the allowable costs for the plan for the year are at least 97 percent, but do not exceed 103 percent, of the target amount for the plan and year, there shall be no payment adjustment under this subsection for the plan and year.

''(B) INCREASE IN PAYMENT IF ALLOWABLE COSTS ABOVE 103 PERCENT OF TARGET AMOUNT.—

''(i) COSTS BETWEEN 103 AND 108 PERCENT OF TARGET AMOUNT.—If the allowable costs for the plan for the year are greater than 103 percent, but not greater than 108 percent, of the target amount for the plan and year, the Secretary shall increase the total of the monthly payments made to the organization offering the plan for the year under section 1853(a) by an amount equal to 50 percent of the difference between such allowable costs and 103 percent of such target amount.

''(ii) COSTS ABOVE 108 PERCENT OF TARGET AMOUNT.—If the allowable costs for the plan for the year are greater than 108 percent of the target amount for the plan and year, the Secretary shall increase the total of the monthly payments made to the organization offering the plan for the year under section 1853(a) by an amount equal to the sum of—

''(I) 2.5 percent of such target amount; and

''(II) 80 percent of the difference between such allowable costs and 108 percent of such target amount.

''(C) REDUCTION IN PAYMENT IF ALLOWABLE COSTS BELOW 97 PERCENT OF TARGET AMOUNT.—

''(i) COSTS BETWEEN 92 AND 97 PERCENT OF TARGET AMOUNT.—If the allowable costs for the plan for the year are less than 97 percent, but greater than or equal to 92 percent, of the target amount for the plan and year, the Secretary shall reduce the total of the monthly payments made to the organization offering the plan for the year under section 1853(a) by an amount (or otherwise recover from the plan an amount) equal to 50 percent of the difference between 97 percent of the target amount and such allowable costs.

''(ii) COSTS BELOW 92 PERCENT OF TARGET AMOUNT.—If the allowable costs for the plan for the year are less than 92 percent of the target amount for the plan and year, the Secretary shall reduce the total of the monthly payments made to the organization offering the plan for the year under section 1853(a) by an amount (or otherwise recover from the plan an amount) equal to the sum of—

''(I) 2.5 percent of such target amount; and

''(II) 80 percent of the difference between 92 percent of such target amount and such allowable costs.

''(D) TARGET AMOUNT DESCRIBED.—For purposes of this paragraph, the term 'target amount' means, with respect to an MA regional plan offered by an organization in a year, an amount equal to—

''(i) the sum of—

''(I) the total monthly payments made to the organization for enrollees in the plan for the year that are attributable to benefits under the original medicare fee-for-service program option (as defined in section 1852(a)(1)(B));

''(II) the total of the MA monthly basic beneficiary premium collectable for such enrollees for the year; and

''(III) the total amount of the rebates under section 1854(b)(1)(C)(ii) that are attributable to rebatable integrated benefits; reduced by

''(ii) the amount of administrative expenses assumed in the bid insofar as the bid is attributable to benefits described in clause (i)(I) or (i)(III).

''(3) DISCLOSURE OF INFORMATION.—

''(A) IN GENERAL.—Each contract under this part shall provide—

''(i) that an MA organization offering an MA regional plan shall provide the Secretary with such information as the Secretary determines is necessary to carry out this subsection; and

''(ii) that, pursuant to section 1857(d)(2)(B), the Secretary has the right to inspect and audit any books and records of the organization that pertain to the information regarding costs provided to the Secretary under paragraph (1)(B).

''(B) RESTRICTION ON USE OF INFORMATION.—Information disclosed or obtained pursuant to the provisions of this subsection may be used by officers, employees, and contractors of the Department of Health and Human Services only for the purposes of, and to the extent necessary in, carrying out this subsection.

''(d) ORGANIZATIONAL AND FINANCIAL REQUIREMENTS.—

''(1) IN GENERAL.—In the case of an MA organization that is offering an MA regional plan in an MA region and—

''(A) meets the requirements of section 1855(a)(1) with respect to at least one such State in such region; and

''(B) with respect to each other State in such region in which it does not meet requirements, it demonstrates to the satisfaction of the Secretary that it has filed the necessary application to meet such requirements,

the Secretary may waive such requirement with respect to each State described in subparagraph (B) for such period of time as the Secretary determines appropriate for the timely processing of such an application by the State (and, if such application is denied, through the end of such plan year as the Secretary determines appropriate to provide for a transition).

''(2) SELECTION OF APPROPRIATE STATE.—In applying paragraph (1) in the case of an MA organization that meets the requirements of section 1855(a)(1) with respect to more than one State in a region, the organization shall select, in a manner specified by the Secretary among such States, one State the rules of which shall apply in the case of the States described in paragraph (1)(B).

''(e) STABILIZATION FUND.—

''(1) ESTABLISHMENT.—The Secretary shall establish under this subsection an MA Regional Plan Stabilization Fund (in this subsection referred to as the 'Fund') which shall be available for 2 purposes:

''(A) PLAN ENTRY.—To provide incentives to have MA regional plans offered in each MA region under paragraph (3).

''(B) PLAN RETENTION.—To provide incentives to retain MA regional plans in certain MA regions with below-national-average MA market penetration under paragraph (4).

''(2) FUNDING.—

''(A) INITIAL FUNDING.—

''(i) IN GENERAL.—There shall be available to the Fund, for expenditures from the Fund during the period beginning on January 1, 2007, and ending on December 31, 2013, a total of $10,000,000,000.

''(ii) PAYMENT FROM TRUST FUNDS.—Such amount shall be available to the Fund, as expenditures are made from the Fund, from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund in the proportion specified in section 1853(f).

''(B) ADDITIONAL FUNDING FROM SAVINGS.—

''(i) IN GENERAL.—There shall also be made available to the Fund, 50 percent of savings described in clause (ii).

''(ii) SAVINGS.—The savings described in this clause are 25 percent of the average per capita savings described in section 1854(b)(4)(C) for which monthly rebates are provided under section 1854(b)(1)(C) in the fiscal year involved that are attributable to MA regional plans.

''(iii) AVAILABILITY.—Funds made available under this subparagraph shall be transferred into a special account in the Treasury from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund in the proportion specified in section 1853(f) on a monthly basis.

''(C) OBLIGATIONS.—Amounts in the Fund shall be available in advance of appropriations to MA regional plans in qualifying MA regions only in accordance with paragraph (5).

''(D) ORDERING.—Expenditures from the Fund shall first be made from amounts made available under subparagraph (A).

''(3) PLAN ENTRY FUNDING.—

''(A) IN GENERAL.—Funding is available under this paragraph for a year only as follows:

''(i) NATIONAL PLAN.—For a national bonus payment described in subparagraph (B) for the offering by a single MA organization of an MA regional plan in each MA region in the year, but only if there was not such a plan offered in each such region in the previous year. Funding under this clause is only available with respect to any individual MA organization for a single year, but may be made available to more than one such organization in the same year.

''(ii) REGIONAL PLANS.—Subject to clause (iii), for an increased amount under subparagraph (C) for an MA regional plan offered in an MA region which did not have any MA regional plan offered in the prior year.

''(iii) LIMITATION ON REGIONAL PLAN FUNDING IN CASE OF NATIONAL PLAN.—In no case shall there be any payment adjustment under subparagraph (C) for a year for which a national payment adjustment is made under subparagraph (B).

''(B) NATIONAL BONUS PAYMENT.—The national bonus payment under this subparagraph shall—

''(i) be available to an MA organization only if the organization offers MA regional plans in every MA region;

''(ii) be available with respect to all MA regional plans of the organization regardless of whether any other MA regional plan is offered in any region; and

''(iii) subject to amounts available under paragraph (5) for a year, be equal to 3 percent of the benchmark amount otherwise applicable for each MA regional plan offered by the organization.

''(C) REGIONAL PAYMENT ADJUSTMENT.—

''(i) IN GENERAL.—The increased amount under this subparagraph for an MA regional

plan in an MA region for a year shall be an amount, determined by the Secretary, based on the bid submitted for such plan (or plans) and shall be available to all MA regional plans offered in such region and year. Such amount may be based on the mean, mode, or median, or other measure of such bids and may vary from region to region. The Secretary may not limit the number of plans or bids in a region.

''(ii) MULTI-YEAR FUNDING.—

''(I) IN GENERAL.—Subject to amounts available under paragraph (5), funding under this subparagraph shall be available for a period determined by the Secretary.

''(II) REPORT.—If the Secretary determines that funding will be provided for a second consecutive year with respect to an MA region, the Secretary shall submit to the Congress a report that describes the underlying market dynamics in the region and that includes recommendations concerning changes in the payment methodology otherwise provided for MA regional plans under this part.

''(iii) APPLICATION TO ALL PLANS IN A REGION.—Funding under this subparagraph with respect to an MA region shall be made available with respect to all MA regional plans offered in the region.

''(iv) LIMITATION ON AVAILABILITY OF PLAN RETENTION FUNDING IN NEXT YEAR.—If an increased amount is made available under this subparagraph with respect to an MA region for a period determined by the Secretary under clause (ii)(I), in no case shall funding be available under paragraph (4) with respect to MA regional plans offered in the region in the year following such period.

''(D) APPLICATION.—Any additional payment under this paragraph provided for an MA regional plan for a year shall be treated as if it were an addition to the benchmark amount otherwise applicable to such plan and year, but shall not be taken into account in the computation of any benchmark amount for any subsequent year.

''(4) PLAN RETENTION FUNDING.—

''(A) IN GENERAL.—Funding is available under this paragraph for a year with respect to MA regional plans offered in an MA region for the increased amount specified in subparagraph (B) but only if the region meets the requirements of subparagraphs (C) and (E).

''(B) PAYMENT INCREASE.—The increased amount under this subparagraph for an MA regional plan in an MA region for a year shall be an amount, determined by the Secretary, that does not exceed the greater of—

''(i) 3 percent of the benchmark amount applicable in the region; or

''(ii) such amount as (when added to the benchmark amount applicable to the region) will result in the ratio of—

''(I) such additional amount plus the benchmark amount computed under section 1854(b)(4)(B)(i) for the region and year, to the adjusted average per capita cost for the region and year, as estimated by the Secretary under section 1876(a)(4) and adjusted as appropriate for the purpose of risk adjustment; being equal to

''(II) the weighted average of such benchmark amounts for all the regions and such year, to the average per capita cost for the United States and such year, as estimated by the Secretary under section 1876(a)(4) and adjusted as appropriate for the purpose of risk adjustment.

''(C) REGIONAL REQUIREMENTS.—The requirements of this subparagraph for an MA region for a year are as follows:

''(i) NOTIFICATION OF PLAN EXIT.—The Secretary has received notice (in such form and manner as the Secretary specifies) before a year that one or more MA regional plans that were offered in the region in the previous year will not be offered in the succeeding year.

''(ii) REGIONAL PLANS AVAILABLE FROM FEWER THAN 2 MA ORGANIZATIONS IN THE REGION.—The Secretary determines that if the plans referred to in clause (i) are not offered in the year, fewer than 2 MA organizations will be offering MA regional plans in the region in the year involved.

''(iii) PERCENTAGE ENROLLMENT IN MA REGIONAL PLANS BELOW NATIONAL AVERAGE.—For the previous year, the Secretary determines that the average percentage of MA eligible individuals residing in the region who are enrolled in MA regional plans is less than the average percentage of such individuals in the United States enrolled in such plans.

''(D) APPLICATION.—Any additional payment under this paragraph provided for an MA regional plan for a year shall be treated as if it were an addition to the benchmark amount otherwise applicable to such plan and year, but shall not be taken into account in the computation of any benchmark amount for any subsequent year.

''(E) 2-CONSECUTIVE-YEAR LIMITATION.—

''(i) IN GENERAL.—In no case shall any funding be available under this paragraph in an MA region in a period of consecutive years that exceeds 2 years.

''(ii) REPORT.—If the Secretary determines that funding will be provided under this paragraph for a second consecutive year with respect to an MA region, the Secretary shall submit to the Congress a report that describes the underlying market dynamics in the region and that includes recommendations concerning changes in the payment methodology otherwise provided for MA regional plans under this part.

''(5) FUNDING LIMITATION.—

''(A) IN GENERAL.—The total amount expended from the Fund as a result of the application of this subsection through the end of a calendar year may not exceed the amount available to the Fund as of the first day of such year. For purposes of this subsection, amounts that are expended under this title insofar as such amounts would not have been expended but for the application of this subsection shall be counted as amounts expended as a result of such application.

''(B) APPLICATION OF LIMITATION.—The Secretary may obligate funds from the Fund for a year only if the Secretary determines (and the Chief Actuary of the Centers for Medicare & Medicaid Services and the appropriate budget officer certify) that there are available in the Fund at the beginning of the year sufficient amounts to cover all such obligations incurred during the year consistent with subparagraph (A). The Secretary shall take such steps, in connection with computing additional payment amounts under paragraphs (3) and (4) and including limitations on enrollment in MA regional plans receiving such payments, as will ensure that sufficient funds are available to make such payments for the entire year. Funds shall only be made available from the Fund pursuant to an apportionment made in accordance with applicable procedures.

''(6) SECRETARY REPORTS.—Not later than April 1 of each year (beginning in 2008), the Secretary shall submit a report to Congress and the Comptroller General of the United States that includes—

''(A) a detailed description of—

''(i) the total amount expended as a result of the application of this subsection in the previous year compared to the total amount that would have been expended under this title in the year if this subsection had not been enacted;

''(ii) the projections of the total amount that will be expended as a result of the application of this subsection in the year in which the report is submitted compared to the total amount that would have been expended under this title in the year if this subsection had not been enacted;

''(iii) amounts remaining within the funding limitation specified in paragraph (5); and

''(iv) the steps that the Secretary will take under paragraph (5)(B) to ensure that the application of this subsection will not cause expenditures to exceed the amount available in the Fund; and

''(B) a certification from the Chief Actuary of the Centers for Medicare & Medicaid Services that the description provided under subparagraph (A) is reasonable, accurate, and based on generally accepted actuarial principles and methodologies.

''(7) BIENNIAL GAO REPORTS.—Not later than January 1 of 2009, 2011, 2013, and 2015, the Comptroller General of the United States shall submit to the Secretary and Congress a report on the application of additional payments under this subsection. Each report shall include—

''(A) an evaluation of—

''(i) the quality of care provided to individuals enrolled in MA regional plans for which additional payments were made under this subsection;

''(ii) the satisfaction of such individuals with benefits under such a plan;

''(iii) the costs to the medicare program for payments made to such plans; and

''(iv) any improvements in the delivery of health care services under such a plan;

''(B) a comparative analysis of the performance of MA regional plans receiving payments under this subsection with MA regional plans not receiving such payments; and

''(C) recommendations for such legislation or administrative action as the Comptroller General determines to be appropriate.

''(f) COMPUTATION OF APPLICABLE MA REGION-SPECIFIC NON-DRUG MONTHLY BENCHMARK AMOUNTS.—

''(1) COMPUTATION FOR REGIONS.—For purposes of section 1853(j)(2) and this section, subject to subsection (e), the term 'MA region-specific non-drug monthly benchmark amount' means, with respect to an MA region for a month in a year, the sum of the 2 components described in paragraph (2) for the region and year. The Secretary shall compute such benchmark amount for each MA region before the beginning of each annual, coordinated election period under section 1851(e)(3)(B) for each year (beginning with 2006).

''(2) 2 COMPONENTS.—For purposes of paragraph (1), the 2 components described in this paragraph for an MA region and a year are the following:

''(A) STATUTORY COMPONENT.—The product of the following:

''(i) STATUTORY REGION-SPECIFIC NON-DRUG AMOUNT.—The statutory region-specific non-drug amount (as defined in paragraph (3)) for the region and year.

''(ii) STATUTORY NATIONAL MARKET SHARE.—The statutory national market share percentage, determined under paragraph (4) for the year.

''(B) PLAN-BID COMPONENT.—The product of the following:

''(i) WEIGHTED AVERAGE OF MA PLAN BIDS IN REGION.—The weighted average of the plan bids for the region and year (as determined under paragraph (5)(A)).

''(ii) NON-STATUTORY MARKET SHARE.—1 minus the statutory national market share percentage, determined under paragraph (4) for the year.

''(3) STATUTORY REGION-SPECIFIC NON-DRUG AMOUNT.—For purposes of paragraph (2)(A)(i), the term 'statutory region-specific non-drug amount' means, for an MA region and year, an amount equal the sum (for each MA local area within the region) of the product of—

''(A) MA area-specific non-drug monthly benchmark amount under section 1853(j)(1)(A) for that area and year; and

''(B) the number of MA eligible individuals residing in the local area, divided by the total number of MA eligible individuals residing in the region.

''(4) COMPUTATION OF STATUTORY MARKET SHARE PERCENTAGE.—

''(A) IN GENERAL.—The Secretary shall determine for each year a statutory national market share percentage that is equal to the proportion of MA eligible individuals nationally who were not enrolled in an MA plan during the reference month.

''(B) REFERENCE MONTH DEFINED.—For purposes of this part, the term 'reference month' means, with respect to a year, the most recent month during the previous year for which the Secretary determines that data are available to compute the percentage specified in subparagraph (A) and other relevant percentages under this part.

''(5) DETERMINATION OF WEIGHTED AVERAGE MA BIDS FOR A REGION.—

''(A) IN GENERAL.—For purposes of paragraph (2)(B)(i), the weighted average of plan bids for an MA region and a year is the sum, for MA regional plans described in subparagraph (D) in the region and year, of the products (for each such plan) of the following:

''(i) MONTHLY MA STATUTORY NON-DRUG BID AMOUNT.—The unadjusted MA statutory non-drug monthly bid amount for the plan.

''(ii) PLAN'S SHARE OF MA ENROLLMENT IN REGION.—The factor described in subparagraph (B) for the plan.

''(B) PLAN'S SHARE OF MA ENROLLMENT IN REGION.—

''(i) IN GENERAL.—Subject to the succeeding provisions of this subparagraph, the factor described in this subparagraph for a plan is equal to the number of individuals described in subparagraph (C) for such plan, divided by the total number of such individuals for all MA regional plans described in subparagraph (D) for that region and year.

''(ii) SINGLE PLAN RULE.—In the case of an MA region in which only a single MA regional plan is being offered, the factor described in this subparagraph shall be equal to 1.

''(iii) EQUAL DIVISION AMONG MULTIPLE PLANS IN YEAR IN WHICH PLANS ARE FIRST AVAILABLE.—In the case of an MA region in the first year in which any MA regional plan is offered, if more than one MA regional plan is offered in such year, the factor described in this subparagraph for a plan shall (as specified by the Secretary) be equal to—

''(I) 1 divided by the number of such plans offered in such year; or

''(II) a factor for such plan that is based upon the organization's estimate of projected enrollment, as reviewed and adjusted by the Secretary to ensure reasonableness and as is certified by the Chief Actuary of the Centers for Medicare & Medicaid Services.

''(C) COUNTING OF INDIVIDUALS.—For purposes of subparagraph (B)(i), the Secretary shall count for each MA regional plan described in subparagraph (D) for an MA region and year, the number of individuals who reside in the region and who were enrolled under such plan under this part during the reference month.

''(D) PLANS COVERED.—For an MA region and year, an MA regional plan described in this subparagraph is an MA regional plan that is offered in the region and year and was offered in the region in the reference month.

''(g) ELECTION OF UNIFORM COVERAGE DETERMINATION.—Instead of applying section 1852(a)(2)(C) with respect to an MA regional plan, the organization offering the plan may elect to have a local coverage determination for the entire MA region be the local coverage determination applied for any part of such region (as selected by the organization).

''(h) ASSURING NETWORK ADEQUACY.—

''(1) IN GENERAL.—For purposes of enabling MA organizations that offer MA regional plans to meet applicable provider access requirements under section 1852 with respect to such plans, the Secretary may provide for payment under this section to an essential hospital that provides inpatient hospital services to enrollees in such a plan where the MA organization offering the plan certifies to the Secretary that the organization was unable to reach an agreement between the hospital and the organization regarding provision of such services under the plan. Such payment shall be available only if—

''(A) the organization provides assurances satisfactory to the Secretary that the organization will make payment to the hospital for inpatient hospital services of an amount that is not less than the amount that would be payable to the hospital under section 1886 with respect to such services; and

''(B) with respect to specific inpatient hospital services provided to an enrollee, the hospital demonstrates to the satisfaction of the Secretary that the hospital's costs of such services exceed the payment amount described in subparagraph (A).

''(2) PAYMENT AMOUNTS.—The payment amount under this subsection for inpatient hospital services provided by a subsection (d) hospital to an enrollee in an MA regional plan shall be, subject to the limitation of funds under paragraph (3), the amount (if any) by which—

''(A) the amount of payment that would have been paid for such services under this title if the enrollees were covered under the original medicare fee-for-service program option and the hospital were a critical access hospital; exceeds

''(B) the amount of payment made for such services under paragraph (1)(A).

''(3) AVAILABLE AMOUNTS.—There shall be available for payments under this subsection—

''(A) in 2006, $25,000,000; and

''(B) in each succeeding year the amount specified in this paragraph for the preceding year increased by the market basket percentage increase (as defined in section 1886(b)(3)(B)(iii)) for the fiscal year ending in such succeeding year.

Payments under this subsection shall be made from the Federal Hospital Insurance Trust Fund.

''(4) ESSENTIAL HOSPITAL.—In this subsection, the term 'essential hospital' means, with respect to an MA regional plan offered by an MA organization, a subsection (d) hospital (as defined in section 1886(d)) that the Secretary determines, based upon an application filed by the organization with the Secretary, is necessary to meet the requirements referred to in paragraph (1) for such plan.''.

(d) CONFORMING AMENDMENTS.—

(1) RELATING TO MA REGIONS.—Section 1853(d) (42 U.S.C. 1395w–23(d)) is amended—

(A) by amending the heading to read as follows: ''MA PAYMENT AREA; MA LOCAL AREA; MA REGION DEFINED'';

(B) by redesignating paragraphs (2) and (3) as paragraphs (3) and (4), respectively;

(C) by amending paragraph (1) to read as follows:

''(1) MA PAYMENT AREA.—In this part, except as provided in this subsection, the term 'MA payment area' means—

''(A) with respect to an MA local plan, an MA local area (as defined in paragraph (2)); and

''(B) with respect to an MA regional plan, an MA region (as established under section 1858(a)(2)).'';

(D) by inserting after paragraph (1) the following new paragraph:

''(2) MA LOCAL AREA.—The term 'MA local area' means a county or equivalent area specified by the Secretary.''; and

(E) in paragraph (4), as so redesignated—

(i) in subparagraph (A), by inserting ''for MA local plans'' after ''paragraph (1)'';

(ii) in subparagraph (A)(iii), by striking ''paragraph (1)'' and inserting ''paragraph (1)(A)''; and

(iii) in subparagraph (B)—

(I) by inserting ''with respect to MA local plans'' after ''established under this section'';

(II) by inserting ''for such plans'' after ''payments under this section''; and

(III) by inserting ''for such plans'' after ''made under this section''.

(2) MA LOCAL AREA DEFINED.—Section 1859(c) (42 U.S.C. 1395w–29(c)) is amended by adding at the end the following:

''(5) MA LOCAL AREA.—The term 'MA local area' is defined in section 1853(d)(2).''.

(3) APPLICATION OF SPECIAL BENEFIT RULES TO PPOS AND REGIONAL PLANS.—Section 1852(a) (42 U.S.C. 1395w–22(a)) is amended—

(A) in paragraph (1), by inserting ''and except as provided in paragraph (6) for MA regional plans'' after ''MSA plans''; and

(B) by adding at the end the following new paragraph:

''(6) SPECIAL BENEFIT RULES FOR REGIONAL PLANS.—In the case of an MA plan that is an MA regional plan, benefits under the plan shall include the benefits described in paragraphs (1) and (2) of section 1858(b).''.

(4) APPLICATION OF CAPITATION RATES TO LOCAL AREAS.—Section 1853(c)(1) (42 U.S.C. 1395w–23(c)(1)) is amended by inserting ''that is an MA local area'' after ''for a Medicare+Choice payment area''.

(5) NETWORK ADEQUACY HOSPITAL PAYMENTS.—Section 1851(i)(2) (42 U.S.C. 1395w–21(i)(2)) is amended by inserting ''1858(h),'' after ''1857(f)(2),''.

SEC. 222. COMPETITION PROGRAM BEGINNING IN 2006.

(a) SUBMISSION OF BIDDING AND REBATE INFORMATION BEGINNING IN 2006.—

(1) IN GENERAL.—Section 1854 (42 U.S.C. 1395w–24) is amended—

(A) by amending paragraph (1) of subsection (a) to read as follows:

''(1) IN GENERAL.—

''(A) INITIAL SUBMISSION.—Not later than the second Monday in September of 2002, 2003, and 2004 (or the first Monday in June of each subsequent year), each MA organization shall submit to the Secretary, in a form and manner specified by the Secretary and for each MA plan for the service area (or segment of such an area if permitted under subsection (h)) in which it intends to be offered in the following year the following:

''(i) The information described in paragraph (2), (3), (4), or (6)(A) for the type of plan and year involved.

''(ii) The plan type for each plan.

''(iii) The enrollment capacity (if any) in relation to the plan and area.

''(B) BENEFICIARY REBATE INFORMATION.—In the case of a plan required to provide a monthly rebate under subsection (b)(1)(C) for a year, the MA organization offering the plan shall submit to the Secretary, in such form and manner and at such time as the Secretary specifies, information on—

''(i) the manner in which such rebate will be provided under clause (ii) of such subsection; and

''(ii) the MA monthly prescription drug beneficiary premium (if any) and the MA monthly supplemental beneficiary premium (if any).

''(C) PAPERWORK REDUCTION FOR OFFERING OF MA REGIONAL PLANS NATIONALLY OR IN MULTI-REGION AREAS.—The Secretary shall establish requirements for information submission under this subsection in a manner that promotes the offering of MA regional plans in more than one region (including all regions) through the filing of consolidated information.''; and

(B) by adding at the end of subsection (a) the following:

''(6) SUBMISSION OF BID AMOUNTS BY MA ORGANIZATIONS BEGINNING IN 2006.—

''(A) INFORMATION TO BE SUBMITTED.—For an MA plan (other than an MSA plan) for a plan year beginning on or after January 1, 2006, the information described in this subparagraph is as follows:

''(i) The monthly aggregate bid amount for the provision of all items and services under the plan, which amount shall be based on average revenue requirements (as used for purposes of section 1302(8) of the Public Health Service Act) in the payment area for an enrollee with a national average risk profile for the factors described in section 1853(a)(1)(C) (as specified by the Secretary).

''(ii) The proportions of such bid amount that are attributable to—

''(I) the provision of benefits under the original medicare fee-for-service program option (as defined in section 1852(a)(1)(B));

''(II) the provision of basic prescription drug coverage; and

''(III) the provision of supplemental health care benefits.

''(iii) The actuarial basis for determining the amount under clause (i) and the proportions described in clause (ii) and such additional information as the Secretary may require to verify such actuarial bases and the projected number of enrollees in each MA local area.

''(iv) A description of deductibles, coinsurance, and copayments applicable under the plan and the actuarial value of such deductibles, coinsurance, and copayments, described in subsection (e)(4)(A).

''(v) With respect to qualified prescription drug coverage, the information required under section 1860D–4, as incorporated under section 1860D–11(b)(2), with respect to such coverage.

In the case of a specialized MA plan for special needs individuals, the information described in this subparagraph is such information as the Secretary shall specify.

''(B) ACCEPTANCE AND NEGOTIATION OF BID AMOUNTS.—

''(i) AUTHORITY.—Subject to clauses (iii) and (iv), the Secretary has the authority to negotiate regarding monthly bid amounts submitted under subparagraph (A) (and the proportions described in subparagraph (A)(ii)), including supplemental benefits provided under subsection (b)(1)(C)(ii)(I) and in exercising such authority the Secretary shall have authority similar to the authority of the Director of the Office of Personnel Management with respect to health benefits plans under chapter 89 of title 5, United States Code.

''(ii) APPLICATION OF FEHBP STANDARD.—Subject to clause (iv), the Secretary may only accept such a bid amount or proportion if the Secretary determines that such amount and proportions are supported by the actuarial bases provided under subparagraph (A) and reasonably and equitably reflects the revenue requirements (as used for purposes of section 1302(8) of the Public Health Service Act) of benefits provided under that plan.

''(iii) NONINTERFERENCE.—In order to promote competition under this part and part D and in carrying out such parts, the Secretary may not require any MA organization to contract with a particular hospital, physician, or other entity or individual to furnish items and services under this title or require a particular price structure for payment under such a contract to the extent consistent with the Secretary's authority under this part.

''(iv) EXCEPTION.—In the case of a plan described in section 1851(a)(2)(C), the provisions of clauses (i) and (ii) shall not apply and the provisions of paragraph (5)(B), prohibiting the review, approval, or disapproval of amounts described in such paragraph, shall apply to the negotiation and rejection of the monthly bid amounts and the proportions referred to in subparagraph (A).''.

(2) DEFINITION OF BENEFITS UNDER THE ORIGINAL MEDICARE FEE-FOR-SERVICE PROGRAM OPTION.—Section 1852(a)(1) (42 U.S.C. 1395w–22(a)(1)) is amended—

(A) by striking ''IN GENERAL.—Except'' and inserting ''REQUIREMENT.—

''(A) IN GENERAL.—Except''; and

(B) by striking ''title XI'' and all that follows and inserting the following: ''title XI, benefits under the original medicare fee-for-service program option (and, for plan years before 2006, additional benefits required under section 1854(f)(1)(A)).

''(B) BENEFITS UNDER THE ORIGINAL MEDICARE FEE-FOR-SERVICE PROGRAM OPTION DEFINED.—

''(i) IN GENERAL.—For purposes of this part, the term 'benefits under the original medicare fee-for-service program option' means those items and services (other than hospice care) for which benefits are available under parts A and B to individuals entitled to benefits under part A and enrolled under part B, with cost-sharing for those services as required under parts A and B or an actuarially equivalent level of cost-sharing as determined in this part.

''(ii) SPECIAL RULE FOR REGIONAL PLANS.—In the case of an MA regional plan in determining an actuarially equivalent level of cost-sharing with respect to benefits under the original medicare fee-for-service program option, there shall only be taken into account, with respect to the application of section 1858(b)(2), such expenses only with respect to subparagraph (A) of such section.''.

(3) CONFORMING AMENDMENT RELATING TO SUPPLEMENTAL HEALTH BENEFITS.—Section 1852(a)(3) (42 U.S.C. 1395w–22(a)(3)) is amended by adding at the end the following: ''Such benefits may include reductions in cost-sharing below the actuarial value specified in section 1854(e)(4)(B).''.

(b) PROVIDING FOR BENEFICIARY SAVINGS FOR CERTAIN PLANS.—

(1) BENEFICIARY REBATES.—Section 1854(b)(1) (42 U.S.C. 1395w–24(b)(1)) is amended—

(A) in subparagraph (A), by striking ''The monthly amount'' and inserting ''Subject to the rebate under subparagraph (C), the monthly amount (if any)''; and

(B) by adding at the end the following new subparagraph:

''(C) BENEFICIARY REBATE RULE.—

''(i) REQUIREMENT.—The MA plan shall provide to the enrollee a monthly rebate equal to 75 percent of the average per capita savings (if any) described in paragraph (3)(C) or (4)(C), as applicable to the plan and year involved.

''(ii) FORM OF REBATE.—A rebate required under this subparagraph shall be provided through the application of the amount of the rebate toward one or more of the following:

''(I) PROVISION OF SUPPLEMENTAL HEALTH CARE BENEFITS AND PAYMENT FOR PREMIUM FOR SUPPLEMENTAL BENEFITS.—The provision of supplemental health care benefits described in section 1852(a)(3) in a manner specified under the plan, which may include the reduction of cost-sharing otherwise applicable as well as additional health care benefits which are not benefits under the original medicare fee-for-service program option, or crediting toward an MA monthly supplemental beneficiary premium (if any).

''(II) PAYMENT FOR PREMIUM FOR PRESCRIPTION DRUG COVERAGE.—Crediting toward the MA monthly prescription drug beneficiary premium.

''(III) PAYMENT TOWARD PART B PREMIUM.—Crediting toward the premium imposed under part B (determined without regard to the application of subsections (b), (h), and (i) of section 1839).

''(iii) DISCLOSURE RELATING TO REBATES.—The plan shall disclose to the Secretary information on the form and amount of the rebate provided under this subparagraph or the actuarial value in the case of supplemental health care benefits.

''(iv) APPLICATION OF PART B PREMIUM REDUCTION.—Insofar as an MA organization elects to provide a rebate under this subparagraph under a plan as a credit toward the part B premium under clause (ii)(III), the Secretary shall apply such credit to reduce the premium under section 1839 of each enrollee in such plan as provided in section 1840(i).''.

(2) REVISION OF PREMIUM TERMINOLOGY.—Section 1854(b)(2) (42 U.S.C. 1395w–24(b)(2)) is amended—

(A) in the heading, by inserting ''AND BID'' after ''PREMIUM'';

(B) by redesignating subparagraph (C) as subparagraph (D);

(C) by striking subparagraphs (A) and (B) and inserting the following:

''(A) MA MONTHLY BASIC BENEFICIARY PREMIUM.—The term 'MA monthly basic beneficiary premium' means, with respect to an MA plan—

''(i) described in section 1853(a)(1)(B)(i) (relating to plans providing rebates), zero; or

''(ii) described in section 1853(a)(1)(B)(ii), the amount (if any) by which the unadjusted MA statutory non-drug monthly bid amount (as defined in subparagraph (E)) exceeds the applicable unadjusted MA area-specific non-drug monthly benchmark amount (as defined in section 1853(j)).

''(B) MA MONTHLY PRESCRIPTION DRUG BENEFICIARY PREMIUM.—The term 'MA monthly prescription drug beneficiary premium' means, with respect to an MA plan, the base beneficiary premium (as determined under section 1860D–13(a)(2) and as adjusted under section 1860D–13(a)(1)(B)), less the amount of rebate credited toward such amount under section 1854(b)(1)(C)(ii)(II).

''(C) MA MONTHLY SUPPLEMENTAL BENEFICIARY PREMIUM.—The term 'MA monthly supplemental beneficiary premium' means, with respect to an MA plan, the portion of the aggregate monthly bid amount submitted under clause (i) of subsection (a)(6)(A) for the year that is attributable under clause (ii)(III) of such subsection to the provision of supplemental health care benefits, less the amount of rebate credited toward such portion under section 1854(b)(1)(C)(ii)(I).''; and

(D) by adding at the end the following:

''(E) UNADJUSTED MA STATUTORY NON-DRUG MONTHLY BID AMOUNT.—The term 'unadjusted MA statutory non-drug monthly bid amount' means the portion of the bid amount submitted under clause (i) of subsection (a)(6)(A) for the year that is attributable under clause (ii)(I) of such subsection to the provision of benefits under the original medicare fee-for-service program option (as defined in section 1852(a)(1)(B)).''.

(3) COMPUTATION OF SAVINGS.—Section 1854(b) (42 U.S.C. 1395w–24(b)) is further amended by adding at the end the following new paragraphs:

''(3) COMPUTATION OF AVERAGE PER CAPITA MONTHLY SAVINGS FOR LOCAL PLANS.—For purposes of paragraph (1)(C)(i), the average per capita monthly savings referred to in such paragraph for an MA local plan and year is computed as follows:

''(A) DETERMINATION OF STATEWIDE AVERAGE RISK ADJUSTMENT FOR LOCAL PLANS.—

''(i) IN GENERAL.—Subject to clause (iii), the Secretary shall determine, at the same time rates are promulgated under section 1853(b)(1) (beginning with 2006) for each State, the average of the risk adjustment factors to be applied under section 1853(a)(1)(C) to payment for enrollees in that State for MA local plans.

''(ii) TREATMENT OF STATES FOR FIRST YEAR IN WHICH LOCAL PLAN OFFERED.—In the case of a State in which no MA local plan was offered in the previous year, the Secretary shall estimate such average. In making such estimate, the Secretary may use average risk adjustment factors applied to comparable States or applied on a national basis.

''(iii) AUTHORITY TO DETERMINE RISK ADJUSTMENT FOR AREAS OTHER THAN STATES.—The Secretary may provide for the determination and application of risk adjustment factors under this subparagraph on the basis of areas other than States or on a plan-specific basis.

''(B) DETERMINATION OF RISK ADJUSTED BENCHMARK AND RISK-ADJUSTED BID FOR LOCAL PLANS.—For each MA plan offered in a local area in a State, the Secretary shall—

''(i) adjust the applicable MA area-specific non-drug monthly benchmark amount (as defined in section 1853(j)(1)) for the area by the average risk adjustment factor computed under subparagraph (A); and

''(ii) adjust the unadjusted MA statutory non-drug monthly bid amount by such applicable average risk adjustment factor.

''(C) DETERMINATION OF AVERAGE PER CAPITA MONTHLY SAVINGS.—The average per capita monthly savings described in this subparagraph for an MA local plan is equal to the amount (if any) by which—

''(i) the risk-adjusted benchmark amount computed under subparagraph (B)(i); exceeds

''(ii) the risk-adjusted bid computed under subparagraph (B)(ii).

''(4) COMPUTATION OF AVERAGE PER CAPITA MONTHLY SAVINGS FOR REGIONAL PLANS.—For purposes of paragraph (1)(C)(i), the average per capita monthly savings referred to in such paragraph for an MA regional plan and year is computed as follows:

''(A) DETERMINATION OF REGIONWIDE AVERAGE RISK ADJUSTMENT FOR REGIONAL PLANS.—

''(i) IN GENERAL.—The Secretary shall determine, at the same time rates are promulgated under section 1853(b)(1) (beginning with 2006) for each MA region the average of the risk adjustment factors to be applied under section 1853(a)(1)(C) to payment for enrollees in that region for MA regional plans.

''(ii) TREATMENT OF REGIONS FOR FIRST YEAR IN WHICH REGIONAL PLAN OFFERED.—In the case of an MA region in which no MA regional plan was offered in the previous year, the Secretary shall estimate such average. In making such estimate, the Secretary may use average risk adjustment factors applied to comparable regions or applied on a national basis.

''(iii) AUTHORITY TO DETERMINE RISK ADJUSTMENT FOR AREAS OTHER THAN REGIONS.—The Secretary may provide for the determination and application of risk adjustment factors under this subparagraph on the basis of areas other than MA regions or on a plan-specific basis.

''(B) DETERMINATION OF RISK-ADJUSTED BENCHMARK AND RISK-ADJUSTED BID FOR REGIONAL PLANS.—For each MA regional plan offered in a region, the Secretary shall—

''(i) adjust the applicable MA area-specific non-drug monthly benchmark amount (as defined in section 1853(j)(2)) for the region by the average risk adjustment factor computed under subparagraph (A); and

''(ii) adjust the unadjusted MA statutory non-drug monthly bid amount by such applicable average risk adjustment factor.

''(C) DETERMINATION OF AVERAGE PER CAPITA MONTHLY SAVINGS.—The average per capita monthly savings described in this subparagraph for an MA regional plan is equal to the amount (if any) by which—

''(i) the risk-adjusted benchmark amount computed under subparagraph (B)(i); exceeds

''(ii) the risk-adjusted bid computed under subparagraph (B)(ii).''.

(c) COLLECTION OF PREMIUMS.—Section 1854(d) (42 U.S.C. 1395w–24(d)) is amended—

(1) by striking ''PREMIUMS.—Each'' and inserting ''PREMIUMS.—

''(1) IN GENERAL.—Each''; and

(2) by adding at the end the following new paragraphs:

''(2) BENEFICIARY'S OPTION OF PAYMENT THROUGH WITHHOLDING FROM SOCIAL SECURITY PAYMENT OR USE OF ELECTRONIC FUNDS TRANSFER MECHANISM.—In accordance with regulations, an MA organization shall permit each enrollee, at the enrollee's option, to make payment of premiums (if any) under this part to the organization through—

''(A) withholding from benefit payments in the manner provided under section 1840 with respect to monthly premiums under section 1839;

''(B) an electronic funds transfer mechanism (such as automatic charges of an account at a financial institution or a credit or debit card account); or

''(C) such other means as the Secretary may specify, including payment by an employer or under employment-based retiree health coverage (as defined in section 1860D–22(c)(1)) on behalf of an employee or former employee (or dependent).

All premium payments that are withheld under subparagraph (A) shall be credited to the appropriate Trust Fund (or Account thereof), as specified by the Secretary, under this title and shall be paid to the MA organization involved. No charge may be imposed under an MA plan with respect to the election of the payment option described in subparagraph (A). The Secretary shall consult with the Commissioner of Social Security and the Secretary of the Treasury regarding methods for allocating premiums withheld under subparagraph (A) among the appropriate Trust Funds and Account.

''(3) INFORMATION NECESSARY FOR COLLECTION.—In order to carry out paragraph (2)(A) with respect to an enrollee who has elected such paragraph to apply, the Secretary shall transmit to the Commissioner of Social Security—

''(A) by the beginning of each year, the name, social security account number, consolidated monthly beneficiary premium described in paragraph (4) owed by such enrollee for each month during the year, and other information determined appropriate by the Secretary, in consultation with the Commissioner of Social Security; and

''(B) periodically throughout the year, information to update the information previously transmitted under this paragraph for the year.

''(4) CONSOLIDATED MONTHLY BENEFICIARY PREMIUM.—In the case of an enrollee in an MA plan, the Secretary shall provide a mechanism for the consolidation of—

''(A) the MA monthly basic beneficiary premium (if any);

''(B) the MA monthly supplemental beneficiary premium (if any); and

''(C) the MA monthly prescription drug beneficiary premium (if any).''.

(d) COMPUTATION OF MA AREA-SPECIFIC NON-DRUG BENCHMARK.—Section 1853 (42 U.S.C. 1395w–23) is amended by adding at the end the following new subsection:

''(j) COMPUTATION OF BENCHMARK AMOUNTS.—For purposes of this part, the term 'MA area-specific non-drug monthly benchmark amount' means for a month in a year—

''(1) with respect to—

''(A) a service area that is entirely within an MA local area, an amount equal to 1/12 of the annual MA capitation rate under section 1853(c)(1) for the area for the year, adjusted as appropriate for the purpose of risk adjustment; or

''(B) a service area that includes more than one MA local area, an amount equal to the average of the amounts described in subparagraph (A) for each such local MA area, weighted by the projected number of enrollees in the plan residing in the respective local MA areas (as used by the plan for purposes of the bid and disclosed to the Secretary under section 1854(a)(6)(A)(iii)), adjusted as appropriate for the purpose of risk adjustment; or

''(2) with respect to an MA region for a month in a year, the MA region-specific non-drug monthly benchmark amount, as defined in section 1858(f) for the region for the year.''.

(e) PAYMENT OF PLANS BASED ON BID AMOUNTS.—

(1) IN GENERAL.—Section 1853(a)(1) (42 U.S.C. 1395w–23(a)(1)) (42 U.S.C. 1395w–23) is amended—

(A) by redesignating subparagraph (B) as subparagraph (H); and

(B) in subparagraph (A), by striking ''in an amount'' and all that follows and inserting the following: ''in an amount determined as follows:

''(i) PAYMENT BEFORE 2006.—For years before 2006, the payment amount shall be equal to 1/12 of the annual MA capitation rate (as calculated under subsection (c)(1)) with respect to that individual for that area, adjusted under subparagraph (C) and reduced by the amount of any reduction elected under section 1854(f)(1)(E).

''(ii) PAYMENT FOR ORIGINAL FEE-FOR-SERVICE BENEFITS BEGINNING WITH 2006.—For years beginning with 2006, the amount specified in subparagraph (B).

''(B) PAYMENT AMOUNT FOR ORIGINAL FEE-FOR-SERVICE BENEFITS BEGINNING WITH 2006.—

''(i) PAYMENT OF BID FOR PLANS WITH BIDS BELOW BENCHMARK.—In the case of a plan for which there are average per capita monthly savings described in section 1854(b)(3)(C) or 1854(b)(4)(C), as the case may be, the amount specified in this subparagraph is equal to the unadjusted MA statutory non-drug monthly bid amount, adjusted under subparagraph (C) and (if applicable) under subparagraphs (F) and (G), plus the amount (if any) of any rebate under subparagraph (E).

''(ii) PAYMENT OF BENCHMARK FOR PLANS WITH BIDS AT OR ABOVE BENCHMARK.—In the case of a plan for which there are no average per capita monthly savings described in section 1854(b)(3)(C) or 1854(b)(4)(C), as the case may be, the amount specified in this subparagraph is equal to the MA area-specific non-drug monthly benchmark amount, adjusted under subparagraph (C) and (if applicable) under subparagraphs (F) and (G).

''(iii) PAYMENT OF BENCHMARK FOR MSA PLANS.—Notwithstanding clauses (i) and (ii), in the case of an MSA plan, the amount specified in this subparagraph is equal to the MA area-specific non-drug monthly benchmark amount, adjusted under subparagraph (C).

''(C) DEMOGRAPHIC ADJUSTMENT, INCLUDING ADJUSTMENT FOR HEALTH STATUS.—The Secretary shall adjust the payment amount under subparagraph (A)(i) and the amount specified under subparagraph (B)(i), (B)(ii), and (B)(iii) for such risk factors as age, disability status, gender, institutional status, and such other factors as the Secretary determines to be appropriate, including adjustment for health status under paragraph (3), so as to ensure actuarial equivalence. The Secretary may add to, modify, or substitute for such adjustment factors if such changes will improve the determination of actuarial equivalence.

''(D) SEPARATE PAYMENT FOR FEDERAL DRUG SUBSIDIES.—In the case of an enrollee in an MA–PD plan, the MA organization offering such plan also receives—

''(i) subsidies under section 1860D–15 (other than under subsection (g)); and

''(ii) reimbursement for premium and cost-sharing reductions for low-income individuals under section 1860D–14(c)(1)(C).

''(E) PAYMENT OF REBATE FOR PLANS WITH BIDS BELOW BENCHMARK.—In the case of a plan for which there are average per capita monthly savings described in section 1854(b)(3)(C) or 1854(b)(4)(C), as the case may be, the amount specified in this subparagraph is the amount of the monthly rebate computed under section 1854(b)(1)(C)(i) for that plan and year (as reduced by the amount of any credit provided under section 1854(b)(1)(C)(iv)).

''(F) ADJUSTMENT FOR INTRA-AREA VARIATIONS.—

''(i) INTRA-REGIONAL VARIATIONS.—In the case of payment with respect to an MA regional plan for an MA region, the Secretary shall also adjust the amounts specified under subparagraphs (B)(i) and (B)(ii) in a manner to take into account variations in MA local payment rates under this part among the different MA local areas included in such region.

''(ii) INTRA-SERVICE AREA VARIATIONS.—In the case of payment with respect to an MA local plan for a service area that covers more than one MA local area, the Secretary shall also adjust the amounts specified under subparagraphs (B)(i) and (B)(ii) in a manner to take into account variations in MA local payment rates under this part among the different MA local areas included in such service area.

''(G) ADJUSTMENT RELATING TO RISK ADJUSTMENT.—The Secretary shall adjust payments with respect to MA plans as necessary to ensure that—

''(i) the sum of—

''(I) the monthly payment made under subparagraph (A)(ii); and

''(II) the MA monthly basic beneficiary premium under section 1854(b)(2)(A); equals

''(ii) the unadjusted MA statutory non-drug monthly bid amount, adjusted in the manner described in subparagraph (C) and, for an MA regional plan, subparagraph (F).''.

(f) CONFORMING CHANGES TO ANNUAL ANNOUNCEMENT PROCESS.—Section 1853(b) (42 U.S.C. 1395w–23(b)(1)) is amended—

(1) by amending paragraph (1) to read as follows:

''(1) ANNUAL ANNOUNCEMENTS.—

''(A) FOR 2005.—The Secretary shall determine, and shall announce (in a manner intended to provide notice to interested parties), not later than the second Monday in May of 2004, with respect to each MA payment area, the following:

''(i) MA CAPITATION RATES.—The annual MA capitation rate for each MA payment area for 2005.

''(ii) ADJUSTMENT FACTORS.—The risk and other factors to be used in adjusting such rates under subsection (a)(1)(C) for payments for months in 2005.

''(B) FOR 2006 AND SUBSEQUENT YEARS.—For a year after 2005—

''(i) INITIAL ANNOUNCEMENT.—The Secretary shall determine, and shall announce (in a manner intended to provide notice to interested parties), not later than the first Monday in April before the calendar year concerned, with respect to each MA payment area, the following:

''(I) MA CAPITATION RATES; MA LOCAL AREA BENCHMARK.—The annual MA capitation rate for each MA payment area for the year.

''(II) ADJUSTMENT FACTORS.—The risk and other factors to be used in adjusting such rates under subsection (a)(1)(C) for payments for months in such year.

''(ii) REGIONAL BENCHMARK ANNOUNCEMENT.—The Secretary shall determine, and shall announce (in a manner intended to provide notice to interested parties), on a timely basis before the calendar year concerned, with respect to each MA region and each MA regional plan for which a bid was submitted under section 1854, the MA region-specific non-drug monthly benchmark amount for that region for the year involved.''; and

(2) in paragraph (3), by striking ''in the announcement'' and all that follows and inserting ''in such announcement.''.

(g) OTHER AMENDMENTS RELATING TO PREMIUMS AND BID AMOUNTS.—

(1) IN GENERAL.—Section 1854 (42 U.S.C. 1395w–24) is amended—

(A) by amending the section heading to read as follows:

''PREMIUMS AND BID AMOUNTS'';

(B) in the heading of subsection (a), by inserting '', BID AMOUNTS,'' after ''PREMIUMS'';

(C) in subsection (a)(2)—

(i) by inserting ''BEFORE 2006'' after ''FOR COORDINATED CARE PLANS''; and

(ii) by inserting ''for a year before 2006'' after ''section 1851(a)(2)(A)'';

(D) in subsection (a)(3), by striking ''described'' and inserting ''for any year'';

(E) in subsection (a)(4)—

(i) by inserting ''BEFORE 2006'' after ''FOR PRIVATE FEE-FOR-SERVICE PLANS''; and

(ii) by inserting ''for a year before 2006'' after ''section 1852(a)(1)(A)'';

(F) in subsection (a)(5)(A), by inserting ''paragraphs (2) and (4) of'' after ''filed under'';

(G) in subsection (a)(5)(B), by inserting after ''paragraph (3) or'' the following: '', in the case of an MA private fee-for-service plan,''; and

(H) in subsection (b)(1)(A) by striking ''and'' and inserting a comma and by inserting before the period at the end the following: '', and, if the plan provides qualified prescription drug coverage, the MA monthly prescription drug beneficiary premium''.

(2) UNIFORMITY.—Section 1854(c) (42 U.S.C. 1395w–24(c)) is amended to read as follows:

''(c) UNIFORM PREMIUM AND BID AMOUNTS.—Except as permitted under section 1857(i), the MA monthly bid amount submitted under subsection (a)(6), the amounts of the MA monthly basic, prescription drug, and supplemental beneficiary premiums, and the MA monthly MSA premium charged under subsection (b) of an MA organization under this part may not vary among individuals enrolled in the plan.''.

(3) PREMIUMS.—Section 1854(d)(1) (42 U.S.C. 1395w–24(d)(1)), as amended by subsection (c)(1), is amended by inserting '', prescription drug,'' after ''basic''.

(4) LIMITATION ON ENROLLEE LIABILITY.—Section 1854(e) (42 U.S.C. 1395w–24(e)) is amended—

(A) in paragraph (1), by striking ''.—In'' and inserting ''BEFORE 2006.—For periods before 2006, in'';

(B) in paragraph (2), by striking ''.—If'' and insert ''BEFORE 2006.—For periods before 2006, if'';

(C) in paragraph (3), by striking ''or (2)'' and inserting '', (2), or (4)''; and

(D) in paragraph (4)—

(i) by inserting ''AND FOR BASIC BENEFITS BEGINNING IN 2006'' after ''PLANS'';

(ii) in the matter before subparagraph (A), by inserting ''and for periods beginning with 2006, with respect to an MA plan described in section 1851(a)(2)(A)'' after ''MSA plan'';

(iii) in subparagraph (A), by striking ''required benefits described in section 1852(a)(1)'' and inserting ''benefits under the original medicare fee-for-service program option''; and

(iv) in subparagraph (B), by inserting ''with respect to such benefits'' after ''would be applicable''.

(5) MODIFICATION OF ACR PROCESS.—Section 1854(f) (42 U.S.C. 1395w–24(f)) is amended—

(A) in the heading, by inserting ''BEFORE 2006'' after ''ADDITIONAL BENEFITS''; and

(B) in paragraph (1)(A), by striking ''Each'' and inserting ''For years before 2006, each''.

(h) PLAN INCENTIVES.—Section 1852(j)(4) (42 U.S.C. 1395w–22(j)(4)) is amended—

(1) by inserting ''the organization provides assurances satisfactory to the Secretary that'' after ''unless'';

(2) in clause (ii)—

(A) by striking ''the organization—'' and all that follows through ''(I) provides'' and inserting ''the organization provides'';

(B) by striking '', and'' and inserting a period; and

(C) by striking subclause (II); and

(3) by striking clause (iii).

(i) CONTINUATION OF TREATMENT OF ENROLLEES WITH END-STAGE RENAL DISEASE.—Section 1853(a)(1)(H), as redesignated under subsection (d)(1)(A), is amended—

(1) by amending the second sentence to read as follows: ''Such rates of payment shall be actuarially equivalent to rates that would have been paid with respect to other enrollees in the MA payment area (or such other area as specified by the Secretary) under the provisions of this section as in effect before the date of the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.''; and

(2) by adding at the end the following new sentence: ''The Secretary may apply the competitive bidding methodology provided for in this section, with appropriate adjustments to account for the risk adjustment methodology applied to end stage renal disease payments.''.

(j) FACILITATION OF EMPLOYER SPONSORSHIP OF MA PLANS.—Section 1857(i) (42 U.S.C. 1395w–27(i)) is amended—

(1) by designating the matter following the heading as a paragraph (1) with the heading ''CONTRACTS WITH MA ORGANIZATIONS.—'' and appropriate indentation; and

(2) by adding at the end the following new paragraph:

''(2) EMPLOYER SPONSORED MA PLANS.—To facilitate the offering of MA plans by employers, labor organizations, or the trustees of a fund established by one or more employers or labor organizations (or combination thereof) to furnish benefits to the entity's employees, former employees (or combination thereof) or members or former members (or combination thereof) of the labor organizations, the Secretary may waive or modify requirements that hinder the design of, the offering of, or the enrollment in such MA plans. Notwithstanding section 1851(g), an MA plan described in the previous sentence may restrict the enrollment of individuals under this part to individuals who are beneficiaries and participants in such plan.''.

(k) EXPANSION OF MEDICARE BENEFICIARY EDUCATION AND INFORMATION CAMPAIGN.—Section 1857(e)(2) (42 U.S.C. 1395w–27(e)(2)) is amended—

(1) in subparagraph (A) by inserting ''and a PDP sponsor under part D'' after ''organization'';

(2) in subparagraph (B)—

(A) by inserting ''and each PDP sponsor with a contract under part D'' after ''contract under this part'';

(B) by inserting ''or sponsor's'' after ''organization's''; and

(C) by inserting '', section 1860D–1(c),'' after ''information)'';

(3) in subparagraph (C)—

(A) by inserting ''and ending with fiscal year 2005'' after ''beginning with fiscal year 2001'';

(B) by inserting ''and for each fiscal year beginning with fiscal year 2006 an amount equal to $200,000,000,'' after ''$100,000,000,''; and

(C) by inserting ''and section 1860D–12(b)(3)(D)'' after ''under this paragraph'';

(4) in subparagraph (D)—

(A) in clause (i) by inserting ''and section 1860D–1(c)'' after ''section 1851'';

(B) in clause (ii)(III), by striking ''and'' at the end of subclause (III);

(C) in clause (ii)(IV), by striking ''each succeeding fiscal year.'' and inserting ''each succeeding fiscal year before fiscal year 2006; and''; and

(D) in clause (ii), by adding at the end the following new subclause:

''(V) the applicable portion (as defined in subparagraph (F)) of $200,000,000 in fiscal year 2006 and each succeeding fiscal year.''; and

(5) by adding at the end the following new subparagraph:

''(F) APPLICABLE PORTION DEFINED.—In this paragraph, the term 'applicable portion' means, for a fiscal year—

''(i) with respect to MA organizations, the Secretary's estimate of the total proportion of expenditures under this title that are attributable to expenditures made under this part (including payments under part D that are made to such organizations); or

''(ii) with respect to PDP sponsors, the Secretary's estimate of the total proportion of expenditures under this title that are attributable to expenditures made to such sponsors under part D.''.

(l) CONFORMING AMENDMENTS.—

(1) PROTECTION AGAINST BENEFICIARY SELECTION.—Section 1852(b)(1)(A) (42 U.S.C. 1395w–22(b)(1)(A)) is amended by adding at the end the following: ''The Secretary shall not approve a plan of an organization if the Secretary determines that the design of the plan and its benefits are likely to substantially discourage enrollment by certain MA eligible individuals with the organization.''.

(2) RELATING TO REBATES.—

(A) Section 1839(a)(2) (42 U.S.C. 1395r(a)(2)) is amended by striking ''80 percent of any reduction elected under section 1854(f)(1)(E)'' and inserting ''any credit provided under section 1854(b)(1)(C)(ii)(III)''.

(B) The first sentence of section 1840(i) (42 U.S.C. 1395s(i)) is amended by inserting ''and to reflect any credit provided under section 1854(b)(1)(C)(iv)'' after ''section 1854(f)(1)(E)''.

(C) Section 1844(c) (42 U.S.C. 1395w(c)) is amended by inserting ''or any credits provided under section 1854(b)(1)(C)(iv)'' after ''section 1854(f)(1)(E)''.

(3) OTHER CONFORMING AND TECHNICAL AMENDMENTS.—

(A) Section 1851(b)(1) (42 U.S.C. 1395w–21(b)(1)) is amended—

(i) in subparagraph (B), by striking ''a plan'' and inserting ''an MA local plan'';

(ii) in subparagraph (B), by striking ''basic benefits described in section 1852(a)(1)(A)'' and inserting ''benefits under the original medicare fee-for-service program option''; and

(iii) in subparagraph (C), by striking ''in a Medicare+Choice plan'' and inserting ''in an MA local plan''.

(B) Section 1851(d) (42 U.S.C. 1395w–21(d)) is amended—

(i) in paragraph (3), by adding at the end the following new subparagraph:

''(F) CATASTROPHIC COVERAGE AND SINGLE DEDUCTIBLE.—In the case of an MA regional plan, a description of the catastrophic coverage and single deductible applicable under the plan.'';

(ii) in paragraph (4)(A)(ii), by inserting '', including information on the single deductible (if applicable) under section 1858(b)(1)'' after ''cost sharing'';

(iii) in paragraph (4)(B)(i), by striking ''Medicare+Choice monthly basic'' and all that follows and inserting ''monthly amount of the premium charged to an individual.''; and

(iv) by amending subparagraph (E) of subsection (d)(4) to read as follows:

''(E) SUPPLEMENTAL BENEFITS.—Supplemental health care benefits, including any reductions in cost-sharing under section 1852(a)(3) and the terms and conditions (including premiums) for such benefits.''.

(C) Section 1857(d)(1) (42 U.S.C. 1395w–27(d)(1)) is amended by striking '', costs, and computation of the adjusted community rate'' and inserting ''and costs, including allowable costs under section 1858(c)''.

(D) Section 1851(a)(3)(B)(ii) (42 U.S.C. 1395w–21(a)(3)(B)(ii)) is amended by striking ''section 1851(e)(4)(A)'' and inserting ''subsection (e)(4)(A)''.

(E) Section 1851(f)(1) (42 U.S.C. 1395w–21(f)(1)) is amended by striking ''subsection (e)(1)(A)'' and inserting ''subsection (e)(1)''.

SEC. 223. EFFECTIVE DATE.

(a) EFFECTIVE DATE.—The amendments made by this subtitle shall apply with respect to plan years beginning on or after January 1, 2006.

(b) ISSUANCE OF REGULATIONS.—The Secretary shall revise the regulations previously promulgated to carry out part C of title XVIII of the Social Security Act to carry out the provisions of this Act.

Subtitle D—Additional Reforms

SEC. 231. SPECIALIZED MA PLANS FOR SPECIAL NEEDS INDIVIDUALS.

(a) TREATMENT AS COORDINATED CARE PLAN.—Section 1851(a)(2)(A) (42 U.S.C. 1395w–21(a)(2)(A)), as amended by section 221(a), is amended by adding at the end the following new clause:

''(ii) SPECIALIZED MA PLANS FOR SPECIAL NEEDS INDIVIDUALS.—Specialized MA plans for special needs individuals (as defined in section 1859(b)(6)) may be any type of coordinated care plan.''.

(b) SPECIALIZED MA PLAN FOR SPECIAL NEEDS INDIVIDUALS DEFINED.—Section 1859(b) (42 U.S.C. 1395w–29(b)), as amended by section 221(b), is amended by adding at the end the following new paragraph:

''(6) SPECIALIZED MA PLANS FOR SPECIAL NEEDS INDIVIDUALS.—

''(A) IN GENERAL.—The term 'specialized MA plan for special needs individuals' means an MA plan that exclusively serves special needs individuals (as defined in subparagraph (B)).

''(B) SPECIAL NEEDS INDIVIDUAL.—The term 'special needs individual' means an MA eligible individual who—

''(i) is institutionalized (as defined by the Secretary);

''(ii) is entitled to medical assistance under a State plan under title XIX; or

''(iii) meets such requirements as the Secretary may determine would benefit from enrollment in such a specialized MA plan described in subparagraph (A) for individuals with severe or disabling chronic conditions.

The Secretary may waive application of section 1851(a)(3)(B) in the case of an individual described in clause (i), (ii), or (iii) of this subparagraph and may apply rules similar to the rules of section 1894(c)(4) for continued eligibility of special needs individuals.''.

(c) RESTRICTION ON ENROLLMENT PERMITTED.—Section 1859 (42 U.S.C. 1395w–29) is amended by adding at the end the following new subsection:

''(f) RESTRICTION ON ENROLLMENT FOR SPECIALIZED MA PLANS FOR SPECIAL NEEDS INDIVIDUALS.—In the case of a specialized MA plan for special needs individuals (as defined in subsection (b)(6)), notwithstanding any other provision of this part and in accordance with regulations of the Secretary and for periods before January 1, 2009, the plan may restrict the enrollment of individuals under the plan to individuals who are within one or more classes of special needs individuals.''.

(d) AUTHORITY TO DESIGNATE OTHER PLANS AS SPECIALIZED MA PLANS.—In promulgating regulations to carry out section 1851(a)(2)(A)(ii) of the Social Security Act (as added by subsection (a)) and section 1859(b)(6) of such Act (as added by subsection (b)), the Secretary may provide (notwithstanding section 1859(b)(6)(A) of such Act) for the offering of specialized MA plans for special needs individuals by MA plans that disproportionately serve special needs individuals.

(e) REPORT TO CONGRESS.—Not later than December 31, 2007, the Secretary shall submit to Congress a report that assesses the impact of specialized MA plans for special needs individuals on the cost and quality of services provided to enrollees. Such report shall include an assessment of the costs and savings to the medicare program as a result of amendments made by subsections (a), (b), and (c).

(f) EFFECTIVE DATES.—

(1) IN GENERAL.—The amendments made by subsections (a), (b), and (c) shall take effect upon the date of the enactment of this Act.

(2) DEADLINE FOR ISSUANCE OF REQUIREMENTS FOR SPECIAL NEEDS INDIVIDUALS; TRANSITION.—No later than 1 year after the date of the enactment of this Act, the Secretary shall issue final regulations to establish requirements for special needs individuals under section 1859(b)(6)(B)(iii) of the Social Security Act, as added by subsection (b).

SEC. 232. AVOIDING DUPLICATIVE STATE REGULATION.

(a) IN GENERAL.—Section 1856(b)(3) (42 U.S.C. 1395w–26(b)(3)) is amended to read as follows:

''(3) RELATION TO STATE LAWS.—The standards established under this part shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to MA plans which are offered by MA organizations under this part.''.

(b) CONFORMING AMENDMENT.—Section 1854(g) (42 U.S.C. 1395w–24(g)) is amended by inserting ''or premiums paid to such organizations under this part'' after ''section 1853''.

(c) EFFECTIVE DATE.—The amendments made by this subsection shall take effect on the date of the enactment of this Act.

SEC. 233. MEDICARE MSAS.

(a) EXEMPTION FROM REPORTING REQUIREMENT.—

(1) IN GENERAL.—Section 1852(e)(1) (42 U.S.C. 1395w–22(e)(1)) is amended by inserting ''(other than MSA plans)'' after ''plans''.

(2) CONFORMING AMENDMENTS.—Section 1852 (42 U.S.C. 1395w–22) is amended—

(A) in subsection (c)(1)(I), by inserting before the period at the end the following: '', if required under such section''; and

(B) in subsection (e)(2)(A), by striking '', a non-network MSA plan,''; and

(C) in subsection (e)(2)(B), by striking '', NON-NETWORK MSA PLANS,'' and '', a non-network MSA plan,''.

(3) EFFECTIVE DATE.—The amendments made by this subsection shall apply on and after the date of the enactment of this Act but shall not apply to contract years beginning on or after January 1, 2006.

(b) MAKING PROGRAM PERMANENT AND ELIMINATING CAP.—Section 1851(b)(4) (42 U.S.C. 1395w–21(b)(4)) is amended—

(1) in the heading, by striking ''ON A DEMONSTRATION BASIS'';

(2) by striking the first sentence of subparagraph (A); and

(3) by striking the second sentence of subparagraph (C).

(c) APPLYING LIMITATIONS ON BALANCE BILLING.—Section 1852(k)(1) (42 U.S.C. 1395w–22(k)(1)) is amended by inserting ''or with an organization offering an MSA plan'' after ''section 1851(a)(2)(A)''.

(d) ADDITIONAL AMENDMENT.—Section 1851(e)(5)(A) (42 U.S.C. 1395w–21(e)(5)(A)) is amended—

(1) by adding ''or'' at the end of clause (i);

(2) by striking '', or'' at the end of clause (ii) and inserting a semicolon; and

(3) by striking clause (iii).

SEC. 234. EXTENSION OF REASONABLE COST CONTRACTS.

Subparagraph (C) of section 1876(h)(5) (42 U.S.C. 1395mm(h)(5)) is amended to read as follows:

''(C)(i) Subject to clause (ii), a reasonable cost reimbursement contract under this subsection may be extended or renewed indefinitely.

''(ii) For any period beginning on or after January 1, 2008, a reasonable cost reimbursement contract under this subsection may not be extended or renewed for a service area insofar as such area during the entire previous year was within the service area of—

''(I) 2 or more MA regional plans described in clause (iii); or

''(II) 2 or more MA local plans described in clause (iii).

''(iii) A plan described in this clause for a year for a service area is a plan described in section 1851(a)(2)(A)(i) if the service area for the year meets the following minimum enrollment requirements:

''(I) With respect to any portion of the area involved that is within a Metropolitan Statistical Area with a population of more than 250,000 and counties contiguous to such Metropolitan Statistical Area, 5,000 individuals.

''(II) With respect to any other portion of such area, 1,500 individuals.''.

SEC. 235. 2-YEAR EXTENSION OF MUNICIPAL HEALTH SERVICE DEMONSTRATION PROJECTS.

The last sentence of section 9215(a) of the Consolidated Omnibus Budget Reconciliation Act of 1985 (42 U.S.C. 1395b–1 note), as amended by section 6135 of the Omnibus Budget Reconciliation Act of 1989, section 13557 of the Omnibus Budget Reconciliation Act of 1993, section 4017 of BBA, section 534 of BBRA (113 Stat. 1501A–390), and section 633 of BIPA, is amended by striking ''December 31, 2004'' and inserting ''December 31, 2006''.

SEC. 236. PAYMENT BY PACE PROVIDERS FOR MEDICARE AND MEDICAID SERVICES FURNISHED BY NONCONTRACT PROVIDERS.

(a) MEDICARE SERVICES.—

(1) MEDICARE SERVICES FURNISHED BY PROVIDERS OF SERVICES.—Section 1866(a)(1)(O) (42 U.S.C. 1395cc(a)(1)(O)) is amended—

(A) by striking ''part C or'' and inserting ''part C, with a PACE provider under section 1894 or 1934, or'';

(B) by striking ''(i)'';

(C) by striking ''and (ii)'';

(D) by inserting ''(or, in the case of a PACE provider, contract or other agreement)'' after ''have a contract''; and

(E) by striking ''members of the organization'' and inserting ''members of the organization or PACE program eligible individuals enrolled with the PACE provider,''.

(2) MEDICARE SERVICES FURNISHED BY PHYSICIANS AND OTHER ENTITIES.—Section 1894(b) (42 U.S.C. 1395eee(b)) is amended by adding at the end the following new paragraphs:

''(3) TREATMENT OF MEDICARE SERVICES FURNISHED BY NONCONTRACT PHYSICIANS AND OTHER ENTITIES.—

''(A) APPLICATION OF MEDICARE ADVANTAGE REQUIREMENT WITH RESPECT TO MEDICARE SERVICES FURNISHED BY NONCONTRACT PHYSICIANS AND OTHER ENTITIES.—Section 1852(k)(1) (relating to limitations on balance billing against MA organizations for noncontract physicians and other entities with respect to services covered under this title) shall apply to PACE providers, PACE program eligible individuals enrolled with such PACE providers, and physicians and other entities that do not have a contract or other agreement establishing payment amounts for services furnished to such an individual in the same manner as such section applies to MA organizations, individuals enrolled with such organizations, and physicians and other entities referred to in such section.

''(B) REFERENCE TO RELATED PROVISION FOR NONCONTRACT PROVIDERS OF SERVICES.—For the provision relating to limitations on balance billing against PACE providers for services covered under this title furnished by noncontract providers of services, see section 1866(a)(1)(O).

''(4) REFERENCE TO RELATED PROVISION FOR SERVICES COVERED UNDER TITLE XIX BUT NOT UNDER THIS TITLE.—For provisions relating to limitations on payments to providers participating under the State plan under title XIX that do not have a contract or other agreement with a PACE provider establishing payment amounts for services covered under such plan (but not under this title) when such services are furnished to enrollees of that PACE provider, see section 1902(a)(66).''.

(b) MEDICAID SERVICES.—

(1) REQUIREMENT UNDER STATE PLAN.—Section 1902(a) (42 U.S.C. 1396a(a)), as amended by section 103(a), is amended—

(A) in paragraph (65), by striking ''and'' at the end;

(B) in paragraph (66), by striking the period at the end and inserting ''; and''; and

(C) by inserting after paragraph (66) the following new paragraph:

''(67) provide, with respect to services covered under the State plan (but not under title XVIII) that are furnished to a PACE program eligible individual enrolled with a PACE provider by a provider participating under the State plan that does not have a contract or other agreement with the PACE provider that establishes payment amounts for such services, that such participating provider may not require the PACE provider to pay the participating provider an amount greater than the amount that would otherwise be payable for the service to the participating provider under the State plan for the State where the PACE provider is located (in accordance with regulations issued by the Secretary).''.

(2) APPLICATION UNDER MEDICAID.—Section 1934(b) (42 U.S.C. 1396u–4(b)) is amended by adding at the end the following new paragraphs:

''(3) TREATMENT OF MEDICARE SERVICES FURNISHED BY NONCONTRACT PHYSICIANS AND OTHER ENTITIES.—

''(A) APPLICATION OF MEDICARE ADVANTAGE REQUIREMENT WITH RESPECT TO MEDICARE SERVICES FURNISHED BY NONCONTRACT PHYSICIANS AND OTHER ENTITIES.—Section 1852(k)(1) (relating to limitations on balance billing against MA organizations for noncontract physicians and other entities with respect to services covered under title XVIII) shall apply to PACE providers, PACE program eligible individuals enrolled with such PACE providers, and physicians and other entities that do not have a contract or other agreement establishing payment amounts for services furnished to such an individual in the same manner as such section applies to MA organizations, individuals enrolled with such organizations, and physicians and other entities referred to in such section.

''(B) REFERENCE TO RELATED PROVISION FOR NONCONTRACT PROVIDERS OF SERVICES.—For the provision relating to limitations on balance billing against PACE providers for services covered under title XVIII furnished by noncontract providers of services, see section 1866(a)(1)(O).

''(4) REFERENCE TO RELATED PROVISION FOR SERVICES COVERED UNDER THIS TITLE BUT NOT UNDER TITLE XVIII.—For provisions relating to limitations on payments to providers participating under the State plan under this title that do not have a contract or other agreement with a PACE provider establishing payment amounts for services covered under such plan (but not under title XVIII) when such services are furnished to enrollees of that PACE provider, see section 1902(a)(67).''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to services furnished on or after January 1, 2004.

SEC. 237. REIMBURSEMENT FOR FEDERALLY QUALIFIED HEALTH CENTERS PROVIDING SERVICES UNDER MA PLANS.

(a) REIMBURSEMENT.—Section 1833(a)(3) (42 U.S.C. 1395l(a)(3)) is amended to read as follows:

''(3) in the case of services described in section 1832(a)(2)(D)—

''(A) except as provided in subparagraph (B), the costs which are reasonable and related to the cost of furnishing such services or which are based on such other tests of reasonableness as the Secretary may prescribe in regulations, including those authorized under section 1861(v)(1)(A), less the amount a provider may charge as described in clause (ii) of section 1866(a)(2)(A), but in no case may the payment for such services (other than for items and services described in section 1861(s)(10)(A)) exceed 80 percent of such costs; or

''(B) with respect to the services described in clause (ii) of section 1832(a)(2)(D) that are furnished to an individual enrolled with a MA plan under part C pursuant to a written agreement described in section 1853(a)(4), the amount (if any) by which—

''(i) the amount of payment that would have otherwise been provided under subparagraph (A) (calculated as if '100 percent' were substituted for '80 percent' in such subparagraph) for such services if the individual had not been so enrolled; exceeds

''(ii) the amount of the payments received under such written agreement for such services (not including any financial incentives provided for in such agreement such as risk pool payments, bonuses, or withholds),

less the amount the Federally qualified health center may charge as described in section 1857(e)(3)(B);''.

(b) CONTINUATION OF MONTHLY PAYMENTS.—

(1) IN GENERAL.—Section 1853(a) (42 U.S.C. 1395w–23(a)) is amended by adding at the end the following new paragraph:

''(4) PAYMENT RULE FOR FEDERALLY QUALIFIED HEALTH CENTER SERVICES.—If an individual who is enrolled with an MA plan under this part receives a service from a Federally qualified health center that has a written agreement with the MA organization that offers such plan for providing such a service (including any agreement required under section 1857(e)(3))—

''(A) the Secretary shall pay the amount determined under section 1833(a)(3)(B) directly to the Federally qualified health center not less frequently than quarterly; and

''(B) the Secretary shall not reduce the amount of the monthly payments under this subsection as a result of the application of subparagraph (A).''.

(2) CONFORMING AMENDMENTS.—

(A) Section 1851(i) (42 U.S.C. 1395w–21(i)) is amended—

(i) in paragraph (1), by inserting ''1853(a)(4),'' after ''Subject to sections 1852(a)(5),''; and

(ii) in paragraph (2), by inserting ''1853(a)(4),'' after ''Subject to sections''.

(B) Section 1853(c)(5) is amended by striking ''subsections (a)(3)(C)(iii) and (i)'' and inserting ''subsections (a)(3)(C)(iii), (a)(4), and (i)''.

(c) ADDITIONAL CONTRACT REQUIREMENTS.—Section 1857(e) (42 U.S.C. 1395w–27(e)) is amended by adding at the end the following new paragraph:

''(3) AGREEMENTS WITH FEDERALLY QUALIFIED HEALTH CENTERS.—

''(A) PAYMENT LEVELS AND AMOUNTS.—A contract under this section with an MA organization shall require the organization to provide, in any written agreement described in section 1853(a)(4) between the organization and a Federally qualified health center, for a level and amount of payment to the Federally qualified health center for services provided by such health center that is not less than the level and amount of payment that the plan would make for such services if the services had been furnished by a entity providing similar services that was not a Federally qualified health center.

''(B) COST-SHARING.—Under the written agreement referred to in subparagraph (A), a Federally qualified health center must accept the payment amount referred to in such subparagraph plus the Federal payment provided for in section 1833(a)(3)(B) as payment in full for services covered by the agreement, except that such a health center may collect any amount of cost-sharing permitted under the contract under this section, so long as the amounts of any deductible, coinsurance, or copayment comply with the requirements under section 1854(e).''.

(d) SAFE HARBOR.—Section 1128B(b)(3) (42 U.S.C. 1320a–7b(b)(3)), as amended by section 101(f)(2), is amended—

(1) in subparagraph (F), by striking ''and'' after the semicolon at the end;

(2) in subparagraph (G), by striking the period at the end and inserting ''; and''; and

(3) by adding at the end the following new subparagraph:

''(H) any remuneration between a Federally qualified health center (or an entity controlled by such a health center) and an MA organization pursuant to a written agreement described in section 1853(a)(4).''.

(e) EFFECTIVE DATE.—The amendments made by this section shall apply to services provided on or after January 1, 2006, and contract years beginning on or after such date.

SEC. 238. INSTITUTE OF MEDICINE EVALUATION AND REPORT ON HEALTH CARE PERFORMANCE MEASURES.

(a) EVALUATION.—

(1) IN GENERAL.—Not later than the date that is 2 months after the date of the enactment of this Act, the Secretary shall enter into an arrangement under which the Institute of Medicine of the National Academy of Sciences (in this section referred to as the ''Institute'') shall conduct an evaluation of leading health care performance measures in the public and private sectors and options to implement policies that align performance with payment under the medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.).

(2) SPECIFIC MATTERS EVALUATED.—In conducting the evaluation under paragraph (1), the Institute shall—

(A) catalogue, review, and evaluate the validity of leading health care performance measures;

(B) catalogue and evaluate the success and utility of alternative performance incentive programs in public or private sector settings; and

(C) identify and prioritize options to implement policies that align performance with payment under the medicare program that indicate—

(i) the performance measurement set to be used and how that measurement set will be updated;

(ii) the payment policy that will reward performance; and

(iii) the key implementation issues (such as data and information technology requirements) that must be addressed.

(3) SCOPE OF HEALTH CARE PERFORMANCE MEASURES.—The health care performance measures described in paragraph (2)(A) shall encompass a variety of perspectives, including physicians, hospitals, other health care providers, health plans, purchasers, and patients.

(4) CONSULTATION WITH MEDPAC.—In evaluating the matters described in paragraph (2)(C), the Institute shall consult with the Medicare Payment Advisory Commission established under section 1805 of the Social Security Act (42 U.S.C. 1395b–6).

(b) REPORT.—Not later than the date that is 18 months after the date of enactment of this Act, the Institute shall submit to the Secretary and appropriate committees of jurisdiction of the Senate and House of Representatives a report on the evaluation conducted under subsection (a)(1) describing the findings of such evaluation and recommendations for an overall strategy and approach for aligning payment with performance, including options for updating performance measures, in the original medicare fee-for-service program under parts A and B of title XVIII of the Social Security Act, the Medicare Advantage program under part C of such title, and any other programs under such title XVIII.

(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary for purposes of conducting the evaluation and preparing the report required by this section.

Subtitle E—Comparative Cost Adjustment (CCA) Program

SEC. 241. COMPARATIVE COST ADJUSTMENT (CCA) PROGRAM.

(a) IN GENERAL.—Part C of title XVIII is amended by adding at the end the following new section:

''COMPARATIVE COST ADJUSTMENT (CCA) PROGRAM

''SEC. 1860C–1. (a) ESTABLISHMENT OF PROGRAM.—

''(1) IN GENERAL.—The Secretary shall establish a program under this section (in this section referred to as the 'CCA program') for the application of comparative cost adjustment in CCA areas selected under this section.

''(2) DURATION.—The CCA program shall begin January 1, 2010, and shall extend over a period of 6 years, and end on December 31, 2015.

''(3) REPORT.—Upon the completion of the CCA program, the Secretary shall submit a report to Congress. Such report shall include the following, with respect to both this part and the original medicare fee-for-service program:

''(A) An evaluation of the financial impact of the CCA program.

''(B) An evaluation of changes in access to physicians and other health care providers.

''(C) Beneficiary satisfaction.

''(D) Recommendations regarding any extension or expansion of the CCA program.

''(b) REQUIREMENTS FOR SELECTION OF CCA AREAS.—

''(1) CCA AREA DEFINED.—

''(A) IN GENERAL.—For purposes of this section, the term 'CCA area' means an MSA that meets the requirements of paragraph (2) and is selected by the Secretary under subsection (c).

''(B) MSA DEFINED.—For purposes of this section, the term 'MSA' means a Metropolitan Statistical Area (or such similar area as the Secretary recognizes).

''(2) REQUIREMENTS FOR CCA AREAS.—The requirements of this paragraph for an MSA to be a CCA area are as follows:

''(A) MA ENROLLMENT REQUIREMENT.—For the reference month (as defined under section 1858(f)(4)(B)) with respect to 2010, at least 25 percent of the total number of MA eligible individuals who reside in the MSA were enrolled in an MA local plan described in section 1851(a)(2)(A)(i).

''(B) 2 PLAN REQUIREMENT.—There will be offered in the MSA during the annual, coordinated election period under section 1851(e)(3)(B) before the beginning of 2010 at least 2 MA local plans described in section 1851(a)(2)(A)(i) (in addition to the fee-for-service program under parts A and B), each offered by a different MA organization and each of which met the minimum enrollment requirements of paragraph (1) of section 1857(b) (as applied without regard to paragraph (3) thereof) as of the reference month.

''(c) SELECTION OF CCA AREAS.—

''(1) GENERAL SELECTION CRITERIA.—The Secretary shall select CCA areas from among those MSAs qualifying under subsection (b) in a manner that—

''(A) seeks to maximize the opportunity to test the application of comparative cost adjustment under this title;

''(B) does not seek to maximize the number of MA eligible individuals who reside in such areas; and

''(C) provides for geographic diversity consistent with the criteria specified in paragraph (2).

''(2) SELECTION CRITERIA.—With respect to the selection of MSAs that qualify to be CCA areas under subsection (b), the following rules apply, to the maximum extent feasible:

''(A) MAXIMUM NUMBER.—The number of such MSAs selected may not exceed the lesser of (i) 6, or (ii) 25 percent of the number of MSAs that meet the requirement of subsection (b)(2)(A).

''(B) ONE OF 4 LARGEST AREAS BY POPULATION.—At least one such qualifying MSA shall be selected from among the 4 such qualifying MSAs with the largest total population of MA eligible individuals.

''(C) ONE OF 4 AREAS WITH LOWEST POPULATION DENSITY.—At least one such qualifying MSA shall be selected from among the 4 such qualifying MSAs with the lowest population density (as measured by residents per square mile or similar measure of density).

''(D) MULTISTATE AREA.—At least one such qualifying MSA shall be selected that includes a multi-State area. Such an MSA may be an MSA described in subparagraph (B) or (C).

''(E) LIMITATION WITHIN SAME GEOGRAPHIC REGION.—No more than 2 such MSAs shall be selected that are, in whole or in part, within the same geographic region (as specified by the Secretary) of the United States.

''(F) PRIORITY TO AREAS NOT WITHIN CERTAIN DEMONSTRATION PROJECTS.—Priority shall be provided for those qualifying MSAs that do not have a demonstration project in effect as of the date of the enactment of this section for medicare preferred provider organization plans under this part.

''(d) APPLICATION OF COMPARATIVE COST ADJUSTMENT.—

''(1) IN GENERAL.—In the case of a CCA area for a year—

''(A) for purposes of applying this part with respect to payment for MA local plans, any reference to an MA area-specific non-drug monthly benchmark amount shall be treated as a reference to such benchmark computed as if the CCA area-specific non-drug monthly benchmark amount (as defined in subsection (e)(1)) were substituted for the amount described in section 1853(j)(1)(A) for the CCA area and year involved, as phased in under paragraph (3); and

''(B) with respect to months in the year for individuals residing in the CCA area who are not enrolled in an MA plan, the amount of the monthly premium under section 1839 is subject to adjustment under subsection (f).

''(2) EXCLUSION OF MA LOCAL AREAS WITH FEWER THAN 2 ORGANIZATIONS OFFERING MA PLANS.—

''(A) IN GENERAL.—In no case shall an MA local area that is within an MSA be included as part of a CCA area unless for 2010 (and, except as provided in subparagraph (B), for a subsequent year) there is offered in each part of such MA local area at least 2 MA local plans described in section 1851(a)(2)(A)(i) each of which is offered by a different MA organization.

''(B) CONTINUATION.—If an MA local area meets the requirement of subparagraph (A) and is included in a CCA area for 2010, such local area shall continue to be included in such CCA area for a subsequent year notwithstanding that it no longer meets such requirement so long as there is at least one MA local plan described in section 1851(a)(2)(A)(i) that is offered in such local area.

''(3) PHASE-IN OF CCA BENCHMARK.—

''(A) IN GENERAL.—In applying this section for a year before 2013, paragraph (1)(A) shall be applied as if the phase-in fraction under subparagraph (B) of the CCA non-drug monthly benchmark amount for the year were substituted for such fraction of the MA area-specific non-drug monthly benchmark amount.

''(B) PHASE-IN FRACTION.—The phase-in fraction under this subparagraph is—

''(i) for 2010 ¼; and

''(ii) for a subsequent year is the phase-in fraction under this subparagraph for the previous year increased by ¼, but in no case more than 1.

''(e) COMPUTATION OF CCA BENCHMARK AMOUNT.—

''(1) CCA NON-DRUG MONTHLY BENCHMARK AMOUNT.—For purposes of this section, the term 'CCA non-drug monthly benchmark amount' means, with respect to a CCA area for a month in a year, the sum of the 2 components described in paragraph (2) for the area and year. The Secretary shall compute such benchmark amount for each such CCA area before the beginning of each annual, coordinated election period under section 1851(e)(3)(B) for each year (beginning with 2010) in which the CCA area is so selected.

''(2) 2 COMPONENTS.—For purposes of paragraph (1), the 2 components described in this paragraph for a CCA area and a year are the following:

''(A) MA LOCAL COMPONENT.—The product of the following:

''(i) WEIGHTED AVERAGE OF MEDICARE ADVANTAGE PLAN BIDS IN AREA.—The weighted average of the plan bids for the area and year (as determined under paragraph (3)(A)).

''(ii) NON-FFS MARKET SHARE.—1 minus the fee-for-service market share percentage, determined under paragraph (4) for the area and year.

''(B) FEE-FOR-SERVICE COMPONENT.—The product of the following:

''(i) FEE-FOR-SERVICE AREA-SPECIFIC NON-DRUG AMOUNT.—The fee-for-service area-specific non-drug amount (as defined in paragraph (5)) for the area and year.

''(ii) FEE-FOR-SERVICE MARKET SHARE.—The fee-for-service market share percentage, determined under paragraph (4) for the area and year.

''(3) DETERMINATION OF WEIGHTED AVERAGE MA BIDS FOR A CCA AREA.—

''(A) IN GENERAL.—For purposes of paragraph (2)(A)(i), the weighted average of plan bids for a CCA area and a year is, subject to subparagraph (D), the sum of the following products for MA local plans described in subparagraph (C) in the area and year:

''(i) MONTHLY MEDICARE ADVANTAGE STATUTORY NON-DRUG BID AMOUNT.—The accepted unadjusted MA statutory non-drug monthly bid amount.

''(ii) PLAN'S SHARE OF MEDICARE ADVANTAGE ENROLLMENT IN AREA.—The number of individuals described in subparagraph (B), divided by the total number of such individuals for all MA plans described in subparagraph (C) for that area and year.

''(B) COUNTING OF INDIVIDUALS.—The Secretary shall count, for each MA local plan described in subparagraph (C) for an area and year, the number of individuals who reside in the area and who were enrolled under such plan under this part during the reference month for that year.

''(C) EXCLUSION OF PLANS NOT OFFERED IN PREVIOUS YEAR.—For an area and year, the MA local plans described in this subparagraph are MA local plans described in section

1851(a)(2)(A)(i) that are offered in the area and year and were offered in the CCA area in the reference month.

''(D) COMPUTATION OF WEIGHTED AVERAGE OF PLAN BIDS.—In calculating the weighted average of plan bids for a CCA area under subparagraph (A)—

''(i) in the case of an MA local plan that has a service area only part of which is within such CCA area, the MA organization offering such plan shall submit a separate bid for such plan for the portion within such CCA area; and

''(ii) the Secretary shall adjust such separate bid (or, in the case of an MA local plan that has a service area entirely within such CCA area, the plan bid) as may be necessary to take into account differences between the service area of such plan within the CCA area and the entire CCA area and the distribution of plan enrollees of all MA local plans offered within the CCA area.

''(4) COMPUTATION OF FEE-FOR-SERVICE MARKET SHARE PERCENTAGE.—The Secretary shall determine, for a year and a CCA area, the proportion (in this subsection referred to as the 'fee-for-service market share percentage') equal to—

''(A) the total number of MA eligible individuals residing in such area who during the reference month for the year were not enrolled in any MA plan; divided by

''(B) the sum of such number and the total number of MA eligible individuals residing in such area who during such reference month were enrolled in an MA local plan described in section 1851(a)(2)(A)(i),

or, if greater, such proportion determined for individuals nationally.

''(5) FEE-FOR-SERVICE AREA-SPECIFIC NON-DRUG AMOUNT.—

''(A) IN GENERAL.—For purposes of paragraph (2)(B)(i) and subsection (f)(2)(A), subject to subparagraph (C), the term 'fee-for-service area-specific non-drug amount' means, for a CCA area and a year, the adjusted average per capita cost for such area and year involved, determined under section 1876(a)(4) and adjusted as appropriate for the purpose of risk adjustment for benefits under the original medicare fee-for-service program option for individuals entitled to benefits under part A and enrolled under part B who are not enrolled in an MA plan for the year, but adjusted to exclude costs attributable to payments under section 1886(h).

''(B) USE OF FULL RISK ADJUSTMENT TO STANDARDIZE FEE-FOR-SERVICE COSTS TO TYPICAL BENEFICIARY.—In determining the adjusted average per capita cost for an area and year under subparagraph (A), such costs shall be adjusted to fully take into account the demographic and health status risk factors established under section 1853(a)(1)(A)(iv) so that such per capita costs reflect the average costs for a typical beneficiary residing in the CCA area.

''(C) INCLUSION OF COSTS OF VA AND DOD MILITARY FACILITY SERVICES TO MEDICARE-ELIGIBLE BENEFICIARIES.—In determining the adjusted average per capita cost under subparagraph (A) for a year, such cost shall be adjusted to include the Secretary's estimate, on a per capita basis, of the amount of additional payments that would have been made in the area involved under this title if individuals entitled to benefits under this title had not received services from facilities of the Department of Veterans Affairs or the Department of Defense.

''(f) PREMIUM ADJUSTMENT.—

''(1) APPLICATION.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), in the case of an individual who is enrolled under part B, who resides in a CCA area, and who is not enrolled in an MA plan under this part, the monthly premium otherwise applied under part B (determined without regard to subsections (b), (f), and (i) of section 1839 or any adjustment under this subsection) shall be adjusted in accordance with paragraph (2), but only in the case of premiums for months during the period in which the CCA program under this section for such area is in effect.

''(B) NO PREMIUM ADJUSTMENT FOR SUBSIDY ELIGIBLE BENEFICIARIES.—No premium adjustment shall be made under this subsection for a premium for a month if the individual is determined to be a subsidy eligible individual (as defined in section 1860D–14(a)(3)(A)) for the month.

''(2) AMOUNT OF ADJUSTMENT.—

''(A) IN GENERAL.—Under this paragraph, subject to the exemption under paragraph (1)(B) and the limitation under subparagraph (B), if the fee-for-service area-specific non-drug amount (as defined in section (e)(5)) for a CCA area in which an individual resides for a month—

''(i) does not exceed the CCA non-drug monthly benchmark amount (as determined under subsection (e)(1)) for such area and month, the amount of the premium for the individual for the month shall be reduced, by an amount equal to 75 percent of the amount by which such CCA benchmark exceeds such fee-for-service area-specific non-drug amount; or

''(ii) exceeds such CCA non-drug benchmark, the amount of the premium for the individual for the month shall be adjusted to ensure, that—

''(I) the sum of the amount of the adjusted premium and the CCA non-drug benchmark for the area; is equal to

''(II) the sum of the unadjusted premium plus the amount of such fee-for-service area-specific non-drug amount for the area.

''(B) LIMITATION.—In no case shall the actual amount of an adjustment under subparagraph (A) for an area and month in a year result in an adjustment that exceeds the maximum adjustment permitted under subparagraph (C) for the area and year, or, if less, the maximum annual adjustment permitted under subparagraph (D) for the area and year.

''(C) PHASE-IN OF ADJUSTMENT.—The amount of an adjustment under subparagraph (A) for a CCA area and year may not exceed the product of the phase-in fraction for the year under subsection (d)(3)(B) multiplied by the amount of the adjustment otherwise computed under subparagraph (A) for the area and year, determined without regard to this subparagraph and subparagraph (D).

''(D) 5-PERCENT LIMITATION ON ADJUSTMENT.—The amount of the adjustment under this subsection for months in a year shall not exceed 5 percent of the amount of the monthly premium amount determined for months in the year under section 1839 without regard to subsections (b), (f), and (i) of such section and this subsection.''.

(b) CONFORMING AMENDMENTS.—

(1) MA LOCAL PLANS.—

(A) Section 1853(j)(1)(A) (42 U.S.C. 1395w–23(j)(1)(A)), as added by section 222(d), is amended by inserting ''subject to section 1860C–1(d)(2)(A),'' after ''within an MA local area,''.

(B) Section 1853(b)(1)(B), as amended by section 222(f)(1), is amended by adding at the end the following new clause:

''(iii) BENCHMARK ANNOUNCEMENT FOR CCA LOCAL AREAS.—The Secretary shall determine, and shall announce (in a manner intended to provide notice to interested parties), on a timely basis before the calendar year concerned, with respect to each CCA area (as defined in section 1860C–1(b)(1)(A)), the CCA non-drug monthly benchmark amount under section 1860C–1(e)(1) for that area for the year involved.''.

(2) PREMIUM ADJUSTMENT.—

(A) Section 1839 (42 U.S.C. 1395r) is amended by adding at the end the following new subsection:

''(h) POTENTIAL APPLICATION OF COMPARATIVE COST ADJUSTMENT IN CCA AREAS.—

''(1) IN GENERAL.—Certain individuals who are residing in a CCA area under section 1860C–1 who are not enrolled in an MA plan under part C may be subject to a premium adjustment under subsection (f) of such section for months in which the CCA program under such section is in effect in such area.

''(2) NO EFFECT ON LATE ENROLLMENT PENALTY OR INCOME-RELATED ADJUSTMENT IN SUBSIDIES.—Nothing in this subsection or section 1860C–1(f) shall be construed as affecting the amount of any premium adjustment under subsection (b) or (i). Subsection (f) shall be applied without regard to any premium adjustment referred to in paragraph (1).

''(3) IMPLEMENTATION.—In order to carry out a premium adjustment under this subsection and section 1860C–1(f) (insofar as it is effected through the manner of collection of premiums under section 1840(a)), the Secretary shall transmit to the Commissioner of Social Security—

''(A) at the beginning of each year, the name, social security account number, and the amount of the premium adjustment (if any) for each individual enrolled under this part for each month during the year; and

''(B) periodically throughout the year, information to update the information previously transmitted under this paragraph for the year.''.

(B) Section 1844(c) (42 U.S.C. 1395w(c)) is amended by inserting ''and without regard to any premium adjustment effected under sections 1839(h) and 1860C–1(f)'' before the period at the end.

(c) NO CHANGE IN MEDICARE'S DEFINED BENEFIT PACKAGE.—Nothing in this part (or the amendments made by this part) shall be construed as changing the entitlement to defined benefits under parts A and B of title XVIII of the Social Security Act.

TITLE III—COMBATTING WASTE, FRAUD, AND ABUSE

SEC. 301. MEDICARE SECONDARY PAYOR (MSP) PROVISIONS.

(a) TECHNICAL AMENDMENT CONCERNING SECRETARY'S AUTHORITY TO MAKE CONDITIONAL PAYMENT WHEN CERTAIN PRIMARY PLANS DO NOT PAY PROMPTLY.—Section 1862(b)(2) (42 U.S.C. 1395y(b)(2)) is amended—

(1) in subparagraph (A)(ii), by striking ''promptly (as determined in accordance with regulations)''; and

(2) in subparagraph (B)—

(A) by redesignating clauses (i) through (v) as clauses (ii) through (vi), respectively; and

(B) by inserting before clause (ii), as so redesignated, the following new clause:

''(i) AUTHORITY TO MAKE CONDITIONAL PAYMENT.—The Secretary may make payment under this title with respect to an item or service if a primary plan described in subparagraph (A)(ii) has not made or cannot reasonably be expected to make payment with respect to such item or service promptly (as determined in accordance with regulations). Any such payment by the Secretary shall be conditioned on reimbursement to the appropriate Trust Fund in accordance with the succeeding provisions of this subsection.''.

(b) CLARIFYING AMENDMENTS TO CONDITIONAL PAYMENT PROVISIONS.—Section 1862(b)(2) (42 U.S.C. 1395y(b)(2)), as amended by subsection (a), is amended—

(1) in subparagraph (A), in the matter following clause (ii), by inserting the following sentence at the end: ''An entity that engages in a business, trade, or profession shall be deemed to have a self-insured plan if it carries its own risk (whether by a failure to obtain insurance, or otherwise) in whole or in part.'';

(2) in subparagraph (B)(ii), as redesignated by subsection (a)(2)(A)—

(A) by striking the first sentence and inserting the following: ''A primary plan, and an entity that receives payment from a primary plan, shall reimburse the appropriate Trust Fund for any payment made by the Secretary under this title with respect to an item or service if it is demonstrated that such primary plan has or had a responsibility to make payment with respect to such item or service. A primary plan's

responsibility for such payment may be demonstrated by a judgment, a payment conditioned upon the recipient's compromise, waiver, or release (whether or not there is a determination or admission of liability) of payment for items or services included in a claim against the primary plan or the primary plan's insured, or by other means.''; and

(B) in the final sentence, by striking ''on the date such notice or other information is received'' and inserting ''on the date notice of, or information related to, a primary plan's responsibility for such payment or other information is received''; and

(3) in subparagraph (B)(iii), as redesignated by subsection (a)(2)(A), by striking the first sentence and inserting the following: ''In order to recover payment made under this title for an item or service, the United States may bring an action against any or all entities that are or were required or responsible (directly, as an insurer or self-insurer, as a third-party administrator, as an employer that sponsors or contributes to a group health plan, or large group health plan, or otherwise) to make payment with respect to the same item or service (or any portion thereof) under a primary plan. The United States may, in accordance with paragraph (3)(A) collect double damages against any such entity. In addition, the United States may recover under this clause from any entity that has received payment from a primary plan or from the proceeds of a primary plan's payment to any entity.''.

(c) CLERICAL AMENDMENTS.—Section 1862(b) (42 U.S.C. 1395y(b)) is amended—

(1) in paragraph (1)(A), by moving the indentation of clauses (ii) through (v) 2 ems to the left; and

(2) in paragraph (3)(A), by striking ''such'' before ''paragraphs''.

(d) EFFECTIVE DATES.—The amendments made by this section shall be effective—

(1) in the case of subsection (a), as if included in the enactment of title III of the Medicare and Medicaid Budget Reconciliation Amendments of 1984 (Public Law 98–369); and

(2) in the case of subsections (b) and (c), as if included in the enactment of section 953 of the Omnibus Reconciliation Act of 1980 (Public Law 96–499; 94 Stat. 2647).

SEC. 302. PAYMENT FOR DURABLE MEDICAL EQUIPMENT; COMPETITIVE ACQUISITION OF CERTAIN ITEMS AND SERVICES.

(a) QUALITY ENHANCEMENT AND FRAUD REDUCTION.—

(1) ESTABLISHMENT OF QUALITY STANDARDS AND ACCREDITATION REQUIREMENTS FOR DURABLE MEDICAL EQUIPMENT SUPPLIERS.—Section 1834(a) (42 U.S.C. 1395m(a)) is amended—

(A) by transferring paragraph (17), as added by section 4551(c)(1) of the Balanced Budget Act of 1997 (111 Stat. 458), to the end of such section and redesignating such paragraph as paragraph (19); and

(B) by adding at the end the following new paragraph:

''(20) IDENTIFICATION OF QUALITY STANDARDS.—

''(A) IN GENERAL.—Subject to subparagraph (C), the Secretary shall establish and implement quality standards for suppliers of items and services described in subparagraph (D) to be applied by recognized independent accreditation organizations (as designated under subparagraph (B)) and with which such suppliers shall be required to comply in order to—

''(i) furnish any such item or service for which payment is made under this part; and

''(ii) receive or retain a provider or supplier number used to submit claims for reimbursement for any such item or service for which payment may be made under this title.

''(B) DESIGNATION OF INDEPENDENT ACCREDITATION ORGANIZATIONS.—Not later than the date that is 1 year after the date on which the Secretary implements the quality standards under subparagraph (A), notwithstanding section 1865(b), the Secretary shall designate and approve one or more independent accreditation organizations for purposes of such subparagraph.

''(C) QUALITY STANDARDS.—The quality standards described in subparagraph (A) may not be less stringent than the quality standards that would otherwise apply if this paragraph did not apply and shall include consumer services standards.

''(D) ITEMS AND SERVICES DESCRIBED.—The items and services described in this subparagraph are the following items and services, as the Secretary determines appropriate:

''(i) Covered items (as defined in paragraph (13)) for which payment may otherwise be made under this subsection.

''(ii) Prosthetic devices and orthotics and prosthetics described in section 1834(h)(4).

''(iii) Items and services described in section 1842(s)(2).

''(E) IMPLEMENTATION.—The Secretary may establish by program instruction or otherwise the quality standards under this paragraph, after consultation with representatives of relevant parties. Such standards shall be applied prospectively and shall be published on the Internet website of the Centers for Medicare & Medicaid Services.''.

(2) ESTABLISHMENT OF CLINICAL CONDITIONS OF COVERAGE STANDARDS FOR ITEMS OF DURABLE MEDICAL EQUIPMENT.—Section 1834(a)(1) (42 U.S.C. 1395m(a)(1)) is amended by adding at the end the following new subparagraph:

''(E) CLINICAL CONDITIONS FOR COVERAGE.—

''(i) IN GENERAL.—The Secretary shall establish standards for clinical conditions for payment for covered items under this subsection.

''(ii) REQUIREMENTS.—The standards established under clause (i) shall include the specification of types or classes of covered items that require, as a condition of payment under this subsection, a face-to-face examination of the individual by a physician (as defined in section 1861(r)(1)), a physician assistant, nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1861(aa)(5)) and a prescription for the item.

''(iii) PRIORITY OF ESTABLISHMENT OF STANDARDS.—In establishing the standards under this subparagraph, the Secretary shall first establish standards for those covered items for which the Secretary determines there has been a proliferation of use, consistent findings of charges for covered items that are not delivered, or consistent findings of falsification of documentation to provide for payment of such covered items under this part.

''(iv) STANDARDS FOR POWER WHEELCHAIRS.—Effective on the date of the enactment of this subparagraph, in the case of a covered item consisting of a motorized or power wheelchair for an individual, payment may not be made for such covered item unless a physician (as defined in section 1861(r)(1)), a physician assistant, nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1861(aa)(5)) has conducted a face-to-face examination of the individual and written a prescription for the item.

''(v) LIMITATION ON PAYMENT FOR COVERED ITEMS.—Payment may not be made for a covered item under this subsection unless the item meets any standards established under this subparagraph for clinical condition of coverage.''.

(b) COMPETITIVE ACQUISITION.—

(1) IN GENERAL.—Section 1847 (42 U.S.C. 1395w–3) is amended to read as follows:

''COMPETITIVE ACQUISITION OF CERTAIN ITEMS AND SERVICES

''SEC. 1847. (a) ESTABLISHMENT OF COMPETITIVE ACQUISITION PROGRAMS.—

''(1) IMPLEMENTATION OF PROGRAMS.—

''(A) IN GENERAL.—The Secretary shall establish and implement programs under which competitive acquisition areas are established throughout the United States for contract award purposes for the furnishing under this part of competitively priced items and services (described in paragraph (2)) for which payment is made under this part. Such areas may differ for different items and services.

''(B) PHASED-IN IMPLEMENTATION.—The programs—

''(i) shall be phased in among competitive acquisition areas in a manner so that the competition under the programs occurs in—

''(I) 10 of the largest metropolitan statistical areas in 2007;

''(II) 80 of the largest metropolitan statistical areas in 2009; and

''(III) additional areas after 2009; and

''(ii) may be phased in first among the highest cost and highest volume items and services or those items and services that the Secretary determines have the largest savings potential.

''(C) WAIVER OF CERTAIN PROVISIONS.—In carrying out the programs, the Secretary may waive such provisions of the Federal Acquisition Regulation as are necessary for the efficient implementation of this section, other than provisions relating to confidentiality of information and such other provisions as the Secretary determines appropriate.

''(2) ITEMS AND SERVICES DESCRIBED.—The items and services referred to in paragraph (1) are the following:

''(A) DURABLE MEDICAL EQUIPMENT AND MEDICAL SUPPLIES.—Covered items (as defined in section 1834(a)(13)) for which payment would otherwise be made under section 1834(a), including items used in infusion and drugs (other than inhalation drugs) and supplies used in conjunction with durable medical equipment, but excluding class III devices under the Federal Food, Drug, and Cosmetic Act.

''(B) OTHER EQUIPMENT AND SUPPLIES.—Items and services described in section 1842(s)(2)(D), other than parenteral nutrients, equipment, and supplies.

''(C) OFF-THE-SHELF ORTHOTICS.—Orthotics described in section 1861(s)(9) for which payment would otherwise be made under section 1834(h) which require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual.

''(3) EXCEPTION AUTHORITY.—In carrying out the programs under this section, the Secretary may exempt—

''(A) rural areas and areas with low population density within urban areas that are not competitive, unless there is a significant national market through mail order for a particular item or service; and

''(B) items and services for which the application of competitive acquisition is not likely to result in significant savings.

''(4) SPECIAL RULE FOR CERTAIN RENTED ITEMS OF DURABLE MEDICAL EQUIPMENT AND OXYGEN.—In the case of a covered item for which payment is made on a rental basis under section 1834(a) and in the case of payment for oxygen under section 1834(a)(5), the Secretary shall establish a process by which rental agreements for the covered items and supply arrangements with oxygen suppliers entered into before the application of the competitive acquisition program under this section for the item may be continued notwithstanding this section. In the case of any such continuation, the supplier involved shall provide for appropriate servicing and replacement, as required under section 1834(a).

''(5) PHYSICIAN AUTHORIZATION.—

''(A) IN GENERAL.—With respect to items or services included within a particular HCPCS code, the Secretary may establish a process for certain items and services under which a physician may prescribe a particular brand or mode of delivery of an item or service within such code if the physician determines that use of the particular item or service would avoid an adverse medical outcome on the individual, as determined by the Secretary.

''(B) NO EFFECT ON PAYMENT AMOUNT.—A prescription under subparagraph (A) shall not affect the amount of payment otherwise applicable for the item or service under the code involved.

''(6) APPLICATION.—For each competitive acquisition area in which the program is implemented under this subsection with respect to items and services, the payment basis determined under the competition conducted under subsection (b) shall be substituted for the payment basis otherwise applied under section 1834(a), section 1834(h), or section 1842(s), as appropriate.

''(b) PROGRAM REQUIREMENTS.—

''(1) IN GENERAL.—The Secretary shall conduct a competition among entities supplying items and services described in subsection (a)(2) for each competitive acquisition area in which the program is implemented under subsection (a) with respect to such items and services.

''(2) CONDITIONS FOR AWARDING CONTRACT.—

''(A) IN GENERAL.—The Secretary may not award a contract to any entity under the competition conducted in an competitive acquisition area pursuant to paragraph (1) to furnish such items or services unless the Secretary finds all of the following:

''(i) The entity meets applicable quality standards specified by the Secretary under section 1834(a)(20).

''(ii) The entity meets applicable financial standards specified by the Secretary, taking into account the needs of small providers.

''(iii) The total amounts to be paid to contractors in a competitive acquisition area are expected to be less than the total amounts that would otherwise be paid.

''(iv) Access of individuals to a choice of multiple suppliers in the area is maintained.

''(B) TIMELY IMPLEMENTATION OF PROGRAM.—Any delay in the implementation of quality standards under section 1834(a)(20) or delay in the receipt of advice from the program oversight committee established under subsection (c) shall not delay the implementation of the competitive acquisition program under this section.

''(3) CONTENTS OF CONTRACT.—

''(A) IN GENERAL.—A contract entered into with an entity under the competition conducted pursuant to paragraph (1) is subject to terms and conditions that the Secretary may specify.

''(B) TERM OF CONTRACTS.—The Secretary shall recompete contracts under this section not less often than once every 3 years.

''(4) LIMIT ON NUMBER OF CONTRACTORS.—

''(A) IN GENERAL.—The Secretary may limit the number of contractors in a competitive acquisition area to the number needed to meet projected demand for items and services covered under the contracts. In awarding contracts, the Secretary shall take into account the ability of bidding entities to furnish items or services in sufficient quantities to meet the anticipated needs of individuals for such items or services in the geographic area covered under the contract on a timely basis.

''(B) MULTIPLE WINNERS.—The Secretary shall award contracts to multiple entities submitting bids in each area for an item or service.

''(5) PAYMENT.—

''(A) IN GENERAL.—Payment under this part for competitively priced items and services described in subsection (a)(2) shall be based on bids submitted and accepted under this section for such items and services. Based on such bids the Secretary shall determine a single payment amount for each item or service in each competitive acquisition area.

''(B) REDUCED BENEFICIARY COST-SHARING.—

''(i) APPLICATION OF COINSURANCE.—Payment under this section for items and services shall be in an amount equal to 80 percent of the payment basis described in subparagraph (A).

''(ii) APPLICATION OF DEDUCTIBLE.—Before applying clause (i), the individual shall be required to meet the deductible described in section 1833(b).

''(C) PAYMENT ON ASSIGNMENT-RELATED BASIS.—Payment for any item or service furnished by the entity may only be made under this section on an assignment-related basis.

''(D) CONSTRUCTION.—Nothing in this section shall be construed as precluding the use of an advanced beneficiary notice with respect to a competitively priced item and service.

''(6) PARTICIPATING CONTRACTORS.—

''(A) IN GENERAL.—Except as provided in subsection (a)(4), payment shall not be made for items and services described in subsection (a)(2) furnished by a contractor and for which competition is conducted under this section unless—

''(i) the contractor has submitted a bid for such items and services under this section; and

''(ii) the Secretary has awarded a contract to the contractor for such items and services under this section.

''(B) BID DEFINED.—In this section, the term 'bid' means an offer to furnish an item or service for a particular price and time period that includes, where appropriate, any services that are attendant to the furnishing of the item or service.

''(C) RULES FOR MERGERS AND ACQUISITIONS.—In applying subparagraph (A) to a contractor, the contractor shall include a successor entity in the case of a merger or acquisition, if the successor entity assumes such contract along with any liabilities that may have occurred thereunder.

''(D) PROTECTION OF SMALL SUPPLIERS.—In developing procedures relating to bids and the awarding of contracts under this section, the Secretary shall take appropriate steps to ensure that small suppliers of items and services have an opportunity to be considered for participation in the program under this section.

''(7) CONSIDERATION IN DETERMINING CATEGORIES FOR BIDS.—The Secretary may consider the clinical efficiency and value of specific items within codes, including whether some items have a greater therapeutic advantage to individuals.

''(8) AUTHORITY TO CONTRACT FOR EDUCATION, MONITORING, OUTREACH, AND COMPLAINT SERVICES.—The Secretary may enter into contracts with appropriate entities to address complaints from individuals who receive items and services from an entity with a contract under this section and to conduct appropriate education of and outreach to such individuals and monitoring quality of services with respect to the program.

''(9) AUTHORITY TO CONTRACT FOR IMPLEMENTATION.—The Secretary may contract with appropriate entities to implement the competitive bidding program under this section.

''(10) NO ADMINISTRATIVE OR JUDICIAL REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of—

''(A) the establishment of payment amounts under paragraph (5);

''(B) the awarding of contracts under this section;

''(C) the designation of competitive acquisition areas under subsection (a)(1)(A);

''(D) the phased-in implementation under subsection (a)(1)(B);

''(E) the selection of items and services for competitive acquisition under subsection (a)(2); or

''(F) the bidding structure and number of contractors selected under this section.

''(c) PROGRAM ADVISORY AND OVERSIGHT COMMITTEE.—

''(1) ESTABLISHMENT.—The Secretary shall establish a Program Advisory and Oversight Committee (hereinafter in this section referred to as the 'Committee').

''(2) MEMBERSHIP; TERMS.—The Committee shall consist of such members as the Secretary may appoint who shall serve for such term as the Secretary may specify.

''(3) DUTIES.—

''(A) ADVICE.—The Committee shall provide advice to the Secretary with respect to the following functions:

''(i) The implementation of the program under this section.

''(ii) The establishment of financial standards for purposes of subsection (b)(2)(A)(ii).

''(iii) The establishment of requirements for collection of data for the efficient management of the program.

''(iv) The development of proposals for efficient interaction among manufacturers, providers of services, suppliers (as defined in section 1861(d)), and individuals.

''(v) The establishment of quality standards under section 1834(a)(20).

''(B) ADDITIONAL DUTIES.—The Committee shall perform such additional functions to assist the Secretary in carrying out this section as the Secretary may specify.

''(4) INAPPLICABILITY OF FACA.—The provisions of the Federal Advisory Committee Act (5 U.S.C. App.) shall not apply.

''(5) TERMINATION.—The Committee shall terminate on December 31, 2009.

''(d) REPORT.—Not later than July 1, 2009, the Secretary shall submit to Congress a report on the programs under this section. The report shall include information on savings, reductions in cost-sharing, access to and quality of items and services, and satisfaction of individuals.

''(e) DEMONSTRATION PROJECT FOR CLINICAL LABORATORY SERVICES.—

''(1) IN GENERAL.—The Secretary shall conduct a demonstration project on the application of competitive acquisition under this section to clinical diagnostic laboratory tests—

''(A) for which payment would otherwise be made under section 1833(h) (other than for pap smear laboratory tests under paragraph (7) of such section) or section 1834(d)(1) (relating to colorectal cancer screening tests); and

''(B) which are furnished by entities that did not have a face-to-face encounter with the individual.

''(2) TERMS AND CONDITIONS.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), such project shall be under the same conditions as are applicable to items and services described in subsection (a)(2), excluding subsection (b)(5)(B) and other conditions as the Secretary determines to be appropriate.

''(B) APPLICATION OF CLIA QUALITY STANDARDS.—The quality standards established by the Secretary under section 353 of the Public Health Service Act for clinical diagnostic laboratory tests shall apply to such tests under the demonstration project under this section in lieu of quality standards described in subsection (b)(2)(A)(i).

''(3) REPORT.—The Secretary shall submit to Congress—

''(A) an initial report on the project not later than December 31, 2005; and

''(B) such progress and final reports on the project after such date as the Secretary determines appropriate.''.

(2) CONFORMING AMENDMENTS.—Section 1833(a)(1) (42 U.S.C. 1395l(a)(1)) is amended—

(A) by striking ''and (U)'' and inserting ''(U)'';

(B) by inserting before the semicolon at the end the following: '', and (V) notwithstanding subparagraphs (I) (relating to durable medical equipment), (M) (relating to prosthetic devices and orthotics and prosthetics), and (Q) (relating to 1842(s) items), with respect to competitively priced items and services (described in section 1847(a)(2)) that are furnished in a competitive area, the amounts paid shall be the amounts described in section 1847(b)(5)''; and

(C) in clause (D)—

(i) by striking ''or (ii)'' and inserting ''(ii)''; and

(ii) by adding at the end the following: ''or (iii) on the basis of a rate established under a demonstration project under section 1847(e), the amount paid shall be equal to 100 percent of such rate,''.

(3) GAO REPORT ON IMPACT OF COMPETITIVE ACQUISITION ON SUPPLIERS.—

(A) STUDY.—The Comptroller General of the United States shall conduct a study on the impact of competitive acquisition of durable medical equipment under section 1847 of the Social Security Act, as amended by paragraph (1), on suppliers and manufacturers of such equipment and on patients. Such study shall specifically examine the impact of such competitive acquisition on access to, and quality of, such equipment and service related to such equipment.

(B) REPORT.—Not later than January 1, 2009, the Comptroller General shall submit to Congress a report on the study conducted under subparagraph (A) and shall include in the report such recommendations as the Comptroller General determines appropriate.

(c) TRANSITIONAL FREEZE.—

(1) DME.—

(A) IN GENERAL.—Section 1834(a)(14) (42 U.S.C. 1395m(a)(14)) is amended—

(i) in subparagraph (E), by striking ''and'' at the end;

(ii) in subparagraph (F)—

(I) by striking ''a subsequent year'' and inserting ''2003''; and

(II) by striking ''the previous year.'' and inserting ''2002;''; and

(iii) by adding at the end the following new subparagraphs:

''(G) for 2004 through 2006—

''(i) subject to clause (ii), in the case of class III medical devices described in section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(c)(1)(C)), the percentage increase described in subparagraph (B) for the year involved; and

''(ii) in the case of covered items not described in clause (i), 0 percentage points;

''(H) for 2007—

''(i) subject to clause (ii), in the case of class III medical devices described in section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(c)(1)(C)), the percentage change determined by the Secretary to be appropriate taking into account recommendations contained in the report of the Comptroller General of the United States under section 302(c)(1)(B) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003; and

''(ii) in the case of covered items not described in clause (i), 0 percentage points; and

''(I) for 2008—

''(i) subject to clause (ii), in the case of class III medical devices described in section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(c)(1)(C)), the percentage increase described in subparagraph (B) (as applied to the payment amount for 2007 determined after the application of the percentage change under subparagraph (H)(i)); and

''(ii) in the case of covered items not described in clause (i), 0 percentage points; and

''(J) for a subsequent year, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June of the previous year.''.

(B) GAO REPORT ON CLASS III MEDICAL DEVICES.—Not later than March 1, 2006, the Comptroller General of the United States shall submit to Congress, and transmit to the Secretary, a report containing recommendations on the appropriate update percentage under section 1834(a)(14) of the Social Security Act (42 U.S.C. 1395m(a)(14)) for class III medical devices described in section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(a)(1)(C)) furnished to medicare beneficiaries during 2007 and 2008.

(2) PAYMENT RULE FOR SPECIFIED ITEMS.—Section 1834(a) (42 U.S.C. 1395m(a)), as amended by subsection (a), is further amended by adding at the end the following new paragraph:

''(21) SPECIAL PAYMENT RULE FOR SPECIFIED ITEMS AND SUPPLIES.—

''(A) IN GENERAL.—Notwithstanding the preceding provisions of this subsection, for specified items and supplies (described in subparagraph (B)) furnished during 2005, the payment amount otherwise determined under this subsection for such specified items and supplies shall be reduced by the percentage difference between—

''(i) the amount of payment otherwise determined for the specified item or supply under this subsection for 2002, and

''(ii) the amount of payment for the specified item or supply under chapter 89 of title 5, United States Code, as identified in the column entitled 'Median FEHP Price' in the table entitled 'SUMMARY OF MEDICARE PRICES COMPARED TO VA, MEDICAID, RETAIL, AND FEHP PRICES FOR 16 ITEMS' included in the Testimony of the Inspector General before the Senate Committee on Appropriations, June 12, 2002, or any subsequent report by the Inspector General.

''(B) SPECIFIED ITEM OR SUPPLY DESCRIBED.—For purposes of subparagraph (A), a specified item or supply means oxygen and oxygen equipment, standard wheelchairs (including standard power wheelchairs), nebulizers, diabetic supplies consisting of lancets and testing strips, hospital beds, and air mattresses, but only if the HCPCS code for the item or supply is identified in a table referred to in subparagraph (A)(ii).

''(C) APPLICATION OF UPDATE TO SPECIAL PAYMENT AMOUNT.—The covered item update under paragraph (14) for specified items and supplies for 2006 and each subsequent year shall be applied to the payment amount under subparagraph (A) unless payment is made for such items and supplies under section 1847.''.

(3) PROSTHETIC DEVICES AND ORTHOTICS AND PROSTHETICS.—Section 1834(h)(4)(A) (42 U.S.C. 1395m(h)(4)(A)) is amended—

(A) in clause (vii), by striking ''and'' at the end;

(B) in clause (viii), by striking ''a subsequent year'' and inserting ''2003''; and

(C) by adding at the end the following new clauses:

''(ix) for 2004, 2005, and 2006, 0 percent; and

''(x) for a subsequent year, the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year;''.

(d) CONFORMING AMENDMENTS.—

(1) DURABLE MEDICAL EQUIPMENT; LIMITATION OF INHERENT REASONABLENESS AUTHORITY.—Section 1834(a) (42 U.S.C. 1395m(a)) is amended—

(A) in paragraph (1)(B), by striking ''The payment basis'' and inserting ''Subject to subparagraph (F)(i), the payment basis'';

(B) in paragraph (1)(C), by striking ''This subsection'' and inserting ''Subject to subparagraph (F)(ii), this subsection'';

(C) by adding at the end of paragraph (1) the following new subparagraph:

''(F) APPLICATION OF COMPETITIVE ACQUISITION; LIMITATION OF INHERENT REASONABLENESS AUTHORITY.—In the case of covered items furnished on or after January 1, 2009, that are included in a competitive acquisition program in a competitive acquisition area under section 1847(a)—

''(i) the payment basis under this subsection for such items and services furnished in such area shall be the payment basis determined under such competitive acquisition program; and

''(ii) the Secretary may use information on the payment determined under such competitive acquisition programs to adjust the payment amount otherwise recognized under subparagraph (B)(ii) for an area that is not a competitive acquisition area under section 1847 and in the case of such adjustment, paragraph (10)(B) shall not be applied.''; and

(D) in paragraph (10)(B), by inserting ''in an area and with respect to covered items and services for which the Secretary does not make a payment amount adjustment under paragraph (1)(F)'' after ''under this subsection''.

(2) OFF-THE-SHELF ORTHOTICS; LIMITATION OF INHERENT REASONABLENESS AUTHORITY.—Section 1834(h) (42 U.S.C. 1395m(h)) is amended—

(A) in paragraph (1)(B), by striking ''and (E)'' and inserting '', (E), and (H)(i)'';

(B) in paragraph (1)(D), by striking ''This subsection'' and inserting ''Subject to subparagraph (H)(ii), this subsection''; and

(C) by adding at the end of paragraph (1) the following new subparagraph:

''(H) APPLICATION OF COMPETITIVE ACQUISITION TO ORTHOTICS; LIMITATION OF INHERENT REASONABLENESS AUTHORITY.—In the case of orthotics described in paragraph (2)(C) of section 1847(a) furnished on or after January 1, 2009, that are included in a competitive acquisition program in a competitive acquisition area under such section—

''(i) the payment basis under this subsection for such orthotics furnished in such area shall be the payment basis determined under such competitive acquisition program; and

''(ii) the Secretary may use information on the payment determined under such competitive acquisition programs to adjust the payment amount otherwise recognized under subparagraph (B)(ii) for an area that is not a competitive acquisition area under section 1847, and in the case of such adjustment, paragraphs (8) and (9) of section 1842(b) shall not be applied.''.

(3) OTHER ITEMS AND SERVICES; LIMITATION OF INHERENT REASONABLENESS AUTHORITY.—Section 1842(s) (42 U.S.C. 1395u(s)) is amended—

(A) in the first sentence of paragraph (1), by striking ''The Secretary'' and inserting ''Subject to paragraph (3), the Secretary''; and

(B) by adding at the end the following new paragraph:

''(3) In the case of items and services described in paragraph (2)(D) that are included in a competitive acquisition program in a competitive acquisition area under section 1847(a)—

''(A) the payment basis under this subsection for such items and services furnished in such area shall be the payment basis determined under such competitive acquisition program; and

''(B) the Secretary may use information on the payment determined under such competitive acquisition programs to adjust the payment amount otherwise applicable under paragraph (1) for an area that is not a competitive acquisition area under section 1847, and in the case of such adjustment, paragraphs (8) and (9) of section 1842(b) shall not be applied.''.

(e) REPORT ON ACTIVITIES OF SUPPLIERS.—The Inspector General of the Department of Health and Human Services shall conduct a study to determine the extent to which (if any) suppliers of covered items of durable medical equipment that are subject to the competitive acquisition program under section 1847 of the Social Security Act, as amended by subsection (a), are soliciting physicians to prescribe certain brands or modes of delivery of covered items based on profitability. Not later than July 1, 2009, the Inspector General shall submit to Congress a report on such study.

SEC. 303. PAYMENT REFORM FOR COVERED OUTPATIENT DRUGS AND BIOLOGICALS.

(a) ADJUSTMENT TO PHYSICIAN FEE SCHEDULE.—

(1) ADJUSTMENT IN PRACTICE EXPENSE RELATIVE VALUE UNITS.—Section 1848(c)(2) (42 U.S.C. 1395w–4(c)(2)) is amended—

(A) in subparagraph (B)—

(i) in clause (ii)(II), by striking ''The adjustments'' and inserting ''Subject to clause (iv), the adjustments''; and

(ii) by adding at the end of subparagraph (B), the following new clause:

''(iv) EXEMPTION FROM BUDGET NEUTRALITY.—The additional expenditures attributable to—

''(I) subparagraph (H) shall not be taken into account in applying clause (ii)(II) for 2004;

''(II) subparagraph (I) insofar as it relates to a physician fee schedule for 2005 or 2006 shall not be taken into account in applying clause (ii)(II) for drug administration services under the fee schedule for such year for a specialty described in subparagraph (I)(ii)(II); and

''(III) subparagraph (J) insofar as it relates to a physician fee schedule for 2005 or 2006 shall not be taken into account in applying clause (ii)(II) for drug administration services under the fee schedule for such year.''; and

(B) by adding at the end the following new subparagraphs:

''(H) ADJUSTMENTS IN PRACTICE EXPENSE RELATIVE VALUE UNITS FOR CERTAIN DRUG ADMINISTRATION SERVICES BEGINNING IN 2004.—

''(i) USE OF SURVEY DATA.—In establishing the physician fee schedule under subsection (b) with respect to payments for services furnished on or after January 1, 2004, the Secretary shall, in determining practice expense relative value units under this subsection, utilize a survey submitted to the Secretary as of January 1, 2003, by a physician specialty organization pursuant to section 212 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 if the survey—

''(I) covers practice expenses for oncology drug administration services; and

''(II) meets criteria established by the Secretary for acceptance of such surveys.

''(ii) PRICING OF CLINICAL ONCOLOGY NURSES IN PRACTICE EXPENSE METHODOLOGY.—If the survey described in clause (i) includes data on wages, salaries, and compensation of clinical oncology nurses, the Secretary shall utilize such data in the methodology for determining practice expense relative value units under subsection (c).

''(iii) WORK RELATIVE VALUE UNITS FOR CERTAIN DRUG ADMINISTRATION SERVICES.—In establishing the relative value units under this paragraph for drug administration services described in clause (iv) furnished on or after January 1, 2004, the Secretary shall establish work relative value units equal to the work relative value units for a level 1 office medical visit for an established patient.

''(iv) DRUG ADMINISTRATION SERVICES DESCRIBED.—The drug administration services described in this clause are physicians' services—

''(I) which are classified as of October 1, 2003, within any of the following groups of procedures: therapeutic or diagnostic infusions (excluding chemotherapy); chemotherapy administration services; and therapeutic, prophylactic, or diagnostic injections;

''(II) for which there are no work relative value units assigned under this subsection as of such date; and

''(III) for which national relative value units have been assigned under this subsection as of such date.

''(I) ADJUSTMENTS IN PRACTICE EXPENSE RELATIVE VALUE UNITS FOR CERTAIN DRUG ADMINISTRATION SERVICES BEGINNING WITH 2005.—

''(i) IN GENERAL.—In establishing the physician fee schedule under subsection (b) with respect to payments for services furnished on or after January 1, 2005 or 2006, the Secretary shall adjust the practice expense relative value units for such year consistent with clause (ii).

''(ii) USE OF SUPPLEMENTAL SURVEY DATA.—

''(I) IN GENERAL.—Subject to subclause (II), if a specialty submits to the Secretary by not later than March 1, 2004, for 2005, or March 1, 2005, for 2006, data that includes expenses for the administration of drugs and biologicals for which the payment amount is determined pursuant to section 1842(o), the Secretary shall use such supplemental survey data in carrying out this subparagraph for the years involved insofar as they are collected and provided by entities and organizations consistent with the criteria established by the Secretary pursuant to section 212(a) of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999.

''(II) LIMITATION ON SPECIALTY.—Subclause (I) shall apply to a specialty only insofar as not less than 40 percent of payments for the specialty under this title in 2002 are attributable to the administration of drugs and biologicals, as determined by the Secretary.

''(III) APPLICATION.—This clause shall not apply with respect to a survey to which subparagraph (H)(i) applies.

''(J) PROVISIONS FOR APPROPRIATE REPORTING AND BILLING FOR PHYSICIANS' SERVICES ASSOCIATED WITH THE ADMINISTRATION OF COVERED OUTPATIENT DRUGS AND BIOLOGICALS.—

''(i) EVALUATION OF CODES.—The Secretary shall promptly evaluate existing drug administration codes for physicians' services to ensure accurate reporting and billing for such services, taking into account levels of complexity of the administration and resource consumption.

''(ii) USE OF EXISTING PROCESSES.—In carrying out clause (i), the Secretary shall use existing processes for the consideration of coding changes and, to the extent coding changes are made, shall use such processes in establishing relative values for such services.

''(iii) IMPLEMENTATION.—In carrying out clause (i), the Secretary shall consult with representatives of physician specialties affected by the implementation of section 1847A or section 1847B, and shall take such steps within the Secretary's authority to expedite such considerations under clause (ii).

''(iv) SUBSEQUENT, BUDGET NEUTRAL ADJUSTMENTS PERMITTED.—Nothing in subparagraph (H) or (I) or this subparagraph shall be construed as preventing the Secretary from providing for adjustments in practice expense relative value units under (and consistent with) subparagraph (B) for years after 2004, 2005, or 2006, respectively.''.

(2) TREATMENT OF OTHER SERVICES CURRENTLY IN THE NONPHYSICIAN WORK POOL.—The Secretary shall make adjustments to the nonphysician work pool methodology (as such term is used in the final rule promulgated by the Secretary in the Federal Register on December 31, 2002 (67 Fed. Reg. 251)), for the determination of practice expense relative value units under the physician fee schedule under section 1848(c)(2)(C)(ii) of the Social Security Act (42 U.S.C. 1395w–4(c)(2)(C)(ii)), so that the practice expense relative value units for services determined under such methodology are not affected relative to the practice expense relative value units of services not determined under such methodology, as a result of the amendments made by paragraph (1).

(3) PAYMENT FOR MULTIPLE CHEMOTHERAPY AGENTS FURNISHED ON A SINGLE DAY THROUGH THE PUSH TECHNIQUE.—

(A) REVIEW OF POLICY.—The Secretary shall review the policy, as in effect on October 1, 2003, with respect to payment under section 1848 of the Social Security Act (42 U.S.C. 1395w–4) for the administration of more than 1 drug or biological to an individual on a single day through the push technique.

(B) MODIFICATION OF POLICY.—After conducting the review under subparagraph (A), the Secretary shall modify such payment policy as the Secretary determines to be appropriate.

(C) EXEMPTION FROM BUDGET NEUTRALITY UNDER PHYSICIAN FEE SCHEDULE.—If the Secretary modifies such payment policy pursuant to subparagraph (B), any increased expenditures under title XVIII of the Social Security Act resulting from such modification shall be treated as additional expenditures attributable to subparagraph (H) of section 1848(c)(2) of the Social Security Act (42 U.S.C. 1395w–4(c)(2)), as added by paragraph (1)(B), for purposes of applying the exemption to budget neutrality under subparagraph (B)(iv) of such section, as added by paragraph (1)(A).

(4) TRANSITIONAL ADJUSTMENT.—

(A) IN GENERAL.—In order to provide for a transition during 2004 and 2005 to the payment system established under the amendments made by this section, in the case of physicians' services consisting of drug administration services described in subparagraph (H)(iv) of section 1848(c)(2) of the Social Security Act (42 U.S.C. 1395w–4(c)(2)), as added by paragraph (1)(B), furnished on or after January 1, 2004, and before January 1, 2006, in addition to the amount determined under the fee schedule under section 1848(b) of such Act (42 U.S.C. 1395w–4(b)) there also shall be paid to the physician from the Federal Supplementary Medical Insurance Trust Fund an amount equal to the applicable percentage specified in subparagraph (B) of such fee schedule amount for the services so determined.

(B) APPLICABLE PERCENTAGE.—The applicable percentage specified in this subparagraph for services furnished—

(i) during 2004, is 32 percent; and

(ii) during 2005, is 3 percent.

(5) MEDPAC REVIEW AND REPORTS; SECRETARIAL RESPONSE.—

(A) REVIEW.—The Medicare Payment Advisory Commission shall review the payment changes made under this section insofar as they affect payment under part B of title XVIII of the Social Security Act—

(i) for items and services furnished by oncologists; and

(ii) for drug administration services furnished by other specialists.

(B) OTHER MATTERS STUDIED.—In conducting the review under subparagraph (A), the Commission shall also review such changes as they affect—

(i) the quality of care furnished to individuals enrolled under part B and the satisfaction of such individuals with that care;

(ii) the adequacy of reimbursement as applied in, and the availability in, different geographic areas and to different physician practice sizes; and

(iii) the impact on physician practices.

(C) REPORTS.—The Commission shall submit to the Secretary and Congress—

(i) not later than January 1, 2006, a report on the review conducted under subparagraph (A)(i); and

(ii) not later than January 1, 2007, a report on the review conducted under subparagraph (A)(ii).

Each such report may include such recommendations regarding further adjustments in such payments as the Commission deems appropriate.

(D) SECRETARIAL RESPONSE.—As part of the rulemaking with respect to payment for physicians services under section 1848 of the Social Security Act (42 U.S.C. 1395w–4) for 2007, the Secretary may make appropriate adjustments to payment for items and services described in subparagraph (A)(i), taking into account the report submitted under such subparagraph (C)(i).

(b) APPLICATION OF MARKET-BASED PAYMENT SYSTEMS.—Section 1842(o) (42 U.S.C. 1395u(o)) is amended—

(1) in paragraph (1), by striking ''equal to 95 percent of the average wholesale price.'' and inserting ''equal to the following:

''(A) In the case of any of the following drugs or biologicals, 95 percent of the average wholesale price:

''(i) A drug or biological furnished before January 1, 2004.

''(ii) Blood clotting factors furnished during 2004.

''(iii) A drug or biological furnished during 2004 that was not available for payment under this part as of April 1, 2003.

''(iv) A vaccine described in subparagraph (A) or (B) of section 1861(s)(10) furnished on or after January 1, 2004.

''(v) A drug or biological furnished during 2004 in connection with the furnishing of renal dialysis services if separately billed by renal dialysis facilities.

''(B) In the case of a drug or biological furnished during 2004 that is not described in—

''(i) clause (ii), (iii), (iv), or (v) of subparagraph (A),

''(ii) subparagraph (D)(i), or

''(iii) subparagraph (F),

the amount determined under paragraph (4).

''(C) In the case of a drug or biological that is not described in subparagraph (A)(iv), (D)(i), or (F) furnished on or after January 1, 2005, the amount provided under section 1847, section 1847A, section 1847B, or section 1881(b)(13), as the case may be for the drug or biological.

''(D)(i) Except as provided in clause (ii), in the case of infusion drugs furnished through an item of durable medical equipment covered under section 1861(n) on or after January 1, 2004, 95 percent of the average wholesale price for such drug in effect on October 1, 2003.

''(ii) In the case of such infusion drugs furnished in a competitive acquisition area under section 1847 on or after January 1, 2007, the amount provided under section 1847.

''(E) In the case of a drug or biological, consisting of intravenous immune globulin, furnished—

''(i) in 2004, the amount of payment provided under paragraph (4); and

''(ii) in 2005 and subsequent years, the amount of payment provided under section 1847A.

''(F) In the case of blood and blood products (other than blood clotting factors), the amount of payment shall be determined in the same manner as such amount of payment was determined on October 1, 2003.

''(G) The provisions of subparagraphs (A) through (F) of this paragraph shall not apply to an inhalation drug or biological furnished through durable medical equipment covered under section 1861(n).''; and

(2) by adding at the end the following new paragraph:

''(4)(A) Subject to the succeeding provisions of this paragraph, the amount of payment for a drug or biological under this paragraph furnished in 2004 is equal to 85 percent of the average wholesale price (determined as of April 1, 2003) for the drug or biological.

''(B) The Secretary shall substitute for the percentage under subparagraph (A) for a drug or biological the percentage that would apply to the drug or biological under the column entitled 'Average of GAO and OIG data (percent)' in the table entitled 'Table 3.—Medicare Part B Drugs in the Most Recent GAO and OIG Studies' published on August 20, 2003, in the Federal Register (68 Fed. Reg. 50445).

''(C)(i) The Secretary may substitute for the percentage under subparagraph (A) a percentage that is based on data and information submitted by the manufacturer of the drug or biological by October 15, 2003.

''(ii) The Secretary may substitute for the percentage under subparagraph (A) with respect to drugs and biologicals furnished during 2004 on or after April 1, 2004, a percentage that is based on data and information submitted by the manufacturer of the drug or biological after October 15, 2003, and before January 1, 2004.

''(D) In no case may the percentage substituted under subparagraph (B) or (C) be less than 80 percent.''.

(c) APPLICATION OF AVERAGE SALES PRICE METHODS BEGINNING IN 2005.—

(1) IN GENERAL.—Title XVIII is amended by inserting after section 1847 (42 U.S.C. 1395w–3), as amended by section 302(b), the following new section:

''USE OF AVERAGE SALES PRICE PAYMENT METHODOLOGY

''SEC. 1847A. (a) APPLICATION.—

''(1) IN GENERAL.—Except as provided in paragraph (2), this section shall apply to payment for drugs and biologicals that are described in section 1842(o)(1)(C) and that are furnished on or after January 1, 2005.

''(2) ELECTION.—This section shall not apply in the case of a physician who elects under subsection (a)(1)(A)(ii) of section 1847B for that section to apply instead of this section for the payment for drugs and biologicals.

''(b) PAYMENT AMOUNT.—

''(1) IN GENERAL.—Subject to subsections (d)(3)(C) and (e), the amount of payment determined under this section for the billing and payment code for a drug or biological (based on a minimum dosage unit) is, subject to applicable deductible and coinsurance—

''(A) in the case of a multiple source drug (as defined in subsection (c)(6)(C)), 106 percent of the amount determined under paragraph (3); or

''(B) in the case of a single source drug or biological (as defined in subsection (c)(6)(D)), 106 percent of the amount determined under paragraph (4).

''(2) SPECIFICATION OF UNIT.—

''(A) SPECIFICATION BY MANUFACTURER.—The manufacturer of a drug or biological shall specify the unit associated with each National Drug Code (including package size) as part of the submission of data under section 1927(b)(3)(A)(iii).

''(B) UNIT DEFINED.—In this section, the term 'unit' means, with respect to each National Drug Code (including package size) associated with a drug or biological, the lowest identifiable quantity (such as a capsule or tablet, milligram of molecules, or grams) of the drug or biological that is dispensed, exclusive of any diluent without reference to volume measures pertaining to liquids. For years after 2004, the Secretary may establish the unit for a manufacturer to report and methods for counting units as the Secretary determines appropriate to implement this section.

''(3) MULTIPLE SOURCE DRUG.—For all drug products included within the same multiple source drug billing and payment code, the amount specified in this paragraph is the volume-weighted average of the average sales prices reported under section 1927(b)(3)(A)(iii) determined by—

''(A) computing the sum of the products (for each National Drug Code assigned to such drug products) of—

''(i) the manufacturer's average sales price (as defined in subsection (c)); and

''(ii) the total number of units specified under paragraph (2) sold; and

''(B) dividing the sum determined under subparagraph (A) by the sum of the total number of units under subparagraph (A)(ii) for all National Drug Codes assigned to such drug products.

''(4) SINGLE SOURCE DRUG OR BIOLOGICAL.—The amount specified in this paragraph for a single source drug or biological is the lesser of the following:

''(A) AVERAGE SALES PRICE.—The average sales price as determined using the methodology applied under paragraph (3) for all National Drug Codes assigned to such drug or biological product.

''(B) WHOLESALE ACQUISITION COST (WAC).—The wholesale acquisition cost (as defined in subsection (c)(6)(B)) using the methodology applied under paragraph (3) for all National Drug Codes assigned to such drug or biological product.

''(5) BASIS FOR PAYMENT AMOUNT.—The payment amount shall be determined under this subsection based on information reported under subsection (f) and without regard to any special packaging, labeling, or identifiers on the dosage form or product or package.

''(c) MANUFACTURER'S AVERAGE SALES PRICE.—

''(1) IN GENERAL.—For purposes of this section, subject to paragraphs (2) and (3), the manufacturer's 'average sales price' means, of a drug or biological for a National Drug Code for a calendar quarter for a manufacturer for a unit—

''(A) the manufacturer's sales to all purchasers (excluding sales exempted in paragraph (2)) in the United States for such drug or biological in the calendar quarter; divided by

''(B) the total number of such units of such drug or biological sold by the manufacturer in such quarter.

''(2) CERTAIN SALES EXEMPTED FROM COMPUTATION.—In calculating the manufacturer's average sales price under this subsection, the following sales shall be excluded:

''(A) SALES EXEMPT FROM BEST PRICE.—Sales exempt from the inclusion in the determination of 'best price' under section 1927(c)(1)(C)(i).

''(B) SALES AT NOMINAL CHARGE.—Such other sales as the Secretary identifies as sales to an entity that are merely nominal in amount (as applied for purposes of section 1927(c)(1)(C)(ii)(III), except as the Secretary may otherwise provide).

''(3) SALE PRICE NET OF DISCOUNTS.—In calculating the manufacturer's average sales price under this subsection, such price shall include volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under section 1927). For years after 2004, the Secretary may include in such price other price concessions, which may be based on recommendations of the Inspector General, that would result in a reduction of the cost to the purchaser.

''(4) PAYMENT METHODOLOGY IN CASES WHERE AVERAGE SALES PRICE DURING FIRST QUARTER OF SALES IS UNAVAILABLE.—In the case of a drug or biological during an initial period (not to exceed a full calendar quarter) in which data on the prices for sales for the drug or biological is not sufficiently available from the manufacturer to compute an average sales price for the drug or biological, the Secretary may determine the amount payable under this section for the drug or biological based on—

''(A) the wholesale acquisition cost; or

''(B) the methodologies in effect under this part on November 1, 2003, to determine payment amounts for drugs or biologicals.

''(5) FREQUENCY OF DETERMINATIONS.—

''(A) IN GENERAL ON A QUARTERLY BASIS.—The manufacturer's average sales price, for a drug or biological of a manufacturer, shall be calculated by such manufacturer under this subsection on a quarterly basis. In making such calculation insofar as there is a lag in the reporting of the information on rebates and chargebacks under paragraph (3) so that adequate data are not available on a timely basis, the manufacturer shall apply a methodology based on a 12-month rolling average for the manufacturer to estimate costs attributable to rebates and chargebacks. For years after 2004, the Secretary may establish a uniform methodology under this subparagraph to estimate and apply such costs.

''(B) UPDATES IN PAYMENT AMOUNTS.—The payment amounts under subsection (b) shall be updated by the Secretary on a quarterly basis and shall be applied based upon the manufacturer's average sales price calculated for the most recent calendar quarter for which data is available.

''(C) USE OF CONTRACTORS; IMPLEMENTATION.—The Secretary may contract with appropriate entities to calculate the payment amount under subsection (b). Notwithstanding any other provision of law, the Secretary may implement, by program instruction or otherwise, any of the provisions of this section.

''(6) DEFINITIONS AND OTHER RULES.—In this section:

''(A) MANUFACTURER.—The term 'manufacturer' means, with respect to a drug or biological, the manufacturer (as defined in section 1927(k)(5)).

''(B) WHOLESALE ACQUISITION COST.—The term 'wholesale acquisition cost' means, with respect to a drug or biological, the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.

''(C) MULTIPLE SOURCE DRUG.—

''(i) IN GENERAL.—The term 'multiple source drug' means, for a calendar quarter, a drug for

which there are 2 or more drug products which—

''(I) are rated as therapeutically equivalent (under the Food and Drug Administration's most recent publication of 'Approved Drug Products with Therapeutic Equivalence Evaluations'),

''(II) except as provided in subparagraph (E), are pharmaceutically equivalent and bioequivalent, as determined under subparagraph (F) and as determined by the Food and Drug Administration, and

''(III) are sold or marketed in the United States during the quarter.

''(ii) EXCEPTION.—With respect to single source drugs or biologicals that are within the same billing and payment code as of October 1, 2003, the Secretary shall treat such single source drugs or biologicals as if the single source drugs or biologicals were multiple source drugs.

''(D) SINGLE SOURCE DRUG OR BIOLOGICAL.—The term 'single source drug or biological' means—

''(i) a biological; or

''(ii) a drug which is not a multiple source drug and which is produced or distributed under a new drug application approved by the Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application.

''(E) EXCEPTION FROM PHARMACEUTICAL EQUIVALENCE AND BIOEQUIVALENCE REQUIREMENT.—Subparagraph (C)(ii) shall not apply if the Food and Drug Administration changes by regulation the requirement that, for purposes of the publication described in subparagraph (C)(i), in order for drug products to be rated as therapeutically equivalent, they must be pharmaceutically equivalent and bioequivalent, as defined in subparagraph (F).

''(F) DETERMINATION OF PHARMACEUTICAL EQUIVALENCE AND BIOEQUIVALENCE.—For purposes of this paragraph—

''(i) drug products are pharmaceutically equivalent if the products contain identical amounts of the same active drug ingredient in the same dosage form and meet compendial or other applicable standards of strength, quality, purity, and identity; and

''(ii) drugs are bioequivalent if they do not present a known or potential bioequivalence problem, or, if they do present such a problem, they are shown to meet an appropriate standard of bioequivalence.

''(G) INCLUSION OF VACCINES.—In applying provisions of section 1927 under this section, 'other than a vaccine' is deemed deleted from section 1927(k)(2)(B).

''(d) MONITORING OF MARKET PRICES.—

''(1) IN GENERAL.—The Inspector General of the Department of Health and Human Services shall conduct studies, which may include surveys, to determine the widely available market prices of drugs and biologicals to which this section applies, as the Inspector General, in consultation with the Secretary, determines to be appropriate.

''(2) COMPARISON OF PRICES.—Based upon such studies and other data for drugs and biologicals, the Inspector General shall compare the average sales price under this section for drugs and biologicals with—

''(A) the widely available market price for such drugs and biologicals (if any); and

''(B) the average manufacturer price (as determined under section 1927(k)(1)) for such drugs and biologicals.

''(3) LIMITATION ON AVERAGE SALES PRICE.—

''(A) IN GENERAL.—The Secretary may disregard the average sales price for a drug or biological that exceeds the widely available market price or the average manufacturer price for such drug or biological by the applicable threshold percentage (as defined in subparagraph (B)).

''(B) APPLICABLE THRESHOLD PERCENTAGE DEFINED.—In this paragraph, the term 'applicable threshold percentage' means—

''(i) in 2005, in the case of an average sales price for a drug or biological that exceeds widely available market price or the average manufacturer price, 5 percent; and

''(ii) in 2006 and subsequent years, the percentage applied under this subparagraph subject to such adjustment as the Secretary may specify for the widely available market price or the average manufacturer price, or both.

''(C) AUTHORITY TO ADJUST AVERAGE SALES PRICE.—If the Inspector General finds that the average sales price for a drug or biological exceeds such widely available market price or average manufacturer price for such drug or biological by the applicable threshold percentage, the Inspector General shall inform the Secretary (at such times as the Secretary may specify to carry out this subparagraph) and the Secretary shall, effective as of the next quarter, substitute for the amount of payment otherwise determined under this section for such drug or biological the lesser of—

''(i) the widely available market price for the drug or biological (if any); or

''(ii) 103 percent of the average manufacturer price (as determined under section 1927(k)(1)) for the drug or biological.

''(4) CIVIL MONEY PENALTY.—

''(A) IN GENERAL.—If the Secretary determines that a manufacturer has made a misrepresentation in the reporting of the manufacturer's average sales price for a drug or biological, the Secretary may apply a civil money penalty in an amount of up to $10,000 for each such price misrepresentation and for each day in which such price misrepresentation was applied.

''(B) PROCEDURES.—The provisions of section 1128A (other than subsections (a) and (b)) shall apply to civil money penalties under subparagraph (B) in the same manner as they apply to a penalty or proceeding under section 1128A(a).

''(5) WIDELY AVAILABLE MARKET PRICE.—

''(A) IN GENERAL.—In this subsection, the term 'widely available market price' means the price that a prudent physician or supplier would pay for the drug or biological. In determining such price, the Inspector General shall take into account the discounts, rebates, and other price concessions routinely made available to such prudent physicians or suppliers for such drugs or biologicals.

''(B) CONSIDERATIONS.—In determining the price under subparagraph (A), the Inspector General shall consider information from one or more of the following sources:

''(i) Manufacturers.

''(ii) Wholesalers.

''(iii) Distributors.

''(iv) Physician supply houses.

''(v) Specialty pharmacies.

''(vi) Group purchasing arrangements.

''(vii) Surveys of physicians.

''(viii) Surveys of suppliers.

''(ix) Information on such market prices from insurers.

''(x) Information on such market prices from private health plans.

''(e) AUTHORITY TO USE ALTERNATIVE PAYMENT IN RESPONSE TO PUBLIC HEALTH EMERGENCY.—In the case of a public health emergency under section 319 of the Public Health Service Act in which there is a documented inability to access drugs and biologicals, and a concomitant increase in the price, of a drug or biological which is not reflected in the manufacturer's average sales price for one or more quarters, the Secretary may use the wholesale acquisition cost (or other reasonable measure of drug or biological price) instead of the manufacturer's average sales price for such quarters and for subsequent quarters until the price and availability of the drug or biological has stabilized and is substantially reflected in the applicable manufacturer's average sales price.

''(f) QUARTERLY REPORT ON AVERAGE SALES PRICE.—For requirements for reporting the manufacturer's average sales price (and, if required to make payment, the manufacturer's wholesale acquisition cost) for the drug or biological under this section, see section 1927(b)(3).

''(g) JUDICIAL REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of—

''(1) determinations of payment amounts under this section, including the assignment of National Drug Codes to billing and payment codes;

''(2) the identification of units (and package size) under subsection (b)(2);

''(3) the method to allocate rebates, chargebacks, and other price concessions to a quarter if specified by the Secretary;

''(4) the manufacturer's average sales price when it is used for the determination of a payment amount under this section; and

''(5) the disclosure of the average manufacturer price by reason of an adjustment under subsection (d)(3)(C) or (e).''.

(2) REPORT ON SALES TO PHARMACY BENEFIT MANAGERS.—

(A) STUDY.—The Secretary shall conduct a study on sales of drugs and biologicals to large volume purchasers, such as pharmacy benefit managers and health maintenance organizations, for purposes of determining whether the price at which such drugs and biologicals are sold to such purchasers does not represent the price such drugs and biologicals are made available for purchase to prudent physicians.

(B) REPORT.—Not later than January 1, 2006, the Secretary shall submit to Congress a report on the study conducted under paragraph (1), and shall include recommendations on whether such sales to large volume purchasers should be excluded from the computation of a manufacturer's average sales price under section 1847A of the Social Security Act, as added by paragraph (1).

(3) INSPECTOR GENERAL REPORT ON ADEQUACY OF REIMBURSEMENT RATE UNDER AVERAGE SALES PRICE METHODOLOGY.—

(A) STUDY.—The Inspector General of the Department of Health and Human Services shall conduct a study on the ability of physician practices in the specialties of hematology, hematology/oncology, and medical oncology of different sizes, especially particularly large practices, to obtain drugs and biologicals for the treatment of cancer patients at 106 percent of the average sales price for the drugs and biologicals. In conducting the study, the Inspector General shall conduct an audit of a representative sample of such practices to determine the adequacy of reimbursement under section 1847A of the Social Security Act, as added by paragraph (1).

(B) REPORT.—Not later October 1, 2005, the Inspector General shall submit to Congress a report on the study conducted under subparagraph (A), and shall include recommendations on the adequacy of reimbursement for such drugs and biologicals under such section 1847A.

(d) PAYMENT BASED ON COMPETITION.—

(1) IN GENERAL.—Title XVIII is amended by inserting after section 1847A, as added by subsection (c), the following new section:

''COMPETITIVE ACQUISITION OF OUTPATIENT DRUGS AND BIOLOGICALS

''SEC. 1847B. (a) IMPLEMENTATION OF COMPETITIVE ACQUISITION.—

''(1) IMPLEMENTATION OF PROGRAM.—

''(A) IN GENERAL.—The Secretary shall establish and implement a competitive acquisition program under which—

''(i) competitive acquisition areas are established for contract award purposes for acquisition of and payment for categories of competitively biddable drugs and biologicals (as defined in paragraph (2)) under this part;

''(ii) each physician is given the opportunity annually to elect to obtain drugs and biologicals under the program, rather than under section 1847A; and

''(iii) each physician who elects to obtain drugs and biologicals under the program makes

an annual selection under paragraph (5) of the contractor through which drugs and biologicals within a category of drugs and biologicals will be acquired and delivered to the physician under this part.

This section shall not apply in the case of a physician who elects section 1847A to apply.

''(B) IMPLEMENTATION.—For purposes of implementing the program, the Secretary shall establish categories of competitively biddable drugs and biologicals. The Secretary shall phase in the program with respect to those categories beginning in 2006 in such manner as the Secretary determines to be appropriate.

''(C) WAIVER OF CERTAIN PROVISIONS.—In order to promote competition, in carrying out the program the Secretary may waive such provisions of the Federal Acquisition Regulation as are necessary for the efficient implementation of this section, other than provisions relating to confidentiality of information and such other provisions as the Secretary determines appropriate.

''(D) EXCLUSION AUTHORITY.—The Secretary may exclude competitively biddable drugs and biologicals (including a class of such drugs and biologicals) from the competitive bidding system under this section if the application of competitive bidding to such drugs or biologicals—

''(i) is not likely to result in significant savings; or

''(ii) is likely to have an adverse impact on access to such drugs or biologicals.

''(2) COMPETITIVELY BIDDABLE DRUGS AND BIOLOGICALS AND PROGRAM DEFINED.—For purposes of this section—

''(A) COMPETITIVELY BIDDABLE DRUGS AND BIOLOGICALS DEFINED.—The term 'competitively biddable drugs and biologicals' means a drug or biological described in section 1842(o)(1)(C) and furnished on or after January 1, 2006.

''(B) PROGRAM.—The term 'program' means the competitive acquisition program under this section.

''(C) COMPETITIVE ACQUISITION AREA; AREA.—The terms 'competitive acquisition area' and 'area' mean an appropriate geographic region established by the Secretary under the program.

''(D) CONTRACTOR.—The term 'contractor' means an entity that has entered into a contract with the Secretary under this section.

''(3) APPLICATION OF PROGRAM PAYMENT METHODOLOGY.—

''(A) IN GENERAL.—With respect to competitively biddable drugs and biologicals which are supplied under the program in an area and which are prescribed by a physician who has elected this section to apply—

''(i) the claim for such drugs and biologicals shall be submitted by the contractor that supplied the drugs and biologicals;

''(ii) collection of amounts of any deductible and coinsurance applicable with respect to such drugs and biologicals shall be the responsibility of such contractor and shall not be collected unless the drug or biological is administered to the individual involved; and

''(iii) the payment under this section (and related amounts of any applicable deductible and coinsurance) for such drugs and biologicals—

''(I) shall be made only to such contractor; and

''(II) shall be conditioned upon the administration of such drugs and biologicals.

''(B) PROCESS FOR ADJUSTMENTS.—The Secretary shall provide a process for adjustments to payments in the case in which payment is made for drugs and biologicals which were billed at the time of dispensing but which were not actually administered.

''(C) INFORMATION FOR PURPOSES OF COST-SHARING.—The Secretary shall provide a process by which physicians submit information to contractors for purposes of the collection of any applicable deductible or coinsurance amounts under subparagraph (A)(ii).

''(4) CONTRACT REQUIRED.—Payment may not be made under this part for competitively biddable drugs and biologicals prescribed by a physician who has elected this section to apply within a category and a competitive acquisition area with respect to which the program applies unless—

''(A) the drugs or biologicals are supplied by a contractor with a contract under this section for such category of drugs and biologicals and area; and

''(B) the physician has elected such contractor under paragraph (5) for such category and area.

''(5) CONTRACTOR SELECTION PROCESS.—

''(A) ANNUAL SELECTION.—

''(i) IN GENERAL.—The Secretary shall provide a process for the selection of a contractor, on an annual basis and in such exigent circumstances as the Secretary may provide and with respect to each category of competitively biddable drugs and biologicals for an area by selecting physicians.

''(ii) TIMING OF SELECTION.—The selection of a contractor under clause (i) shall be made at the time of the election described in section 1847A(a) for this section to apply and shall be coordinated with agreements entered into under section 1842(h).

''(B) INFORMATION ON CONTRACTORS.—The Secretary shall make available to physicians on an ongoing basis, through a directory posted on the Internet website of the Centers for Medicare & Medicaid Services or otherwise and upon request, a list of the contractors under this section in the different competitive acquisition areas.

''(C) SELECTING PHYSICIAN DEFINED.—For purposes of this section, the term 'selecting physician' means, with respect to a contractor and category and competitive acquisition area, a physician who has elected this section to apply and has selected to apply under this section such contractor for such category and area.

''(b) PROGRAM REQUIREMENTS.—

''(1) CONTRACT FOR COMPETITIVELY BIDDABLE DRUGS AND BIOLOGICALS.—The Secretary shall conduct a competition among entities for the acquisition of competitively biddable drugs and biologicals. Notwithstanding any other provision of this title, in the case of a multiple source drug, the Secretary shall conduct such competition among entities for the acquisition of at least one competitively biddable drug and biological within each billing and payment code within each category for each competitive acquisition area.

''(2) CONDITIONS FOR AWARDING CONTRACT.—

''(A) IN GENERAL.—The Secretary may not award a contract to any entity under the competition conducted in a competitive acquisition area pursuant to paragraph (1) with respect to the acquisition of competitively biddable drugs and biologicals within a category unless the Secretary finds that the entity meets all of the following with respect to the contract period involved:

''(i) CAPACITY TO SUPPLY COMPETITIVELY BIDDABLE DRUG OR BIOLOGICAL WITHIN CATEGORY.—

''(I) IN GENERAL.—The entity has sufficient arrangements to acquire and to deliver competitively biddable drugs and biologicals within such category in the area specified in the contract.

''(II) SHIPMENT METHODOLOGY.—The entity has arrangements in effect for the shipment at least 5 days each week of competitively biddable drugs and biologicals under the contract and for the timely delivery (including for emergency situations) of such drugs and biologicals in the area under the contract.

''(ii) QUALITY, SERVICE, FINANCIAL PERFORMANCE AND SOLVENCY STANDARDS.—The entity meets quality, service, financial performance, and solvency standards specified by the Secretary, including—

''(I) the establishment of procedures for the prompt response and resolution of complaints of physicians and individuals and of inquiries regarding the shipment of competitively biddable drugs and biologicals; and

''(II) a grievance and appeals process for the resolution of disputes.

''(B) ADDITIONAL CONSIDERATIONS.—The Secretary may refuse to award a contract under this section, and may terminate such a contract, with an entity based upon—

''(i) the suspension or revocation, by the Federal Government or a State government, of the entity's license for the distribution of drugs or biologicals (including controlled substances); or

''(ii) the exclusion of the entity under section 1128 from participation under this title.

''(C) APPLICATION OF MEDICARE PROVIDER OMBUDSMAN.—For provision providing for a program-wide Medicare Provider Ombudsman to review complaints, see section 1868(b), as added by section 923 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

''(3) AWARDING MULTIPLE CONTRACTS FOR A CATEGORY AND AREA.—The Secretary may limit (but not below 2) the number of qualified entities that are awarded such contracts for any category and area. The Secretary shall select among qualified entities based on the following:

''(A) The bid prices for competitively biddable drugs and biologicals within the category and area.

''(B) Bid price for distribution of such drugs and biologicals.

''(C) Ability to ensure product integrity.

''(D) Customer service.

''(E) Past experience in the distribution of drugs and biologicals, including controlled substances.

''(F) Such other factors as the Secretary may specify.

''(4) TERMS OF CONTRACTS.—

''(A) IN GENERAL.—A contract entered into with an entity under the competition conducted pursuant to paragraph (1) is subject to terms and conditions that the Secretary may specify consistent with this section.

''(B) PERIOD OF CONTRACTS.—A contract under this section shall be for a term of 3 years, but may be terminated by the Secretary or the entity with appropriate, advance notice.

''(C) INTEGRITY OF DRUG AND BIOLOGICAL DISTRIBUTION SYSTEM.—A contractor (as defined in subsection (a)(2)(D)) shall—

''(i) acquire all drug and biological products it distributes directly from the manufacturer or from a distributor that has acquired the products directly from the manufacturer; and

''(ii) comply with any product integrity safeguards as may be determined to be appropriate by the Secretary.

Nothing in this subparagraph shall be construed to relieve or exempt any contractor from the provisions of the Federal Food, Drug, and Cosmetic Act that relate to the wholesale distribution of prescription drugs or biologicals.

''(D) COMPLIANCE WITH CODE OF CONDUCT AND FRAUD AND ABUSE RULES.—Under the contract—

''(i) the contractor shall comply with a code of conduct, specified or recognized by the Secretary, that includes standards relating to conflicts of interest; and

''(ii) the contractor shall comply with all applicable provisions relating to prevention of fraud and abuse, including compliance with applicable guidelines of the Department of Justice and the Inspector General of the Department of Health and Human Services.

''(E) DIRECT DELIVERY OF DRUGS AND BIOLOGICALS TO PHYSICIANS.—Under the contract the contractor shall only supply competitively biddable drugs and biologicals directly to the selecting physicians and not directly to individuals, except under circumstances and settings where an individual currently receives a drug or biological in the individual's home or other non-physician office setting as the Secretary may provide. The contractor shall not deliver drugs and biologicals to a selecting physician except upon receipt of a prescription for such drugs and biologicals, and such necessary data as may be required by the Secretary to carry out this section. This section does not—

''(i) require a physician to submit a prescription for each individual treatment; or

''(ii) change a physician's flexibility in terms of writing a prescription for drugs or biologicals for a single treatment or a course of treatment.

''(5) PERMITTING ACCESS TO DRUGS AND BIOLOGICALS.—The Secretary shall establish rules under this section under which drugs and biologicals which are acquired through a contractor under this section may be used to resupply inventories of such drugs and biologicals which are administered consistent with safe drug practices and with adequate safeguards against fraud and abuse. The previous sentence shall apply if the physicians can demonstrate to the Secretary all of the following:

''(A) The drugs or biologicals are required immediately.

''(B) The physician could not have reasonably anticipated the immediate requirement for the drugs or biologicals.

''(C) The contractor could not deliver to the physician the drugs or biologicals in a timely manner.

''(D) The drugs or biologicals were administered in an emergency situation.

''(6) CONSTRUCTION.—Nothing in this section shall be construed as waiving applicable State requirements relating to licensing of pharmacies.

''(c) BIDDING PROCESS.—

''(1) IN GENERAL.—In awarding a contract for a category of drugs and biologicals in an area under the program, the Secretary shall consider with respect to each entity seeking to be awarded a contract the bid price and the other factors referred to in subsection (b)(3).

''(2) BID DEFINED.—In this section, the term 'bid' means an offer to furnish a competitively biddable drug or biological for a particular price and time period.

''(3) BIDDING ON A NATIONAL OR REGIONAL BASIS.—Nothing in this section shall be construed as precluding a bidder from bidding for contracts in all areas of the United States or as requiring a bidder to submit a bid for all areas of the United States.

''(4) UNIFORMITY OF BIDS WITHIN AREA.—The amount of the bid submitted under a contract offer for any competitively biddable drug or biological for an area shall be the same for that drug or biological for all portions of that area.

''(5) CONFIDENTIALITY OF BIDS.—The provisions of subparagraph (D) of section 1927(b)(3) shall apply to periods during which a bid is submitted with respect to a competitively biddable drug or biological under this section in the same manner as it applies to information disclosed under such section, except that any reference—

''(A) in that subparagraph to a 'manufacturer or wholesaler' is deemed a reference to a 'bidder' under this section;

''(B) in that section to 'prices charged for drugs' is deemed a reference to a 'bid' submitted under this section; and

''(C) in clause (i) of that section to 'this section', is deemed a reference to 'part B of title XVIII'.

''(6) INCLUSION OF COSTS.—The bid price submitted in a contract offer for a competitively biddable drug or biological shall—

''(A) include all costs related to the delivery of the drug or biological to the selecting physician (or other point of delivery); and

''(B) include the costs of dispensing (including shipping) of such drug or biological and management fees, but shall not include any costs related to the administration of the drug or biological, or wastage, spillage, or spoilage.

''(7) PRICE ADJUSTMENTS DURING CONTRACT PERIOD; DISCLOSURE OF COSTS.—Each contract awarded shall provide for—

''(A) disclosure to the Secretary the contractor's reasonable, net acquisition costs for periods specified by the Secretary, not more often than quarterly, of the contract; and

''(B) appropriate price adjustments over the period of the contract to reflect significant increases or decreases in a contractor's reasonable, net acquisition costs, as so disclosed.

''(d) COMPUTATION OF PAYMENT AMOUNTS.—

''(1) IN GENERAL.—Payment under this section for competitively biddable drugs or biologicals shall be based on bids submitted and accepted under this section for such drugs or biologicals in an area. Based on such bids the Secretary shall determine a single payment amount for each competitively biddable drug or biological in the area.

''(2) SPECIAL RULES.—The Secretary shall establish rules regarding the use under this section of the alternative payment amount provided under section 1847A to the use of a price for specific competitively biddable drugs and biologicals in the following cases:

''(A) NEW DRUGS AND BIOLOGICALS.—A competitively biddable drug or biological for which a payment and billing code has not been established.

''(B) OTHER CASES.—Such other exceptional cases as the Secretary may specify in regulations.

''(e) COST-SHARING.—

''(1) APPLICATION OF COINSURANCE.—Payment under this section for competitively biddable drugs and biologicals shall be in an amount equal to 80 percent of the payment basis described in subsection (d)(1).

''(2) DEDUCTIBLE.—Before applying paragraph (1), the individual shall be required to meet the deductible described in section 1833(b).

''(3) COLLECTION.—Such coinsurance and deductible shall be collected by the contractor that supplies the drug or biological involved. Subject to subsection (a)(3)(B), such coinsurance and deductible may be collected in a manner similar to the manner in which the coinsurance and deductible are collected for durable medical equipment under this part.

''(f) SPECIAL PAYMENT RULES.—

''(1) USE IN EXCLUSION CASES.—If the Secretary excludes a drug or biological (or class of drugs or biologicals) under subsection (a)(1)(D), the Secretary may provide for payment to be made under this part for such drugs and biologicals (or class) using the payment methodology under section 1847A.

''(2) APPLICATION OF REQUIREMENT FOR ASSIGNMENT.—For provision requiring assignment of claims for competitively biddable drugs and biologicals, see section 1842(o)(3).

''(3) PROTECTION FOR BENEFICIARY IN CASE OF MEDICAL NECESSITY DENIAL.—For protection of individuals against liability in the case of medical necessity determinations, see section 1842(b)(3)(B)(ii)(III).

''(g) JUDICIAL REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of—

''(1) the establishment of payment amounts under subsection (d)(1);

''(2) the awarding of contracts under this section;

''(3) the establishment of competitive acquisition areas under subsection (a)(2)(C);

''(4) the phased-in implementation under subsection (a)(1)(B);

''(5) the selection of categories of competitively biddable drugs and biologicals for competitive acquisition under such subsection or the selection of a drug in the case of multiple source drugs; or

''(6) the bidding structure and number of contractors selected under this section.''.

(2) REPORT.—Not later than July 1, 2008, the Secretary shall submit to Congress a report on the program conducted under section 1847B of the Social Security Act, as added by paragraph (1). Such report shall include information on savings, reductions in cost-sharing, access to competitively biddable drugs and biologicals, the range of choices of contractors available to physicians, the satisfaction of physicians and of individuals enrolled under this part, and information comparing prices for drugs and biologicals under such section and section 1847A of such Act, as added by subsection (c).

(e) ADJUSTMENTS TO PAYMENT AMOUNTS FOR ADMINISTRATION OF DRUGS AND BIOLOGICALS.—

(1) ITEMS AND SERVICES RELATING TO FURNISHING OF BLOOD CLOTTING FACTORS.—Section 1842(o) (42 U.S.C. 1395u(o)), as amended by subsection (b)(2), is amended by adding at the end the following new paragraph:

''(5)(A) Subject to subparagraph (B), in the case of clotting factors furnished on or after January 1, 2005, the Secretary shall, after reviewing the January 2003 report to Congress by the Comptroller General of the United States entitled 'Payment for Blood Clotting Factor Exceeds Providers Acquisition Cost', provide for a separate payment, to the entity which furnishes to the patient blood clotting factors, for items and services related to the furnishing of such factors in an amount that the Secretary determines to be appropriate. Such payment amount may take into account any or all of the following:

''(i) The mixing (if appropriate) and delivery of factors to an individual, including special inventory management and storage requirements.

''(ii) Ancillary supplies and patient training necessary for the self-administration of such factors.

''(B) In determining the separate payment amount under subparagraph (A) for blood clotting factors furnished in 2005, the Secretary shall ensure that the total amount of payments under this part (as estimated by the Secretary) for such factors under paragraph (1)(C) and such separate payments for such factors does not exceed the total amount of payments that would have been made for such factors under this part (as estimated by the Secretary) if the amendments made by section 303 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 had not been enacted.

''(C) The separate payment amount under this subparagraph for blood clotting factors furnished in 2006 or a subsequent year shall be equal to the separate payment amount determined under this paragraph for the previous year increased by the percentage increase in the consumer price index for medical care for the 12-month period ending with June of the previous year.''.

(2) PHARMACY SUPPLYING FEE FOR CERTAIN DRUGS AND BIOLOGICALS.—Section 1842(o) (42 U.S.C. 1395u(o)), as previously amended, is amended by adding at the end the following new paragraph:

''(6) In the case of an immunosuppressive drug described in subparagraph (J) of section 1861(s)(2) and an oral drug described in subparagraph (Q) or (T) of such section, the Secretary shall pay to the pharmacy a supplying fee for such a drug determined appropriate by the Secretary (less the applicable deductible and coinsurance amounts).''.

(f) LINKAGE OF REVISED DRUG PAYMENTS AND INCREASES FOR DRUG ADMINISTRATION.—The Secretary shall not implement the revisions in payment amounts for drugs and biologicals administered by physicians as a result of the amendments made by subsection (b) with respect to 2004 unless the Secretary concurrently makes adjustments to the practice expense payment adjustment under the amendments made by subsection (a).

(g) PROHIBITION OF ADMINISTRATIVE AND JUDICIAL REVIEW.—

(1) DRUGS.—Section 1842(o) (42 U.S.C. 1395u(o)), as previously amended, is amended by adding at the end the following new paragraph:

''(7) There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of determinations of payment amounts, methods, or adjustments under paragraphs (4) through (6).''.

(2) PHYSICIAN FEE SCHEDULE.—Section 1848(i)(1)(B) (42 U.S.C. 1395w-4(i)(1)(B)) is amended by striking ''subsection (c)(2)(F)'' and inserting ''subsections (c)(2)(F), (c)(2)(H), and (c)(2)(I)''.

(3) MULTIPLE CHEMOTHERAPY AGENTS, OTHER SERVICES CURRENTLY ON THE NON-PHYSICIAN WORK POOL, AND TRANSITIONAL ADJUSTMENT.—

There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of determinations of payment amounts, methods, or adjustments under paragraphs (2) through (4) of subsection (a).

(h) CONTINUATION OF PAYMENT METHODOLOGY FOR RADIOPHARMACEUTICALS.—Nothing in the amendments made by this section shall be construed as changing the payment methodology under part B of title XVIII of the Social Security Act for radiopharmaceuticals, including the use by carriers of invoice pricing methodology.

(i) CONFORMING AMENDMENTS.—

(1) APPLICATION OF ASP AND COMPETITIVE BIDDING.—Section 1842(o)(2) (42 U.S.C. 1395u(o)(2)) is amended by adding at the end the following: ''This paragraph shall not apply in the case of payment under paragraph (1)(C).''.

(2) NO CHANGE IN COVERAGE BASIS.—Section 1861(s)(2)(A) (42 U.S.C. 1395x(s)(2)(A)) is amended by inserting ''(or would have been so included but for the application of section 1847B)'' after ''included in the physicians' bills''.

(3) PAYMENT.—(A) Section 1833(a)(1)(S) (42 U.S.C. 1395l(a)(1)(S)) is amended by inserting ''(or, if applicable, under section 1847, 1847A, or 1847B)'' after ''1842(o)''.

(B) Section 1862(a)(1) (42 U.S.C. 1395y(a)(1)) is amended—

(i) by striking ''and'' at the end of subparagraph (H);

(ii) by striking the semicolon at the end of subparagraph (I) and inserting '', and''; and

(iii) by adding at the end the following new subparagraph:

''(J) in the case of a drug or biological specified in section 1847A(c)(6)(C) for which payment is made under part B that is furnished in a competitive area under section 1847B, that is not furnished by an entity under a contract under such section;''.

(4) CONSOLIDATED REPORTING OF PRICING INFORMATION.—Section 1927 (42 U.S.C. 1396r–8) is amended—

(A) in subsection (a)(1), by inserting ''or under part B of title XVIII'' after ''section 1903(a)'';

(B) in subsection (b)(3)(A)—

(i) in clause (i), by striking ''and'' at the end and inserting a semicolon;

(ii) in clause (ii), by striking the period and inserting ''; and''; and

(iii) by adding at the end the following:

''(iii) for calendar quarters beginning on or after January 1, 2004, in conjunction with reporting required under clause (i) and by National Drug Code (including package size)—

''(I) the manufacturer's average sales price (as defined in section 1847A(c)) and the total number of units specified under section 1847A(b)(2)(A);

''(II) if required to make payment under section 1847A, the manufacturer's wholesale acquisition cost, as defined in subsection (c)(6) of such section; and

''(III) information on those sales that were made at a nominal price or otherwise described in section 1847A(c)(2)(B);

for a drug or biological described in subparagraph (C), (D), (E), or (G) of section 1842(o)(1) or section 1881(b)(13)(A)(ii).

Information reported under this subparagraph is subject to audit by the Inspector General of the Department of Health and Human Services.'';

(C) in subsection (b)(3)(B)—

(i) in the heading, by inserting ''AND MANUFACTURER'S AVERAGE SALES PRICE'' after ''PRICE''; and

(ii) by inserting ''and manufacturer's average sales prices (including wholesale acquisition cost) if required to make payment'' after ''manufacturer prices''; and

(D) in subsection (b)(3)(D)—

(i) in the matter preceding clause (i), by inserting ''(other than the wholesale acquisition cost for purposes of carrying out section 1847A)'' after ''subsection (a)(6)(A)(ii)''; and

(ii) in clause (i), by inserting '', to carry out section 1847A (including the determination and implementation of the payment amount), or to carry out section 1847B'' after ''this section''.

(5) IMPLEMENTATION.—The provisions of chapter 8 of title 5, United States Code, shall not apply with respect to regulations implementing the amendments made by subsections (a), (b), and (e)(3), to regulations implementing section 304, and to regulations implementing the amendment made by section 305(a), insofar as such regulations apply in 2004.

(6) REPEAL OF STUDY.—Section 4556 of the Balanced Budget Act of 1997 (42 U.S.C. 1395u note) is amended by striking subsection (c).

(j) APPLICATION TO CERTAIN PHYSICIAN SPECIALTIES.—Insofar as the amendments made by this section apply to payments for drugs or biologicals and drug administration services furnished by physicians, such amendments shall only apply to physicians in the specialties of hematology, hematology/oncology, and medical oncology under title XVIII of the Social Security Act.

SEC. 304. EXTENSION OF APPLICATION OF PAYMENT REFORM FOR COVERED OUTPATIENT DRUGS AND BIOLOGICALS TO OTHER PHYSICIAN SPECIALTIES.

Notwithstanding section 303(j), the amendments made by section 303 shall also apply to payments for drugs or biologicals and drug administration services furnished by physicians in specialties other than the specialties of hematology, hematology/oncology, and medical oncology.

SEC. 305. PAYMENT FOR INHALATION DRUGS.

(a) IN GENERAL.—Section 1842(o)(1)(G) (42 U.S.C. 1395u(o)(1)(G)), as added by section 303(b), is amended to read as follows:

''(G) In the case of inhalation drugs or biologicals furnished through durable medical equipment covered under section 1861(n) that are furnished—

''(i) in 2004, the amount provided under paragraph (4) for the drug or biological; and

''(ii) in 2005 and subsequent years, the amount provided under section 1847A for the drug or biological.''.

(b) GAO STUDY OF MEDICARE PAYMENT FOR INHALATION THERAPY.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study to examine the adequacy of current reimbursements for inhalation therapy under the medicare program.

(2) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General shall submit to Congress a report on the study conducted under paragraph (1).

SEC. 306. DEMONSTRATION PROJECT FOR USE OF RECOVERY AUDIT CONTRACTORS.

(a) IN GENERAL.—The Secretary shall conduct a demonstration project under this section (in this section referred to as the ''project'') to demonstrate the use of recovery audit contractors under the Medicare Integrity Program in identifying underpayments and overpayments and recouping overpayments under the medicare program for services for which payment is made under part A or B of title XVIII of the Social Security Act. Under the project—

(1) payment may be made to such a contractor on a contingent basis;

(2) such percentage as the Secretary may specify of the amount recovered shall be retained by the Secretary and shall be available to the program management account of the Centers for Medicare & Medicaid Services; and

(3) the Secretary shall examine the efficacy of such use with respect to duplicative payments, accuracy of coding, and other payment policies in which inaccurate payments arise.

(b) SCOPE AND DURATION.—

(1) SCOPE.—The project shall cover at least 2 States that are among the States with—

(A) the highest per capita utilization rates of medicare services, and

(B) at least 3 contractors.

(2) DURATION.—The project shall last for not longer than 3 years.

(c) WAIVER.—The Secretary shall waive such provisions of title XVIII of the Social Security Act as may be necessary to provide for payment for services under the project in accordance with subsection (a).

(d) QUALIFICATIONS OF CONTRACTORS.—

(1) IN GENERAL.—The Secretary shall enter into a recovery audit contract under this section with an entity only if the entity has staff that has the appropriate clinical knowledge of and experience with the payment rules and regulations under the medicare program or the entity has or will contract with another entity that has such knowledgeable and experienced staff.

(2) INELIGIBILITY OF CERTAIN CONTRACTORS.—The Secretary may not enter into a recovery audit contract under this section with an entity to the extent that the entity is a fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h), a carrier under section 1842 of such Act (42 U.S.C. 1395u), or a Medicare Administrative Contractor under section 1874A of such Act.

(3) PREFERENCE FOR ENTITIES WITH DEMONSTRATED PROFICIENCY.—In awarding contracts to recovery audit contractors under this section, the Secretary shall give preference to those risk entities that the Secretary determines have demonstrated more than 3 years direct management experience and a proficiency for cost control or recovery audits with private insurers, health care providers, health plans, or under the medicaid program under title XIX of the Social Security Act.

(e) CONSTRUCTION RELATING TO CONDUCT OF INVESTIGATION OF FRAUD.—A recovery of an overpayment to a provider by a recovery audit contractor shall not be construed to prohibit the Secretary or the Attorney General from investigating and prosecuting, if appropriate, allegations of fraud or abuse arising from such overpayment.

(f) REPORT.—The Secretary shall submit to Congress a report on the project not later than 6 months after the date of its completion. Such reports shall include information on the impact of the project on savings to the medicare program and recommendations on the cost-effectiveness of extending or expanding the project.information' means information about a conviction for a relevant crime or a finding of patient or resident abuse.

SEC. 307. PILOT PROGRAM FOR NATIONAL AND STATE BACKGROUND CHECKS ON DIRECT PATIENT ACCESS EMPLOYEES OF LONG-TERM CARE FACILITIES OR PROVIDERS.

(a) AUTHORITY TO CONDUCT PROGRAM.—The Secretary, in consultation with the Attorney General, shall establish a pilot program to identify efficient, effective, and economical procedures for long term care facilities or providers to conduct background checks on prospective direct patient access employees.

(b) REQUIREMENTS.—

(1) IN GENERAL.—Under the pilot program, a long-term care facility or provider in a participating State, prior to employing a direct patient access employee that is first hired on or after the commencement date of the pilot program in the State, shall conduct a background check on the employee in accordance with such procedures as the participating State shall establish.

(2) PROCEDURES.—

(A) IN GENERAL.—The procedures established by a participating State under paragraph (1) should be designed to—

(i) give a prospective direct access patient employee notice that the long-term care facility or provider is required to perform background checks with respect to new employees;

(ii) require, as a condition of employment, that the employee—

(I) provide a written statement disclosing any disqualifying information;

(II) provide a statement signed by the employee authorizing the facility to request national and State criminal history background checks;

(III) provide the facility with a rolled set of the employee's fingerprints; and

(IV) provide any other identification information the participating State may require;

(iii) require the facility or provider to check any available registries that would be likely to contain disqualifying information about a prospective employee of a long-term care facility or provider; and

(iv) permit the facility or provider to obtain State and national criminal history background checks on the prospective employee through a 10-fingerprint check that utilizes State criminal records and the Integrated Automated Fingerprint Identification System of the Federal Bureau of Investigation.

(B) ELIMINATION OF UNNECESSARY CHECKS.—The procedures established by a participating State under paragraph (1) shall permit a long-term care facility or provider to terminate the background check at any stage at which the facility or provider obtains disqualifying information regarding a prospective direct patient access employee.

(3) PROHIBITION ON HIRING OF ABUSIVE WORKERS.—

(A) IN GENERAL.—A long-term care facility or provider may not knowingly employ any direct patient access employee who has any disqualifying information.

(B) PROVISIONAL EMPLOYMENT.—

(i) IN GENERAL.—Under the pilot program, a participating State may permit a long-term care facility or provider to provide for a provisional period of employment for a direct patient access employee pending completion of a background check, subject to such supervision during the employee's provisional period of employment as the participating State determines appropriate.

(ii) SPECIAL CONSIDERATION FOR CERTAIN FACILITIES AND PROVIDERS.—In determining what constitutes appropriate supervision of a provisional employee, a participating State shall take into account cost or other burdens that would be imposed on small rural long-term care facilities or providers, as well as the nature of care delivered by such facilities or providers that are home health agencies or providers of hospice care.

(4) USE OF INFORMATION; IMMUNITY FROM LIABILITY.—

(A) USE OF INFORMATION.—A participating State shall ensure that a long-term care facility or provider that obtains information about a direct patient access employee pursuant to a background check uses such information only for the purpose of determining the suitability of the employee for employment.

(B) IMMUNITY FROM LIABILITY.—A participating State shall ensure that a long-term care facility or provider that, in denying employment for an individual selected for hire as a direct patient access employee (including during any period of provisional employment), reasonably relies upon information obtained through a background check of the individual, shall not be liable in any action brought by the individual based on the employment determination resulting from the information.

(5) AGREEMENTS WITH EMPLOYMENT AGENCIES.—A participating State may establish procedures for facilitating the conduct of background checks on prospective direct patient access employees that are hired by a long-term care facility or provider through an employment agency (including a temporary employment agency).

(6) PENALTIES.—A participating State may impose such penalties as the State determines appropriate to enforce the requirements of the pilot program conducted in that State.

(c) PARTICIPATING STATES.—

(1) IN GENERAL.—The Secretary shall enter into agreements with not more than 10 States to conduct the pilot program under this section in such States.

(2) REQUIREMENTS FOR STATES.—An agreement entered into under paragraph (1) shall require that a participating State—

(A) be responsible for monitoring compliance with the requirements of the pilot program;

(B) have procedures by which a provisional employee or an employee may appeal or dispute the accuracy of the information obtained in a background check performed under the pilot program; and

(C) agree to—

(i) review the results of any State or national criminal history background checks conducted regarding a prospective direct patient access employee to determine whether the employee has any conviction for a relevant crime;

(ii) immediately report to the entity that requested the criminal history background checks the results of such review; and

(iii) in the case of an employee with a conviction for a relevant crime that is subject to reporting under section 1128E of the Social Security Act (42 U.S.C. 1320a–7e), report the existence of such conviction to the database established under that section.

(3) APPLICATION AND SELECTION CRITERIA.—

(A) APPLICATION.—A State seeking to participate in the pilot program established under this section, shall submit an application to the Secretary containing such information and at such time as the Secretary may specify.

(B) SELECTION CRITERIA.—

(i) IN GENERAL.—In selecting States to participate in the pilot program, the Secretary shall establish criteria to ensure—

(I) geographic diversity;

(II) the inclusion of a variety of long-term care facilities or providers;

(III) the evaluation of a variety of payment mechanisms for covering the costs of conducting the background checks required under the pilot program; and

(IV) the evaluation of a variety of penalties (monetary and otherwise) used by participating States to enforce the requirements of the pilot program in such States.

(ii) ADDITIONAL CRITERIA.—The Secretary shall, to the greatest extent practicable, select States to participate in the pilot program in accordance with the following:

(I) At least one participating State should permit long-term care facilities or providers to provide for a provisional period of employment pending completion of a background check and at least one such State should not permit such a period of employment.

(II) At least one participating State should establish procedures under which employment agencies (including temporary employment agencies) may contact the State directly to conduct background checks on prospective direct patient access employees.

(III) At least one participating State should include patient abuse prevention training (including behavior training and interventions) for managers and employees of long-term care facilities and providers as part of the pilot program conducted in that State.

(iii) INCLUSION OF STATES WITH EXISTING PROGRAMS.—Nothing in this section shall be construed as prohibiting any State which, as of the date of the enactment of this Act, has procedures for conducting background checks on behalf of any entity described in subsection (g)(5) from being selected to participate in the pilot program conducted under this section.

(d) PAYMENTS.—Of the amounts made available under subsection (f) to conduct the pilot program under this section, the Secretary shall—

(1) make payments to participating States for the costs of conducting the pilot program in such States; and

(2) reserve up to 4 percent of such amounts to conduct the evaluation required under subsection (e).

(e) EVALUATION.—The Secretary, in consultation with the Attorney General, shall conduct by grant, contract, or interagency agreement an evaluation of the pilot program conducted under this section. Such evaluation shall—

(1) review the various procedures implemented by participating States for long-term care facilities or providers to conduct background checks of direct patient access employees and identify the most efficient, effective, and economical procedures for conducting such background checks;

(2) assess the costs of conducting such background checks (including start-up and administrative costs);

(3) consider the benefits and problems associated with requiring employees or facilities or providers to pay the costs of conducting such background checks;

(4) consider whether the costs of conducting such background checks should be allocated between the medicare and medicaid programs and if so, identify an equitable methodology for doing so;

(5) determine the extent to which conducting such background checks leads to any unintended consequences, including a reduction in the available workforce for such facilities or providers;

(6) review forms used by participating States in order to develop, in consultation with the Attorney General, a model form for such background checks;

(7) determine the effectiveness of background checks conducted by employment agencies; and

(8) recommend appropriate procedures and payment mechanisms for implementing a national criminal background check program for such facilities and providers.

(f) FUNDING.—Out of any funds in the Treasury not otherwise appropriated, there are appropriated to the Secretary to carry out the pilot program under this section for the period of fiscal years 2004 through 2007, $25,000,000.

(g) DEFINITIONS.—In this section:

(1) CONVICTION FOR A RELEVANT CRIME.—The term ''conviction for a relevant crime'' means any Federal or State criminal conviction for—

(A) any offense described in section 1128(a) of the Social Security Act (42 U.S.C. 1320a–7); and

(B) such other types of offenses as a participating State may specify for purposes of conducting the pilot program in such State.

(2) DISQUALIFYING INFORMATION.—The term ''disqualifying information'' means a conviction for a relevant crime or a finding of patient or resident abuse.

(3) FINDING OF PATIENT OR RESIDENT ABUSE.—The term ''finding of patient or resident abuse'' means any substantiated finding by a State agency under section 1819(g)(1)(C) or 1919(g)(1)(C) of the Social Security Act (42 U.S.C. 1395i–3(g)(1)(C), 1396r(g)(1)(C)) or a Federal agency that a direct patient access employee has committed—

(A) an act of patient or resident abuse or neglect or a misappropriation of patient or resident property; or

(B) such other types of acts as a participating State may specify for purposes of conducting the pilot program in such State.

(4) DIRECT PATIENT ACCESS EMPLOYEE.—The term ''direct patient access employee'' means any individual (other than a volunteer) that has access to a patient or resident of a long-term care facility or provider through employment or through a contract with such facility or provider, as determined by a participating State for purposes of conducting the pilot program in such State.

(5) LONG-TERM CARE FACILITY OR PROVIDER.—

(A) IN GENERAL.—The term ''long-term care facility or provider'' means the following facilities or providers which receive payment for services under title XVIII or XIX of the Social Security Act:

(i) A skilled nursing facility (as defined in section 1819(a) of the Social Security Act) (42 U.S.C. 1395i–3(a)).

(ii) A nursing facility (as defined in section 1919(a) in such Act) (42 U.S.C. 1396r(a)).

(iii) A home health agency.

(iv) A provider of hospice care (as defined in section 1861(dd)(1) of such Act) (42 U.S.C. 1395x(dd)(1)).

(v) A long-term care hospital (as described in section 1886(d)(1)(B)(iv) of such Act) (42 U.S.C. 1395ww(d)(1)(B)(iv)).

(vi) A provider of personal care services.

(vii) A residential care provider that arranges for, or directly provides, long-term care services.

(viii) An intermediate care facility for the mentally retarded (as defined in section 1905(d) of such Act) 42 U.S.C. 1396d(d)).

(B) ADDITIONAL FACILITIES OR PROVIDERS.—During the first year in which a pilot program under this section is conducted in a participating State, the State may expand the list of facilities or providers under subparagraph (A) (on a phased-in basis or otherwise) to include such other facilities or providers of long-term care services under such titles as the participating State determines appropriate.

(C) EXCEPTIONS.—Such term does not include—

(i) any facility or entity that provides, or is a provider of, services described in subparagraph (A) that are exclusively provided to an individual pursuant to a self-directed arrangement that meets such requirements as the participating State may establish in accordance with guidance from the Secretary; or

(ii) any such arrangement that is obtained by a patient or resident functioning as an employer.

(6) PARTICIPATING STATE.—The term ''participating State'' means a State with an agreement under subsection (c)(1).

TITLE IV—RURAL PROVISIONS

Subtitle A—Provisions Relating to Part A Only

SEC. 401. EQUALIZING URBAN AND RURAL STANDARDIZED PAYMENT AMOUNTS UNDER THE MEDICARE INPATIENT HOSPITAL PROSPECTIVE PAYMENT SYSTEM.

(a) IN GENERAL.—Section 1886(d)(3)(A)(iv) (42 U.S.C. 1395ww(d)(3)(A)(iv)) is amended—

(1) by striking ''(iv) For discharges'' and inserting ''(iv)(I) Subject to subclause (II), for discharges''; and

(2) by adding at the end the following new subclause:

''(II) For discharges occurring in a fiscal year (beginning with fiscal year 2004), the Secretary shall compute a standardized amount for hospitals located in any area within the United States and within each region equal to the standardized amount computed for the previous fiscal year under this subparagraph for hospitals located in a large urban area (or, beginning with fiscal year 2005, for all hospitals in the previous fiscal year) increased by the applicable percentage increase under subsection (b)(3)(B)(i) for the fiscal year involved.''.

(b) CONFORMING AMENDMENTS.—

(1) COMPUTING DRG-SPECIFIC RATES.—Section 1886(d)(3)(D) (42 U.S.C. 1395ww(d)(3)(D)) is amended—

(A) in the heading, by striking ''IN DIFFERENT AREAS'';

(B) in the matter preceding clause (i), by striking '', each of'';

(C) in clause (i)—

(i) in the matter preceding subclause (I), by inserting ''for fiscal years before fiscal year 2004,'' before ''for hospitals''; and

(ii) in subclause (II), by striking ''and'' after the semicolon at the end;

(D) in clause (ii)—

(i) in the matter preceding subclause (I), by inserting ''for fiscal years before fiscal year 2004,'' before ''for hospitals''; and

(ii) in subclause (II), by striking the period at the end and inserting ''; and''; and

(E) by adding at the end the following new clause:

''(iii) for a fiscal year beginning after fiscal year 2003, for hospitals located in all areas, to the product of—

''(I) the applicable standardized amount (computed under subparagraph (A)), reduced under subparagraph (B), and adjusted or reduced under subparagraph (C) for the fiscal year; and

''(II) the weighting factor (determined under paragraph (4)(B)) for that diagnosis-related group.''.

(2) TECHNICAL CONFORMING SUNSET.—Section 1886(d)(3) (42 U.S.C. 1395ww(d)(3)) is amended—

(A) in the matter preceding subparagraph (A), by inserting '', for fiscal years before fiscal year 1997,'' before ''a regional adjusted DRG prospective payment rate''; and

(B) in subparagraph (D), in the matter preceding clause (i), by inserting '', for fiscal years before fiscal year 1997,'' before ''a regional DRG prospective payment rate for each region,''.

(3) ADDITIONAL TECHNICAL AMENDMENT.—Section 1886(d)(3)(A)(iii) (42 U.S.C. 1395ww(d)(3)(A)(iii)) is amended by striking ''in an other urban area'' and inserting ''in an urban area''.

(c) EQUALIZING URBAN AND RURAL STANDARDIZED PAYMENT AMOUNTS UNDER THE MEDICARE INPATIENT HOSPITAL PROSPECTIVE PAYMENT SYSTEM FOR HOSPITALS IN PUERTO RICO.—

(1) IN GENERAL.—Section 1886(d)(9)(A) (42 U.S.C. 1395ww(d)(9)(A)), as amended by section 504, is amended—

(A) in clause (i), by striking ''and'' after the comma at the end; and

(B) by striking clause (ii) and inserting the following new clause:

''(ii) the applicable Federal percentage (specified in subparagraph (E)) of—

''(I) for discharges beginning in a fiscal year beginning on or after October 1, 1997, and before October 1, 2003, the discharge-weighted average of—

''(aa) the national adjusted DRG prospective payment rate (determined under paragraph (3)(D)) for hospitals located in a large urban area,

''(bb) such rate for hospitals located in other urban areas, and

''(cc) such rate for hospitals located in a rural area,

for such discharges, adjusted in the manner provided in paragraph (3)(E) for different area wage levels; and

''(II) for discharges in a fiscal year beginning on or after October 1, 2003, the national DRG prospective payment rate determined under paragraph (3)(D)(iii) for hospitals located in any area for such discharges, adjusted in the manner provided in paragraph (3)(E) for different area wage levels.

As used in this section, the term 'subsection (d) Puerto Rico hospital' means a hospital that is located in Puerto Rico and that would be a subsection (d) hospital (as defined in paragraph (1)(B)) if it were located in one of the 50 States.''.

(2) APPLICATION OF PUERTO RICO STANDARDIZED AMOUNT BASED ON LARGE URBAN AREAS.—Section 1886(d)(9)(C) (42 U.S.C. 1395ww(d)(9)(C)) is amended—

(A) in clause (i)—

(i) by striking ''(i) The Secretary'' and inserting ''(i)(I) For discharges in a fiscal year after fiscal year 1988 and before fiscal year 2004, the Secretary''; and

(ii) by adding at the end the following new subclause:

''(II) For discharges occurring in a fiscal year (beginning with fiscal year 2004), the Secretary shall compute an average standardized amount for hospitals located in any area of Puerto Rico that is equal to the average standardized amount computed under subclause (I) for fiscal year 2003 for hospitals in a large urban area (or, beginning with fiscal year 2005, for all hospitals in the previous fiscal year) increased by the applicable percentage increase under subsection (b)(3)(B) for the fiscal year involved.'';

(B) in clause (ii), by inserting ''(or for fiscal year 2004 and thereafter, the average standardized amount)'' after ''each of the average standardized amounts''; and

(C) in clause (iii)(I), by striking ''for hospitals located in an urban or rural area, respectively''.

(d) IMPLEMENTATION.—

(1) IN GENERAL.—The amendments made by subsections (a), (b), and (c)(1) of this section shall have no effect on the authority of the Secretary, under subsection (b)(2) of section 402 of Public Law 108–89, to delay implementation of the extension of provisions equalizing urban and rural standardized inpatient hospital payments under subsection (a) of such section 402.

(2) APPLICATION OF PUERTO RICO STANDARDIZED AMOUNT BASED ON LARGE URBAN AREAS.—The authority of the Secretary referred to in paragraph (1) shall apply with respect to the amendments made by subsection (c)(2) of this section in the same manner as that authority applies with respect to the extension of provisions equalizing urban and rural standardized inpatient hospital payments under subsection (a) of such section 402, except that any reference in subsection (b)(2)(A) of such section 402 is deemed to be a reference to April 1, 2004.

SEC. 402. ENHANCED DISPROPORTIONATE SHARE HOSPITAL (DSH) TREATMENT FOR RURAL HOSPITALS AND URBAN HOSPITALS WITH FEWER THAN 100 BEDS.

(a) DOUBLING THE CAP.—Section 1886(d)(5)(F) (42 U.S.C. 1395ww(d)(5)(F)) is amended by adding at the end the following new clause:

''(xiv)(I) In the case of discharges occurring on or after April 1, 2004, subject to subclause (II), there shall be substituted for the disproportionate share adjustment percentage otherwise determined under clause (iv) (other than subclause (I)) or under clause (viii), (x), (xi), (xii), or (xiii), the disproportionate share adjustment percentage determined under clause (vii) (relating to large, urban hospitals).

''(II) Under subclause (I), the disproportionate share adjustment percentage shall not exceed 12 percent for a hospital that is not classified as a rural referral center under subparagraph (C).''.

(b) CONFORMING AMENDMENTS.—Section 1886(d) (42 U.S.C. 1395ww(d)) is amended—

(1) in paragraph (5)(F)—

(A) in each of subclauses (II), (III), (IV), (V), and (VI) of clause (iv), by inserting ''subject to clause (xiv) and'' before ''for discharges occurring'';

(B) in clause (viii), by striking ''The formula'' and inserting ''Subject to clause (xiv), the formula''; and

(C) in each of clauses (x), (xi), (xii), and (xiii), by striking ''For purposes'' and inserting ''Subject to clause (xiv), for purposes''; and

(2) in paragraph (2)(C)(iv)—

(A) by striking ''or'' before ''the enactment of section 303''; and

(B) by inserting before the period at the end the following: '', or the enactment of section 402(a)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003''.

SEC. 403. ADJUSTMENT TO THE MEDICARE INPATIENT HOSPITAL PROSPECTIVE PAYMENT SYSTEM WAGE INDEX TO REVISE THE LABOR-RELATED SHARE OF SUCH INDEX.

(a) ADJUSTMENT.—

(1) IN GENERAL.—Section 1886(d)(3)(E) (42 U.S.C. 1395ww(d)(3)(E)) is amended—

(A) by striking ''WAGE LEVELS.—The Secretary'' and inserting ''WAGE LEVELS.—

''(i) IN GENERAL.—Except as provided in clause (ii), the Secretary''; and

(B) by adding at the end the following new clause:

''(ii) ALTERNATIVE PROPORTION TO BE ADJUSTED BEGINNING IN FISCAL YEAR 2005.—For discharges occurring on or after October 1, 2004, the Secretary shall substitute '62 percent' for the proportion described in the first sentence of clause (i), unless the application of this clause

would result in lower payments to a hospital than would otherwise be made.''.

(2) WAIVING BUDGET NEUTRALITY.—Section 1886(d)(3)(E) (42 U.S.C. 1395ww(d)(3)(E)), as amended by subsection (a), is amended by adding at the end of clause (i) the following new sentence: ''The Secretary shall apply the previous sentence for any period as if the amendments made by section 403(a)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 had not been enacted.''.

(b) APPLICATION TO PUERTO RICO HOSPITALS.—Section 1886(d)(9)(C)(iv) (42 U.S.C. 1395ww(d)(9)(C)(iv)) is amended—

(1) by inserting ''(I)'' after ''(iv)'';

(2) by striking ''paragraph (3)(E)'' and inserting ''paragraph (3)(E)(i)''; and

(3) by adding at the end the following new subclause:

''(II) For discharges occurring on or after October 1, 2004, the Secretary shall substitute '62 percent' for the proportion described in the first sentence of clause (i), unless the application of this subclause would result in lower payments to a hospital than would otherwise be made.''.

SEC. 404. MORE FREQUENT UPDATE IN WEIGHTS USED IN HOSPITAL MARKET BASKET.

(a) MORE FREQUENT UPDATES IN WEIGHTS.—After revising the weights used in the hospital market basket under section 1886(b)(3)(B)(iii) of the Social Security Act (42 U.S.C. 1395ww(b)(3)(B)(iii)) to reflect the most current data available, the Secretary shall establish a frequency for revising such weights, including the labor share, in such market basket to reflect the most current data available more frequently than once every 5 years.

(b) INCORPORATION OF EXPLANATION IN RULEMAKING.—The Secretary shall include in the publication of the final rule for payment for inpatient hospital services under section 1886(d) of the Social Security Act (42 U.S.C. 1395ww(d)) for fiscal year 2006, an explanation of the reasons for, and options considered, in determining frequency established under subsection (a).

SEC. 405. IMPROVEMENTS TO CRITICAL ACCESS HOSPITAL PROGRAM.

(a) INCREASE IN PAYMENT AMOUNTS.—

(1) IN GENERAL.—Sections 1814(l), 1834(g)(1), and 1883(a)(3) (42 U.S.C. 1395f(l), 1395m(g)(1), and 1395tt(a)(3)) are each amended by inserting ''equal to 101 percent of'' before ''the reasonable costs''.

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to payments for services furnished during cost reporting periods beginning on or after January 1, 2004.

(b) COVERAGE OF COSTS FOR CERTAIN EMERGENCY ROOM ON-CALL PROVIDERS.—

(1) IN GENERAL.—Section 1834(g)(5) (42 U.S.C. 1395m(g)(5)) is amended—

(A) in the heading—

(i) by inserting ''CERTAIN'' before ''EMERGENCY''; and

(ii) by striking ''PHYSICIANS'' and inserting ''PROVIDERS'';

(B) by striking ''emergency room physicians who are on-call (as defined by the Secretary)'' and inserting ''physicians, physician assistants, nurse practitioners, and clinical nurse specialists who are on-call (as defined by the Secretary) to provide emergency services''; and

(C) by striking ''physicians' services'' and inserting ''services covered under this title''.

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply with respect to costs incurred for services furnished on or after January 1, 2005.

(c) AUTHORIZATION OF PERIODIC INTERIM PAYMENT (PIP).—

(1) IN GENERAL.—Section 1815(e)(2) (42 U.S.C. 1395g(e)(2)) is amended—

(A) in the matter before subparagraph (A), by inserting '', in the cases described in subparagraphs (A) through (D)'' after ''1986'';

(B) by striking ''and'' at the end of subparagraph (C);

(C) by adding ''and'' at the end of subparagraph (D); and

(D) by inserting after subparagraph (D) the following new subparagraph:

''(E) inpatient critical access hospital services;''.

(2) DEVELOPMENT OF ALTERNATIVE TIMING METHODS OF PERIODIC INTERIM PAYMENTS.—With respect to periodic interim payments to critical access hospitals for inpatient critical access hospital services under section 1815(e)(2)(E) of the Social Security Act, as added by paragraph (1), the Secretary shall develop alternative methods for the timing of such payments.

(3) AUTHORIZATION OF PIP.—The amendments made by paragraph (1) shall apply to payments made on or after July 1, 2004.

(d) CONDITION FOR APPLICATION OF SPECIAL PROFESSIONAL SERVICE PAYMENT ADJUSTMENT.—

(1) IN GENERAL.—Section 1834(g)(2) (42 U.S.C. 1395m(g)(2)) is amended by adding after and below subparagraph (B) the following:

''The Secretary may not require, as a condition for applying subparagraph (B) with respect to a critical access hospital, that each physician or other practitioner providing professional services in the hospital must assign billing rights with respect to such services, except that such subparagraph shall not apply to those physicians and practitioners who have not assigned such billing rights.''.

(2) EFFECTIVE DATE.—

(A) IN GENERAL.—Except as provided in subparagraph (B), the amendment made by paragraph (1) shall apply to cost reporting periods beginning on or after July 1, 2004.

(B) RULE OF APPLICATION.—In the case of a critical access hospital that made an election under section 1834(g)(2) of the Social Security Act (42 U.S.C. 1395m(g)(2)) before November 1, 2003, the amendment made by paragraph (1) shall apply to cost reporting periods beginning on or after July 1, 2001.

(e) REVISION OF BED LIMITATION FOR HOSPITALS.—

(1) IN GENERAL.—Section 1820(c)(2)(B)(iii) (42 U.S.C. 1395i–4(c)(2)(B)(iii)) is amended by striking ''15 (or, in the case of a facility under an agreement described in subsection (f), 25)'' and inserting ''25''.

(2) CONFORMING AMENDMENT.—Section 1820(f) (42 U.S.C. 1395i–4(f)) is amended by striking ''and the number of beds used at any time for acute care inpatient services does not exceed 15 beds''.

(3) EFFECTIVE DATE.—The amendments made by this subsection shall apply to designations made before, on, or after January 1, 2004, but any election made pursuant to regulations promulgated to carry out such amendments shall only apply prospectively.

(f) PROVISIONS RELATING TO FLEX GRANTS.—

(1) ADDITIONAL 4-YEAR PERIOD OF FUNDING.—Section 1820(j) (42 U.S.C. 1395i–4(j)) is amended by inserting before the period at the end the following: '', and for making grants to all States under paragraphs (1) and (2) of subsection (g), $35,000,000 in each of fiscal years 2005 through 2008''.

(2) ADDITIONAL REQUIREMENTS AND ADMINISTRATION.—Section 1820(g) (42 U.S.C. 1395i–4(g)) is amended by adding at the end the following new paragraphs:

''(4) ADDITIONAL REQUIREMENTS WITH RESPECT TO FLEX GRANTS.—With respect to grants awarded under paragraph (1) or (2) from funds appropriated for fiscal year 2005 and subsequent fiscal years—

''(A) CONSULTATION WITH THE STATE HOSPITAL ASSOCIATION AND RURAL HOSPITALS ON THE MOST APPROPRIATE WAYS TO USE GRANTS.—A State shall consult with the hospital association of such State and rural hospitals located in such State on the most appropriate ways to use the funds under such grant.

''(B) LIMITATION ON USE OF GRANT FUNDS FOR ADMINISTRATIVE EXPENSES.—A State may not expend more than the lesser of—

''(i) 15 percent of the amount of the grant for administrative expenses; or

''(ii) the State's federally negotiated indirect rate for administering the grant.

''(5) USE OF FUNDS FOR FEDERAL ADMINISTRATIVE EXPENSES.—Of the total amount appropriated for grants under paragraphs (1) and (2) for a fiscal year (beginning with fiscal year 2005), up to 5 percent of such amount shall be available to the Health Resources and Services Administration for purposes of administering such grants.''.

(g) AUTHORITY TO ESTABLISH PSYCHIATRIC AND REHABILITATION DISTINCT PART UNITS.—

(1) IN GENERAL.—Section 1820(c)(2) (42 U.S.C. 1395i–4(c)(2)) is amended by adding at the end the following:

''(E) AUTHORITY TO ESTABLISH PSYCHIATRIC AND REHABILITATION DISTINCT PART UNITS.—

''(i) IN GENERAL.—Subject to the succeeding provisions of this subparagraph, a critical access hospital may establish—

''(I) a psychiatric unit of the hospital that is a distinct part of the hospital; and

''(II) a rehabilitation unit of the hospital that is a distinct part of the hospital,

if the distinct part meets the requirements (including conditions of participation) that would otherwise apply to the distinct part if the distinct part were established by a subsection (d) hospital in accordance with the matter following clause (v) of section 1886(d)(1)(B), including any regulations adopted by the Secretary under such section.

''(ii) LIMITATION ON NUMBER OF BEDS.—The total number of beds that may be established under clause (i) for a distinct part unit may not exceed 10.

''(iii) EXCLUSION OF BEDS FROM BED COUNT.—In determining the number of beds of a critical access hospital for purposes of applying the bed limitations referred to in subparagraph (B)(iii) and subsection (f), the Secretary shall not take into account any bed established under clause (i).

''(iv) EFFECT OF FAILURE TO MEET REQUIREMENTS.—If a psychiatric or rehabilitation unit established under clause (i) does not meet the requirements described in such clause with respect to a cost reporting period, no payment may be made under this title to the hospital for services furnished in such unit during such period. Payment to the hospital for services furnished in the unit may resume only after the hospital has demonstrated to the Secretary that the unit meets such requirements.''.

(2) PAYMENT ON A PROSPECTIVE PAYMENT BASIS.—Section 1814(l) (42 U.S.C. 1395f(l)) is amended—

(A) by striking ''(l) The amount'' and inserting ''(l)(1) Except as provided in paragraph (2), the amount''; and

(B) by adding at the end the following new paragraph:

''(2) In the case of a distinct part psychiatric or rehabilitation unit of a critical access hospital described in section 1820(c)(2)(E), the amount of payment for inpatient critical access hospital services of such unit shall be equal to the amount of the payment that would otherwise be made if such services were inpatient hospital services of a distinct part psychiatric or rehabilitation unit, respectively, described in the matter following clause (v) of section 1886(d)(1)(B).''.

(3) EFFECTIVE DATE.—The amendments made by this subsection shall apply to cost reporting periods beginning on or after October 1, 2004.

(h) WAIVER AUTHORITY.—

(1) IN GENERAL.—Section 1820(c)(2)(B)(i)(II) (42 U.S.C. 1395i–4(c)(2)(B)(i)(II)) is amended by inserting ''before January 1, 2006,'' after ''is certified''.

(2) GRANDFATHERING WAIVER AUTHORITY FOR CERTAIN FACILITIES.—Section 1820(h) (42 U.S.C. 1395i–4(h)) is amended—

(A) in the heading preceding paragraph (1), by striking ''OF CERTAIN FACILITIES'' and inserting ''PROVISIONS''; and

(B) by adding at the end the following new paragraph:

''(3) STATE AUTHORITY TO WAIVE 35-MILE RULE.—In the case of a facility that was designated as a critical access hospital before January 1, 2006, and was certified by the State as being a necessary provider of health care services to residents in the area under subsection (c)(2)(B)(i)(II), as in effect before such date, the authority under such subsection with respect to any redesignation of such facility shall continue to apply notwithstanding the amendment made by section 405(h)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.''.

SEC. 406. MEDICARE INPATIENT HOSPITAL PAYMENT ADJUSTMENT FOR LOW-VOLUME HOSPITALS.

(a) IN GENERAL.—Section 1886(d) (42 U.S.C. 1395ww(d)) is amended by adding at the end the following new paragraph:

''(12) PAYMENT ADJUSTMENT FOR LOW-VOLUME HOSPITALS.—

''(A) IN GENERAL.—In addition to any payments calculated under this section for a subsection (d) hospital, for discharges occurring during a fiscal year (beginning with fiscal year 2005), the Secretary shall provide for an additional payment amount to each low-volume hospital (as defined in subparagraph (C)(i)) for discharges occurring during that fiscal year that is equal to the applicable percentage increase (determined under subparagraph (B) for the hospital involved) in the amount paid to such hospital under this section for such discharges (determined without regard to this paragraph).

''(B) APPLICABLE PERCENTAGE INCREASE.—The Secretary shall determine an applicable percentage increase for purposes of subparagraph (A) as follows:

''(i) The Secretary shall determine the empirical relationship for subsection (d) hospitals between the standardized cost-per-case for such hospitals and the total number of discharges of such hospitals and the amount of the additional incremental costs (if any) that are associated with such number of discharges.

''(ii) The applicable percentage increase shall be determined based upon such relationship in a manner that reflects, based upon the number of such discharges for a subsection (d) hospital, such additional incremental costs.

''(iii) In no case shall the applicable percentage increase exceed 25 percent.

''(C) DEFINITIONS.—

''(i) LOW-VOLUME HOSPITAL.—For purposes of this paragraph, the term 'low-volume hospital' means, for a fiscal year, a subsection (d) hospital (as defined in paragraph (1)(B)) that the Secretary determines is located more than 25 road miles from another subsection (d) hospital and has less than 800 discharges during the fiscal year.

''(ii) DISCHARGE.—For purposes of subparagraph (B) and clause (i), the term 'discharge' means an inpatient acute care discharge of an individual regardless of whether the individual is entitled to benefits under part A.''.

(b) JUDICIAL REVIEW.—Section 1886(d)(7)(A) (42 U.S.C. 1395ww(d)(7)(A)) is amended by inserting after ''to subsection (e)(1)'' the following: ''or the determination of the applicable percentage increase under paragraph (12)(A)(ii)''.

SEC. 407. TREATMENT OF MISSING COST REPORTING PERIODS FOR SOLE COMMUNITY HOSPITALS.

(a) IN GENERAL.—Section 1886(b)(3)(I) (42 U.S.C. 1395ww(b)(3)(I)) is amended by adding at the end the following new clause:

''(iii) In no case shall a hospital be denied treatment as a sole community hospital or payment (on the basis of a target rate as such as a hospital) because data are unavailable for any cost reporting period due to changes in ownership, changes in fiscal intermediaries, or other extraordinary circumstances, so long as data for at least one applicable base cost reporting period is available.''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to cost reporting periods beginning on or after January 1, 2004.

SEC. 408. RECOGNITION OF ATTENDING NURSE PRACTITIONERS AS ATTENDING PHYSICIANS TO SERVE HOSPICE PATIENTS.

(a) IN GENERAL.—Section 1861(dd)(3)(B) (42 U.S.C. 1395x(dd)(3)(B)) is amended by inserting ''or nurse practitioner (as defined in subsection (aa)(5))'' after ''the physician (as defined in subsection (r)(1))''.

(b) CLARIFICATION OF HOSPICE ROLE OF NURSE PRACTITIONERS.—Section 1814(a)(7)(A)(i)(I) (42 U.S.C. 1395f(a)(7)(A)(i)(I)) is amended by inserting ''(which for purposes of this subparagraph does not include a nurse practitioner)'' after ''attending physician (as defined in section 1861(dd)(3)(B))''.

SEC. 409. RURAL HOSPICE DEMONSTRATION PROJECT.

(a) IN GENERAL.—The Secretary shall conduct a demonstration project for the delivery of hospice care to medicare beneficiaries in rural areas. Under the project medicare beneficiaries who are unable to receive hospice care in the facility for lack of an appropriate caregiver are provided such care in a facility of 20 or fewer beds which offers, within its walls, the full range of services provided by hospice programs under section 1861(dd) of the Social Security Act (42 U.S.C. 1395x(dd)).

(b) SCOPE OF PROJECT.—The Secretary shall conduct the project under this section with respect to no more than 3 hospice programs over a period of not longer than 5 years each.

(c) COMPLIANCE WITH CONDITIONS.—Under the demonstration project—

(1) the hospice program shall comply with otherwise applicable requirements, except that it shall not be required to offer services outside of the home or to meet the requirements of section 1861(dd)(2)(A)(iii) of the Social Security Act; and

(2) payments for hospice care shall be made at the rates otherwise applicable to such care under title XVIII of such Act.

The Secretary may require the program to comply with such additional quality assurance standards for its provision of services in its facility as the Secretary deems appropriate.

(d) REPORT.—Upon completion of the project, the Secretary shall submit a report to Congress on the project and shall include in the report recommendations regarding extension of such project to hospice programs serving rural areas.

SEC. 410. EXCLUSION OF CERTAIN RURAL HEALTH CLINIC AND FEDERALLY QUALIFIED HEALTH CENTER SERVICES FROM THE PROSPECTIVE PAYMENT SYSTEM FOR SKILLED NURSING FACILITIES.

(a) IN GENERAL.—Section 1888(e)(2)(A) (42 U.S.C. 1395yy(e)(2)(A)) is amended—

(1) in clause (i)(II), by striking ''clauses (ii) and (iii)'' and inserting ''clauses (ii), (iii), and (iv)''; and

(2) by adding at the end the following new clause:

''(iv) EXCLUSION OF CERTAIN RURAL HEALTH CLINIC AND FEDERALLY QUALIFIED HEALTH CENTER SERVICES.—Services described in this clause are—

''(I) rural health clinic services (as defined in paragraph (1) of section 1861(aa)); and

''(II) Federally qualified health center services (as defined in paragraph (3) of such section);

that would be described in clause (ii) if such services were furnished by an individual not affiliated with a rural health clinic or a Federally qualified health center.''.

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply to services furnished on or after January 1, 2005.

SEC. 410A. RURAL COMMUNITY HOSPITAL DEMONSTRATION PROGRAM.

(a) ESTABLISHMENT OF RURAL COMMUNITY HOSPITAL (RCH) DEMONSTRATION PROGRAM.—

(1) IN GENERAL.—The Secretary shall establish a demonstration program to test the feasibility and advisability of the establishment of rural community hospitals (as defined in subsection (f)(1)) to furnish covered inpatient hospital services (as defined in subsection (f)(2)) to medicare beneficiaries.

(2) DEMONSTRATION AREAS.—The program shall be conducted in rural areas selected by the Secretary in States with low population densities, as determined by the Secretary.

(3) APPLICATION.—Each rural community hospital that is located in a demonstration area selected under paragraph (2) that desires to participate in the demonstration program under this section shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require.

(4) SELECTION OF HOSPITALS.—The Secretary shall select from among rural community hospitals submitting applications under paragraph (3) not more than 15 of such hospitals to participate in the demonstration program under this section.

(5) DURATION.—The Secretary shall conduct the demonstration program under this section for a 5-year period.

(6) IMPLEMENTATION.—The Secretary shall implement the demonstration program not later than January 1, 2005, but may not implement the program before October 1, 2004.

(b) PAYMENT.—

(1) IN GENERAL.—The amount of payment under the demonstration program for covered inpatient hospital services furnished in a rural community hospital, other than such services furnished in a psychiatric or rehabilitation unit of the hospital which is a distinct part, is—

(A) for discharges occurring in the first cost reporting period beginning on or after the implementation of the demonstration program, the reasonable costs of providing such services; and

(B) for discharges occurring in a subsequent cost reporting period under the demonstration program, the lesser of—

(i) the reasonable costs of providing such services in the cost reporting period involved; or

(ii) the target amount (as defined in paragraph (2), applicable to the cost reporting period involved.

(2) TARGET AMOUNT.—For purposes of paragraph (1)(B)(ii), the term ''target amount'' means, with respect to a rural community hospital for a particular 12-month cost reporting period—

(A) in the case of the second such reporting period for which this subsection is in effect, the reasonable costs of providing such covered inpatient hospital services as determined under paragraph (1)(A), and

(B) in the case of a later reporting period, the target amount for the preceding 12-month cost reporting period,

increased by the applicable percentage increase (under clause (i) of section 1886(b)(3)(B) of the Social Security Act (42 U.S.C. 1395ww(b)(3)(B))) in the market basket percentage increase (as defined in clause (iii) of such section) for that particular cost reporting period.

(c) FUNDING.—

(1) IN GENERAL.—The Secretary shall provide for the transfer from the Federal Hospital Insurance Trust Fund under section 1817 of the Social Security Act (42 U.S.C. 1395i) of such funds as are necessary for the costs of carrying out the demonstration program under this section.

(2) BUDGET NEUTRALITY.—In conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration program under this section was not implemented.

(d) WAIVER AUTHORITY.—The Secretary may waive such requirements of title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) as

may be necessary for the purpose of carrying out the demonstration program under this section.

(e) REPORT.—Not later than 6 months after the completion of the demonstration program under this section, the Secretary shall submit to Congress a report on such program, together with recommendations for such legislation and administrative action as the Secretary determines to be appropriate.

(f) DEFINITIONS.—In this section:

(1) RURAL COMMUNITY HOSPITAL DEFINED.—

(A) IN GENERAL.—The term ''rural community hospital'' means a hospital (as defined in section 1861(e) of the Social Security Act (42 U.S.C. 1395x(e))) that—

(i) is located in a rural area (as defined in section 1886(d)(2)(D) of such Act (42 U.S.C. 1395ww(d)(2)(D))) or treated as being so located pursuant to section 1886(d)(8)(E) of such Act (42 U.S.C. 1395ww(d)(8)(E));

(ii) subject to paragraph (2), has fewer than 51 acute care inpatient beds, as reported in its most recent cost report;

(iii) makes available 24-hour emergency care services; and

(iv) is not eligible for designation, or has not been designated, as a critical access hospital under section 1820.

(B) TREATMENT OF PSYCHIATRIC AND REHABILITATION UNITS.—For purposes of paragraph (1)(B), beds in a psychiatric or rehabilitation unit of the hospital which is a distinct part of the hospital shall not be counted.

(2) COVERED INPATIENT HOSPITAL SERVICES.—The term ''covered inpatient hospital services'' means inpatient hospital services, and includes extended care services furnished under an agreement under section 1883 of the Social Security Act (42 U.S.C. 1395tt).

Subtitle B—Provisions Relating to Part B Only

SEC. 411. 2-YEAR EXTENSION OF HOLD HARMLESS PROVISIONS FOR SMALL RURAL HOSPITALS AND SOLE COMMUNITY HOSPITALS UNDER THE PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES.

(a) HOLD HARMLESS PROVISIONS.—

(1) IN GENERAL.—Section 1833(t)(7)(D)(i) (42 U.S.C. 1395l(t)(7)(D)(i)) is amended—

(A) in the heading, by striking ''SMALL'' and inserting ''CERTAIN'';

(B) by inserting ''or a sole community hospital (as defined in section 1886(d)(5)(D)(iii)) located in a rural area'' after ''100 beds''; and

(C) by striking ''2004'' and inserting ''2006''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1)(B) shall apply with respect to cost reporting periods beginning on and after January 1, 2004.

(b) STUDY; AUTHORIZATION OF ADJUSTMENT.—Section 1833(t) (42 U.S.C. 1395l(t)) is amended—

(1) by redesignating paragraph (13) as paragraph (16); and

(2) by inserting after paragraph (12) the following new paragraph:

''(13) AUTHORIZATION OF ADJUSTMENT FOR RURAL HOSPITALS.—

''(A) STUDY.—The Secretary shall conduct a study to determine if, under the system under this subsection, costs incurred by hospitals located in rural areas by ambulatory payment classification groups (APCs) exceed those costs incurred by hospitals located in urban areas.

''(B) AUTHORIZATION OF ADJUSTMENT.—Insofar as the Secretary determines under subparagraph (A) that costs incurred by hospitals located in rural areas exceed those costs incurred by hospitals located in urban areas, the Secretary shall provide for an appropriate adjustment under paragraph (2)(E) to reflect those higher costs by January 1, 2006.''.

SEC. 412. ESTABLISHMENT OF FLOOR ON WORK GEOGRAPHIC ADJUSTMENT.

Section 1848(e)(1) (42 U.S.C. 1395w–4(e)(1)) is amended—

(1) in subparagraph (A), by striking ''subparagraphs (B) and (C)'' and inserting ''subparagraphs (B), (C), and (E)''; and

(2) by adding at the end the following new subparagraph:

''(E) FLOOR AT 1.0 ON WORK GEOGRAPHIC INDEX.—After calculating the work geographic index in subparagraph (A)(iii), for purposes of payment for services furnished on or after January 1, 2004, and before January 1, 2007, the Secretary shall increase the work geographic index to 1.00 for any locality for which such work geographic index is less than 1.00.''.

SEC. 413. MEDICARE INCENTIVE PAYMENT PROGRAM IMPROVEMENTS FOR PHYSICIAN SCARCITY.

(a) ADDITIONAL INCENTIVE PAYMENT FOR CERTAIN PHYSICIAN SCARCITY AREAS.—Section 1833 (42 U.S.C. 1395l) is amended by adding at the end the following new subsection:

''(u) INCENTIVE PAYMENTS FOR PHYSICIAN SCARCITY AREAS.—

''(1) IN GENERAL.—In the case of physicians' services furnished on or after January 1, 2005, and before January 1, 2008—

''(A) by a primary care physician in a primary care scarcity county (identified under paragraph (4)); or

''(B) by a physician who is not a primary care physician in a specialist care scarcity county (as so identified),

in addition to the amount of payment that would otherwise be made for such services under this part, there also shall be paid an amount equal to 5 percent of the payment amount for the service under this part.

''(2) DETERMINATION OF RATIOS OF PHYSICIANS TO MEDICARE BENEFICIARIES IN AREA.—Based upon available data, the Secretary shall establish for each county or equivalent area in the United States, the following:

''(A) NUMBER OF PHYSICIANS PRACTICING IN THE AREA.—The number of physicians who furnish physicians' services in the active practice of medicine or osteopathy in that county or area, other than physicians whose practice is exclusively for the Federal Government, physicians who are retired, or physicians who only provide administrative services. Of such number, the number of such physicians who are—

''(i) primary care physicians; or

''(ii) physicians who are not primary care physicians.

''(B) NUMBER OF MEDICARE BENEFICIARIES RESIDING IN THE AREA.—The number of individuals who are residing in the county and are entitled to benefits under part A or enrolled under this part, or both (in this subsection referred to as 'individuals').

''(C) DETERMINATION OF RATIOS.—

''(i) PRIMARY CARE RATIO.—The ratio (in this paragraph referred to as the 'primary care ratio') of the number of primary care physicians (determined under subparagraph (A)(i)), to the number of individuals determined under subparagraph (B).

''(ii) SPECIALIST CARE RATIO.—The ratio (in this paragraph referred to as the 'specialist care ratio') of the number of other physicians (determined under subparagraph (A)(ii)), to the number of individuals determined under subparagraph (B).

''(3) RANKING OF COUNTIES.—The Secretary shall rank each such county or area based separately on its primary care ratio and its specialist care ratio.

''(4) IDENTIFICATION OF COUNTIES.—

''(A) IN GENERAL.—The Secretary shall identify—

''(i) those counties and areas (in this paragraph referred to as 'primary care scarcity counties') with the lowest primary care ratios that represent, if each such county or area were weighted by the number of individuals determined under paragraph (2)(B), an aggregate total of 20 percent of the total of the individuals determined under such paragraph; and

''(ii) those counties and areas (in this subsection referred to as 'specialist care scarcity counties') with the lowest specialist care ratios that represent, if each such county or area were weighted by the number of individuals determined under paragraph (2)(B), an aggregate total of 20 percent of the total of the individuals determined under such paragraph.

''(B) PERIODIC REVISIONS.—The Secretary shall periodically revise the counties or areas identified in subparagraph (A) (but not less often than once every three years) unless the Secretary determines that there is no new data available on the number of physicians practicing in the county or area or the number of individuals residing in the county or area, as identified in paragraph (2).

''(C) IDENTIFICATION OF COUNTIES WHERE SERVICE IS FURNISHED.—For purposes of paying the additional amount specified in paragraph (1), if the Secretary uses the 5-digit postal ZIP Code where the service is furnished, the dominant county of the postal ZIP Code (as determined by the United States Postal Service, or otherwise) shall be used to determine whether the postal ZIP Code is in a scarcity county identified in subparagraph (A) or revised in subparagraph (B).

''(D) JUDICIAL REVIEW.—There shall be no administrative or judicial review under section 1869, 1878, or otherwise, respecting—

''(i) the identification of a county or area;

''(ii) the assignment of a specialty of any physician under this paragraph;

''(iii) the assignment of a physician to a county under paragraph (2); or

''(iv) the assignment of a postal ZIP Code to a county or other area under this subsection.

''(5) RURAL CENSUS TRACTS.—To the extent feasible, the Secretary shall treat a rural census tract of a metropolitan statistical area (as determined under the most recent modification of the Goldsmith Modification, originally published in the Federal Register on February 27, 1992 (57 Fed. Reg. 6725)), as an equivalent area for purposes of qualifying as a primary care scarcity county or specialist care scarcity county under this subsection.

''(6) PHYSICIAN DEFINED.—For purposes of this paragraph, the term 'physician' means a physician described in section 1861(r)(1) and the term 'primary care physician' means a physician who is identified in the available data as a general practitioner, family practice practitioner, general internist, or obstetrician or gynecologist.

''(7) PUBLICATION OF LIST OF COUNTIES; POSTING ON WEBSITE.—With respect to a year for which a county or area is identified or revised under paragraph (4), the Secretary shall identify such counties or areas as part of the proposed and final rule to implement the physician fee schedule under section 1848 for the applicable year. The Secretary shall post the list of counties identified or revised under paragraph (4) on the Internet website of the Centers for Medicare & Medicaid Services.''.

(b) IMPROVEMENT TO MEDICARE INCENTIVE PAYMENT PROGRAM.—

(1) IN GENERAL.—Section 1833(m) (42 U.S.C. 1395l(m)) is amended—

(A) by inserting ''(1)'' after ''(m)'';

(B) in paragraph (1), as designated by subparagraph (A)—

(i) by inserting ''in a year'' after ''In the case of physicians' services furnished''; and

(ii) by inserting ''as identified by the Secretary prior to the beginning of such year'' after ''as a health professional shortage area''; and

(C) by adding at the end the following new paragraphs:

''(2) For each health professional shortage area identified in paragraph (1) that consists of an entire county, the Secretary shall provide for the additional payment under paragraph (1) without any requirement on the physician to identify the health professional shortage area

involved. The Secretary may implement the previous sentence using the method specified in subsection (u)(4)(C).

''(3) The Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services a list of the health professional shortage areas identified in paragraph (1) that consist of a partial county to facilitate the additional payment under paragraph (1) in such areas.

''(4) There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, respecting—

''(A) the identification of a county or area;

''(B) the assignment of a specialty of any physician under this paragraph;

''(C) the assignment of a physician to a county under this subsection; or

''(D) the assignment of a postal zip code to a county or other area under this subsection.''.

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to physicians' services furnished on or after January 1, 2005.

(c) GAO STUDY OF GEOGRAPHIC DIFFERENCES IN PAYMENTS FOR PHYSICIANS' SERVICES.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study of differences in payment amounts under the physician fee schedule under section 1848 of the Social Security Act (42 U.S.C. 1395w–4) for physicians' services in different geographic areas. Such study shall include—

(A) an assessment of the validity of the geographic adjustment factors used for each component of the fee schedule;

(B) an evaluation of the measures used for such adjustment, including the frequency of revisions;

(C) an evaluation of the methods used to determine professional liability insurance costs used in computing the malpractice component, including a review of increases in professional liability insurance premiums and variation in such increases by State and physician specialty and methods used to update the geographic cost of practice index and relative weights for the malpractice component; and

(D) an evaluation of the effect of the adjustment to the physician work geographic index under section 1848(e)(1)(E) of the Social Security Act, as added by section 412, on physician location and retention in areas affected by such adjustment, taking into account—

(i) differences in recruitment costs and retention rates for physicians, including specialists, between large urban areas and other areas; and

(ii) the mobility of physicians, including specialists, over the last decade.

(2) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General shall submit to Congress a report on the study conducted under paragraph (1). The report shall include recommendations regarding the use of more current data in computing geographic cost of practice indices as well as the use of data directly representative of physicians' costs (rather than proxy measures of such costs).

SEC. 414. PAYMENT FOR RURAL AND URBAN AMBULANCE SERVICES.

(a) PHASE-IN PROVIDING FLOOR USING BLEND OF FEE SCHEDULE AND REGIONAL FEE SCHEDULES.—Section 1834(l) (42 U.S.C. 1395m(l)) is amended—

(1) in paragraph (2)(E), by inserting ''consistent with paragraph (11)'' after ''in an efficient and fair manner''; and

(2) by redesignating paragraph (8), as added by section 221(a) of BIPA (114 Stat. 2763A–486), as paragraph (9); and

(3) by adding at the end the following new paragraph:

''(10) PHASE-IN PROVIDING FLOOR USING BLEND OF FEE SCHEDULE AND REGIONAL FEE SCHEDULES.—In carrying out the phase-in under paragraph (2)(E) for each level of ground service furnished in a year, the portion of the payment amount that is based on the fee schedule shall be the greater of the amount determined under such fee schedule (without regard to this paragraph) or the following blended rate of the fee schedule under paragraph (1) and of a regional fee schedule for the region involved:

''(A) For 2004 (for services furnished on or after July 1, 2004), the blended rate shall be based 20 percent on the fee schedule under paragraph (1) and 80 percent on the regional fee schedule.

''(B) For 2005, the blended rate shall be based 40 percent on the fee schedule under paragraph (1) and 60 percent on the regional fee schedule.

''(C) For 2006, the blended rate shall be based 60 percent on the fee schedule under paragraph (1) and 40 percent on the regional fee schedule.

''(D) For 2007, 2008, and 2009, the blended rate shall be based 80 percent on the fee schedule under paragraph (1) and 20 percent on the regional fee schedule.

''(E) For 2010 and each succeeding year, the blended rate shall be based 100 percent on the fee schedule under paragraph (1).

For purposes of this paragraph, the Secretary shall establish a regional fee schedule for each of the nine census divisions (referred to in section 1886(d)(2)) using the methodology (used in establishing the fee schedule under paragraph (1)) to calculate a regional conversion factor and a regional mileage payment rate and using the same payment adjustments and the same relative value units as used in the fee schedule under such paragraph.''.

(b) ADJUSTMENT IN PAYMENT FOR CERTAIN LONG TRIPS.—Section 1834(l), as amended by subsection (a), is amended by adding at the end the following new paragraph:

''(11) ADJUSTMENT IN PAYMENT FOR CERTAIN LONG TRIPS.—In the case of ground ambulance services furnished on or after July 1, 2004, and before January 1, 2009, regardless of where the transportation originates, the fee schedule established under this subsection shall provide that, with respect to the payment rate for mileage for a trip above 50 miles the per mile rate otherwise established shall be increased by ¼ of the payment per mile otherwise applicable to miles in excess of 50 miles in such trip.''.

(c) IMPROVEMENT IN PAYMENTS TO RETAIN EMERGENCY CAPACITY FOR AMBULANCE SERVICES IN RURAL AREAS.—

(1) IN GENERAL.—Section 1834(l) (42 U.S.C. 1395m(l)), as amended by subsections (a) and (b), is amended by adding at the end the following new paragraph:

''(12) ASSISTANCE FOR RURAL PROVIDERS FURNISHING SERVICES IN LOW POPULATION DENSITY AREAS.—

''(A) IN GENERAL.—In the case of ground ambulance services furnished on or after July 1, 2004, and before January 1, 2010, for which the transportation originates in a qualified rural area (identified under subparagraph (B)(iii)), the Secretary shall provide for a percent increase in the base rate of the fee schedule for a trip established under this subsection. In establishing such percent increase, the Secretary shall estimate the average cost per trip for such services (not taking into account mileage) in the lowest quartile as compared to the average cost per trip for such services (not taking into account mileage) in the highest quartile of all rural county populations.

''(B) IDENTIFICATION OF QUALIFIED RURAL AREAS.—

''(i) DETERMINATION OF POPULATION DENSITY IN AREA.—Based upon data from the United States decennial census for the year 2000, the Secretary shall determine, for each rural area, the population density for that area.

''(ii) RANKING OF AREAS.—The Secretary shall rank each such area based on such population density.

''(iii) IDENTIFICATION OF QUALIFIED RURAL AREAS.—The Secretary shall identify those areas (in subparagraph (A) referred to as 'qualified rural areas') with the lowest population densities that represent, if each such area were weighted by the population of such area (as used in computing such population densities), an aggregate total of 25 percent of the total of the population of all such areas.

''(iv) RURAL AREA.—For purposes of this paragraph, the term 'rural area' has the meaning given such term in section 1886(d)(2)(D). If feasible, the Secretary shall treat a rural census tract of a metropolitan statistical area (as determined under the most recent modification of the Goldsmith Modification, originally published in the Federal Register on February 27, 1992 (57 Fed. Reg. 6725) as a rural area for purposes of this paragraph.

''(v) JUDICIAL REVIEW.—There shall be no administrative or judicial review under section 1869, 1878, or otherwise, respecting the identification of an area under this subparagraph.''.

(2) USE OF DATA.—In order to promptly implement section 1834(l)(12) of the Social Security Act, as added by paragraph (1), the Secretary may use data furnished by the Comptroller General of the United States.

(d) TEMPORARY INCREASE FOR GROUND AMBULANCE SERVICES.—Section 1834(l) (42 U.S.C. 1395m(l)), as amended by subsections (a), (b), and (c), is amended by adding at the end the following new paragraph:

''(13) TEMPORARY INCREASE FOR GROUND AMBULANCE SERVICES.—

''(A) IN GENERAL.—After computing the rates with respect to ground ambulance services under the other applicable provisions of this subsection, in the case of such services furnished on or after July 1, 2004, and before January 1, 2007, for which the transportation originates in—

''(i) a rural area described in paragraph (9) or in a rural census tract described in such paragraph, the fee schedule established under this section shall provide that the rate for the service otherwise established, after the application of any increase under paragraphs (11) and (12), shall be increased by 2 percent; and

''(ii) an area not described in clause (i), the fee schedule established under this subsection shall provide that the rate for the service otherwise established, after the application of any increase under paragraph (11), shall be increased by 1 percent.

''(B) APPLICATION OF INCREASED PAYMENTS AFTER 2006.—The increased payments under subparagraph (A) shall not be taken into account in calculating payments for services furnished after the period specified in such subparagraph.''.

(e) IMPLEMENTATION.—The Secretary may implement the amendments made by this section, and revise the conversion factor applicable under section 1834(l) of the Social Security Act (42 U.S.C. 1395m(l)) for purposes of implementing such amendments, on an interim final basis, or by program instruction.

(f) GAO REPORT ON COSTS AND ACCESS.—Not later than December 31, 2005, the Comptroller General of the United States shall submit to Congress an initial report on how costs differ among the types of ambulance providers and on access, supply, and quality of ambulance services in those regions and States that have a reduction in payment under the medicare ambulance fee schedule (under section 1834(l) of the Social Security Act, as amended by this Act). Not later than December 31, 2007, the Comptroller General shall submit to Congress a final report on such access and supply.

(g) TECHNICAL AMENDMENTS.—(1) Section 221(c) of BIPA (114 Stat. 2763A–487) is amended by striking ''subsection (b)(2)'' and inserting ''subsection (b)(3)''.

(2) Section 1861(v)(1) (42 U.S.C. 1395x(v)(1)) is amended by moving subparagraph (U) 4 ems to the left.

SEC. 415. PROVIDING APPROPRIATE COVERAGE OF RURAL AIR AMBULANCE SERVICES.

(a) COVERAGE.—Section 1834(l) (42 U.S.C. 1395m(l)), as amended by subsections (a), (b),

(c), and (d) of section 414, is amended by adding at the end the following new paragraph:

''(14) PROVIDING APPROPRIATE COVERAGE OF RURAL AIR AMBULANCE SERVICES.—

''(A) IN GENERAL.—The regulations described in section 1861(s)(7) shall provide, to the extent that any ambulance services (whether ground or air) may be covered under such section, that a rural air ambulance service (as defined in subparagraph (C)) is reimbursed under this subsection at the air ambulance rate if the air ambulance service—

''(i) is reasonable and necessary based on the health condition of the individual being transported at or immediately prior to the time of the transport; and

''(ii) complies with equipment and crew requirements established by the Secretary.

''(B) SATISFACTION OF REQUIREMENT OF MEDICALLY NECESSARY.—The requirement of subparagraph (A)(i) is deemed to be met for a rural air ambulance service if—

''(i) subject to subparagraph (D), such service is requested by a physician or other qualified medical personnel (as specified by the Secretary) who reasonably determines or certifies that the individual's condition is such that the time needed to transport the individual by land or the instability of transportation by land poses a threat to the individual's survival or seriously endangers the individual's health; or

''(ii) such service is furnished pursuant to a protocol that is established by a State or regional emergency medical service (EMS) agency and recognized or approved by the Secretary under which the use of an air ambulance is recommended, if such agency does not have an ownership interest in the entity furnishing such service.

''(C) RURAL AIR AMBULANCE SERVICE DEFINED.—For purposes of this paragraph, the term 'rural air ambulance service' means fixed wing and rotary wing air ambulance service in which the point of pick up of the individual occurs in a rural area (as defined in section 1886(d)(2)(D)) or in a rural census tract of a metropolitan statistical area (as determined under the most recent modification of the Goldsmith Modification, originally published in the Federal Register on February 27, 1992 (57 Fed. Reg. 6725)).

''(D) LIMITATION.—

''(i) IN GENERAL.—Subparagraph (B)(i) shall not apply if there is a financial or employment relationship between the person requesting the rural air ambulance service and the entity furnishing the ambulance service, or an entity under common ownership with the entity furnishing the air ambulance service, or a financial relationship between an immediate family member of such requester and such an entity.

''(ii) EXCEPTION.—Where a hospital and the entity furnishing rural air ambulance services are under common ownership, clause (i) shall not apply to remuneration (through employment or other relationship) by the hospital of the requester or immediate family member if the remuneration is for provider-based physician services furnished in a hospital (as described in section 1887) which are reimbursed under part A and the amount of the remuneration is unrelated directly or indirectly to the provision of rural air ambulance services.''.

(b) CONFORMING AMENDMENT.—Section 1861(s)(7) (42 U.S.C. 1395x(s)(7)) is amended by inserting '', subject to section 1834(l)(14),'' after ''but''.

(c) EFFECTIVE DATE.—The amendments made by this subsection shall apply to services furnished on or after January 1, 2005.

SEC. 416. TREATMENT OF CERTAIN CLINICAL DIAGNOSTIC LABORATORY TESTS FURNISHED TO HOSPITAL OUTPATIENTS IN CERTAIN RURAL AREAS.

(a) IN GENERAL.—Notwithstanding subsections (a), (b), and (h) of section 1833 of the Social Security Act (42 U.S.C. 1395l) and section 1834(d)(1) of such Act (42 U.S.C. 1395m(d)(1)), in the case of a clinical diagnostic laboratory test covered under part B of title XVIII of such Act that is furnished during a cost reporting period described in subsection (b) by a hospital with fewer than 50 beds that is located in a qualified rural area (identified under paragraph (12)(B)(iii) of section 1834(l) of the Social Security Act (42 U.S.C. 1395m(l)), as added by section 414(c)) as part of outpatient services of the hospital, the amount of payment for such test shall be 100 percent of the reasonable costs of the hospital in furnishing such test.

(b) APPLICATION.—A cost reporting period described in this subsection is a cost reporting period beginning during the 2-year period beginning on July 1, 2004.

(c) PROVISION AS PART OF OUTPATIENT HOSPITAL SERVICES.—For purposes of subsection (a), in determining whether clinical diagnostic laboratory services are furnished as part of outpatient services of a hospital, the Secretary shall apply the same rules that are used to determine whether clinical diagnostic laboratory services are furnished as an outpatient critical access hospital service under section 1834(g)(4) of the Social Security Act (42 U.S.C. 1395m(g)(4)).

SEC. 417. EXTENSION OF TELEMEDICINE DEMONSTRATION PROJECT.

Section 4207 of the Balanced Budget Act of 1997 (Public Law 105–33) is amended—

(1) in subsection (a)(4), by striking ''4-year'' and inserting ''8-year''; and

(2) in subsection (d)(3), by striking ''$30,000,000'' and inserting ''$60,000,000''.

SEC. 418. REPORT ON DEMONSTRATION PROJECT PERMITTING SKILLED NURSING FACILITIES TO BE ORIGINATING TELEHEALTH SITES; AUTHORITY TO IMPLEMENT.

(a) EVALUATION.—The Secretary, acting through the Administrator of the Health Resources and Services Administration in consultation with the Administrator of the Centers for Medicare & Medicaid Services, shall evaluate demonstration projects conducted by the Secretary under which skilled nursing facilities (as defined in section 1819(a) of the Social Security Act (42 U.S.C. 1395i–3(a)) are treated as originating sites for telehealth services.

(b) REPORT.—Not later than January 1, 2005, the Secretary shall submit to Congress a report on the evaluation conducted under subsection (a). Such report shall include recommendations on mechanisms to ensure that permitting a skilled nursing facility to serve as an originating site for the use of telehealth services or any other service delivered via a telecommunications system does not serve as a substitute for in-person visits furnished by a physician, or for in-person visits furnished by a physician assistant, nurse practitioner or clinical nurse specialist, as is otherwise required by the Secretary.

(c) AUTHORITY TO EXPAND ORIGINATING TELEHEALTH SITES TO INCLUDE SKILLED NURSING FACILITIES.—Insofar as the Secretary concludes in the report required under subsection (b) that it is advisable to permit a skilled nursing facility to be an originating site for telehealth services under section 1834(m) of the Social Security Act (42 U.S.C. 1395m(m)), and that the Secretary can establish the mechanisms to ensure such permission does not serve as a substitute for in-person visits furnished by a physician, or for in-person visits furnished by a physician assistant, nurse practitioner or clinical nurse specialist, the Secretary may deem a skilled nursing facility to be an originating site under paragraph (4)(C)(ii) of such section beginning on January 1, 2006.

Subtitle C—Provisions Relating to Parts A and B

SEC. 421. 1-YEAR INCREASE FOR HOME HEALTH SERVICES FURNISHED IN A RURAL AREA.

(a) IN GENERAL.—With respect to episodes and visits ending on or after April 1, 2004, and before April 1, 2005, in the case of home health services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Social Security Act (42 U.S.C. 1395ww(d)(2)(D))), the Secretary shall increase the payment amount otherwise made under section 1895 of such Act (42 U.S.C. 1395fff) for such services by 5 percent.

(b) WAIVING BUDGET NEUTRALITY.—The Secretary shall not reduce the standard prospective payment amount (or amounts) under section 1895 of the Social Security Act (42 U.S.C. 1395fff) applicable to home health services furnished during a period to offset the increase in payments resulting from the application of subsection (a).

(c) NO EFFECT ON SUBSEQUENT PERIODS.—The payment increase provided under subsection (a) for a period under such subsection—

(1) shall not apply to episodes and visits ending after such period; and

(2) shall not be taken into account in calculating the payment amounts applicable for episodes and visits occurring after such period.

SEC. 422. REDISTRIBUTION OF UNUSED RESIDENT POSITIONS.

(a) IN GENERAL.—Section 1886(h) (42 U.S.C. 1395ww(h)(4)) is amended—

(1) in paragraph (4)(F)(i), by inserting ''subject to paragraph (7),'' after ''October 1, 1997,'';

(2) in paragraph (4)(H)(i), by inserting ''and subject to paragraph (7)'' after ''subparagraphs (F) and (G)''; and

(3) by adding at the end the following new paragraph:

''(7) REDISTRIBUTION OF UNUSED RESIDENT POSITIONS.—

''(A) REDUCTION IN LIMIT BASED ON UNUSED POSITIONS.—

''(i) PROGRAMS SUBJECT TO REDUCTION.—

''(I) IN GENERAL.—Except as provided in subclause (II), if a hospital's reference resident level (specified in clause (ii)) is less than the otherwise applicable resident limit (as defined in subparagraph (C)(ii)), effective for portions of cost reporting periods occurring on or after July 1, 2005, the otherwise applicable resident limit shall be reduced by 75 percent of the difference between such otherwise applicable resident limit and such reference resident level.

''(II) EXCEPTION FOR SMALL RURAL HOSPITALS.—This subparagraph shall not apply to a hospital located in a rural area (as defined in subsection (d)(2)(D)(ii)) with fewer than 250 acute care inpatient beds.

''(ii) REFERENCE RESIDENT LEVEL.—

''(I) IN GENERAL.—Except as otherwise provided in subclauses (II) and (III), the reference resident level specified in this clause for a hospital is the resident level for the most recent cost reporting period of the hospital ending on or before September 30, 2002, for which a cost report has been settled (or, if not, submitted (subject to audit)), as determined by the Secretary.

''(II) USE OF MOST RECENT ACCOUNTING PERIOD TO RECOGNIZE EXPANSION OF EXISTING PROGRAMS.—If a hospital submits a timely request to increase its resident level due to an expansion of an existing residency training program that is not reflected on the most recent settled cost report, after audit and subject to the discretion of the Secretary, the reference resident level for such hospital is the resident level for the cost reporting period that includes July 1, 2003, as determined by the Secretary.

''(III) EXPANSIONS UNDER NEWLY APPROVED PROGRAMS.—Upon the timely request of a hospital, the Secretary shall adjust the reference resident level specified under subclause (I) or (II) to include the number of medical residents that were approved in an application for a medical residency training program that was approved by an appropriate accrediting organization (as determined by the Secretary) before January 1, 2002, but which was not in operation during the cost reporting period used under subclause (I) or (II), as the case may be, as determined by the Secretary.

''(iii) AFFILIATION.—The provisions of clause (i) shall be applied to hospitals which are members of the same affiliated group (as defined by

the Secretary under paragraph (4)(H)(ii)) as of July 1, 2003.

''(B) REDISTRIBUTION.—

''(i) IN GENERAL.—The Secretary is authorized to increase the otherwise applicable resident limit for each qualifying hospital that submits a timely application under this subparagraph by such number as the Secretary may approve for portions of cost reporting periods occurring on or after July 1, 2005. The aggregate number of increases in the otherwise applicable resident limits under this subparagraph may not exceed the Secretary's estimate of the aggregate reduction in such limits attributable to subparagraph (A).

''(ii) CONSIDERATIONS IN REDISTRIBUTION.—In determining for which hospitals the increase in the otherwise applicable resident limit is provided under clause (i), the Secretary shall take into account the demonstrated likelihood of the hospital filling the positions within the first 3 cost reporting periods beginning on or after July 1, 2005, made available under this subparagraph, as determined by the Secretary.

''(iii) PRIORITY FOR RURAL AND SMALL URBAN AREAS.—In determining for which hospitals and residency training programs an increase in the otherwise applicable resident limit is provided under clause (i), the Secretary shall distribute the increase to programs of hospitals located in the following priority order:

''(I) First, to hospitals located in rural areas (as defined in subsection (d)(2)(D)(ii)).

''(II) Second, to hospitals located in urban areas that are not large urban areas (as defined for purposes of subsection (d)).

''(III) Third, to other hospitals in a State if the residency training program involved is in a specialty for which there are not other residency training programs in the State.

Increases of residency limits within the same priority category under this clause shall be determined by the Secretary.

''(iv) LIMITATION.—In no case shall more than 25 full-time equivalent additional residency positions be made available under this subparagraph with respect to any hospital.

''(v) APPLICATION OF LOCALITY ADJUSTED NATIONAL AVERAGE PER RESIDENT AMOUNT.—With respect to additional residency positions in a hospital attributable to the increase provided under this subparagraph, notwithstanding any other provision of this subsection, the approved FTE resident amount is deemed to be equal to the locality adjusted national average per resident amount computed under paragraph (4)(E) for that hospital.

''(vi) CONSTRUCTION.—Nothing in this subparagraph shall be construed as permitting the redistribution of reductions in residency positions attributable to voluntary reduction programs under paragraph (6), under a demonstration project approved as of October 31, 2003, under the authority of section 402 of Public Law 90–248, or as affecting the ability of a hospital to establish new medical residency training programs under paragraph (4)(H).

''(C) RESIDENT LEVEL AND LIMIT DEFINED.—In this paragraph:

''(i) RESIDENT LEVEL.—The term 'resident level' means, with respect to a hospital, the total number of full-time equivalent residents, before the application of weighting factors (as determined under paragraph (4)), in the fields of allopathic and osteopathic medicine for the hospital.

''(ii) OTHERWISE APPLICABLE RESIDENT LIMIT.—The term 'otherwise applicable resident limit' means, with respect to a hospital, the limit otherwise applicable under subparagraphs (F)(i) and (H) of paragraph (4) on the resident level for the hospital determined without regard to this paragraph.

''(D) JUDICIAL REVIEW.—There shall be no administrative or judicial review under section 1869, 1878, or otherwise, with respect to determinations made under this paragraph.''.

(b) CONFORMING PROVISIONS.—(1) Section 1886(d)(5)(B) (42 U.S.C. 1395ww(d)(5)(B)) is amended—

(A) in the second sentence of clause (ii), by striking ''For discharges'' and inserting ''Subject to clause (ix), for discharges'';

(B) in clause (v), by adding at the end the following: ''The provisions of subsection (h)(7) shall apply with respect to the first sentence of this clause in the same manner as it applies with respect to subsection (h)(4)(F)(i).''; and

(C) by adding at the end the following new clause:

''(ix) For discharges occurring on or after July 1, 2005, insofar as an additional payment amount under this subparagraph is attributable to resident positions redistributed to a hospital under subsection (h)(7)(B), in computing the indirect teaching adjustment factor under clause (ii) the adjustment shall be computed in a manner as if 'c' were equal to 0.66 with respect to such resident positions.''.

(2) Chapter 35 of title 44, United States Code, shall not apply with respect to applications under section 1886(h)(7) of the Social Security Act, as added by subsection (a)(3).

(c) REPORT ON EXTENSION OF APPLICATIONS UNDER REDISTRIBUTION PROGRAM.—Not later than July 1, 2005, the Secretary shall submit to Congress a report containing recommendations regarding whether to extend the deadline for applications for an increase in resident limits under section 1886(h)(4)(I)(ii)(II) of the Social Security Act (as added by subsection (a)).

Subtitle D—Other Provisions

SEC. 431. PROVIDING SAFE HARBOR FOR CERTAIN COLLABORATIVE EFFORTS THAT BENEFIT MEDICALLY UNDERSERVED POPULATIONS.

(a) IN GENERAL.—Section 1128B(b)(3) (42 U.S.C. 1320a–7(b)(3)), as amended by section 101(e)(2), is amended—

(1) in subparagraph (F), by striking ''and'' after the semicolon at the end;

(2) in subparagraph (G), by striking the period at the end and inserting ''; and''; and

(3) by adding at the end the following new subparagraph:

''(H) any remuneration between a health center entity described under clause (i) or (ii) of section 1905(l)(2)(B) and any individual or entity providing goods, items, services, donations, loans, or a combination thereof, to such health center entity pursuant to a contract, lease, grant, loan, or other agreement, if such agreement contributes to the ability of the health center entity to maintain or increase the availability, or enhance the quality, of services provided to a medically underserved population served by the health center entity.''.

(b) RULEMAKING FOR EXCEPTION FOR HEALTH CENTER ENTITY ARRANGEMENTS.—

(1) ESTABLISHMENT.—

(A) IN GENERAL.—The Secretary shall establish, on an expedited basis, standards relating to the exception described in section 1128B(b)(3)(H) of the Social Security Act, as added by subsection (a), for health center entity arrangements to the antikickback penalties.

(B) FACTORS TO CONSIDER.—The Secretary shall consider the following factors, among others, in establishing standards relating to the exception for health center entity arrangements under subparagraph (A):

(i) Whether the arrangement between the health center entity and the other party results in savings of Federal grant funds or increased revenues to the health center entity.

(ii) Whether the arrangement between the health center entity and the other party restricts or limits an individual's freedom of choice.

(iii) Whether the arrangement between the health center entity and the other party protects a health care professional's independent medical judgment regarding medically appropriate treatment.

The Secretary may also include other standards and criteria that are consistent with the intent of Congress in enacting the exception established under this section.

(2) DEADLINE.—Not later than 1 year after the date of the enactment of this Act the Secretary shall publish final regulations establishing the standards described in paragraph (1).

SEC. 432. OFFICE OF RURAL HEALTH POLICY IMPROVEMENTS.

Section 711(b) (42 U.S.C. 912(b)) is amended—

(1) in paragraph (3), by striking ''and'' after the comma at the end;

(2) in paragraph (4), by striking the period at the end and inserting '', and''; and

(3) by inserting after paragraph (4) the following new paragraph:

''(5) administer grants, cooperative agreements, and contracts to provide technical assistance and other activities as necessary to support activities related to improving health care in rural areas.''.

SEC. 433. MEDPAC STUDY ON RURAL HOSPITAL PAYMENT ADJUSTMENTS.

(a) IN GENERAL.—The Medicare Payment Advisory Commission shall conduct a study of the impact of sections 401 through 406, 411, 416, and 505. The Commission shall analyze the effect on total payments, growth in costs, capital spending, and such other payment effects under those sections.

(b) REPORTS.—

(1) INTERIM REPORT.—Not later than 18 months after the date of the enactment of this Act, the Commission shall submit to Congress an interim report on the matters studied under subsection (a) with respect only to changes to the critical access hospital provisions under section 405.

(2) FINAL REPORT.—Not later than 3 years after the date of the enactment of this Act, the Commission shall submit to Congress a final report on all matters studied under subsection (a).

SEC. 434. FRONTIER EXTENDED STAY CLINIC DEMONSTRATION PROJECT.

(a) AUTHORITY TO CONDUCT DEMONSTRATION PROJECT.—The Secretary shall waive such provisions of the medicare program established under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) as are necessary to conduct a demonstration project under which frontier extended stay clinics described in subsection (b) in isolated rural areas are treated as providers of items and services under the medicare program.

(b) CLINICS DESCRIBED.—A frontier extended stay clinic is described in this subsection if the clinic—

(1) is located in a community where the closest short-term acute care hospital or critical access hospital is at least 75 miles away from the community or is inaccessible by public road; and

(2) is designed to address the needs of—

(A) seriously or critically ill or injured patients who, due to adverse weather conditions or other reasons, cannot be transferred quickly to acute care referral centers; or

(B) patients who need monitoring and observation for a limited period of time.

(c) SPECIFICATION OF CODES.—The Secretary shall determine the appropriate life-safety codes for such clinics that treat patients for needs referred to in subsection (b)(2).

(d) FUNDING.—

(1) IN GENERAL.—Subject to paragraph (2), there are authorized to be appropriated, in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund, such sums as are necessary to conduct the demonstration project under this section.

(2) BUDGET NEUTRAL IMPLEMENTATION.—In conducting the demonstration project under this section, the Secretary shall ensure that the aggregate payments made by the Secretary under the medicare program do not exceed the amount which the Secretary would have paid under the

medicare program if the demonstration project under this section was not implemented.

(e) 3-YEAR PERIOD.—The Secretary shall conduct the demonstration under this section for a 3-year period.

(f) REPORT.—Not later than the date that is 1 year after the date on which the demonstration project concludes, the Secretary shall submit to Congress a report on the demonstration project, together with such recommendations for legislation or administrative action as the Secretary determines appropriate.

(g) DEFINITIONS.—In this section, the terms ''hospital'' and ''critical access hospital'' have the meanings given such terms in subsections (e) and (mm), respectively, of section 1861 of the Social Security Act (42 U.S.C. 1395x).

TITLE V—PROVISIONS RELATING TO PART A

Subtitle A—Inpatient Hospital Services

SEC. 501. REVISION OF ACUTE CARE HOSPITAL PAYMENT UPDATES.

(a) IN GENERAL.—Section 1886(b)(3)(B)(i) (42 U.S.C. 1395ww(b)(3)(B)(i)) is amended—

(1) by striking ''and'' at the end of subclause (XVIII);

(2) by striking subclause (XIX); and

(3) by inserting after subclause (XVIII) the following new subclauses:

''(XIX) for each of fiscal years 2004 through 2007, subject to clause (vii), the market basket percentage increase for hospitals in all areas; and

''(XX) for fiscal year 2008 and each subsequent fiscal year, the market basket percentage increase for hospitals in all areas.''.

(b) SUBMISSION OF HOSPITAL QUALITY DATA.—Section 1886(b)(3)(B) (42 U.S.C. 1395ww(b)(3)(B)) is amended by adding at the end the following new clause:

''(vii)(I) For purposes of clause (i)(XIX) for each of fiscal years 2005 through 2007, in a case of a subsection (d) hospital that does not submit data to the Secretary in accordance with subclause (II) with respect to such a fiscal year, the applicable percentage increase under such clause for such fiscal year shall be reduced by 0.4 percentage points. Such reduction shall apply only with respect to the fiscal year involved, and the Secretary shall not take into account such reduction in computing the applicable percentage increase under clause (i)(XIX) for a subsequent fiscal year.

''(II) Each subsection (d) hospital shall submit to the Secretary quality data (for a set of 10 indicators established by the Secretary as of November 1, 2003) that relate to the quality of care furnished by the hospital in inpatient settings in a form and manner, and at a time, specified by the Secretary for purposes of this clause, but with respect to fiscal year 2005, the Secretary shall provide for a 30-day grace period for the submission of data by a hospital.''.

(c) GAO STUDY AND REPORT ON APPROPRIATENESS OF PAYMENTS UNDER THE PROSPECTIVE PAYMENT SYSTEM FOR INPATIENT HOSPITAL SERVICES.—

(1) STUDY.—The Comptroller General of the United States, using the most current data available, shall conduct a study to determine—

(A) the appropriate level and distribution of payments in relation to costs under the prospective payment system under section 1886 of the Social Security Act (42 U.S.C. 1395ww) for inpatient hospital services furnished by subsection (d) hospitals (as defined in subsection (d)(1)(B) of such section); and

(B) whether there is a need to adjust such payments under such system to reflect legitimate differences in costs across different geographic areas, kinds of hospitals, and types of cases.

(2) REPORT.—Not later than 24 months after the date of the enactment of this Act, the Comptroller General of the United States shall submit to Congress a report on the study conducted under paragraph (1) together with such recommendations for legislative and administrative action as the Comptroller General determines appropriate.

SEC. 502. REVISION OF THE INDIRECT MEDICAL EDUCATION (IME) ADJUSTMENT PERCENTAGE.

(a) IN GENERAL.—Section 1886(d)(5)(B)(ii) (42 U.S.C. 1395ww(d)(5)(B)(ii)) is amended—

(1) in subclause (VI), by striking ''and'' after the semicolon at the end;

(2) in subclause (VII)—

(A) by inserting ''and before April 1, 2004,'' after ''on or after October 1, 2002,''; and

(B) by striking the period at the end and inserting a semicolon; and

(3) by adding at the end the following new subclauses:

''(VIII) on or after April 1, 2004, and before October 1, 2004, 'c' is equal to 1.47;

''(IX) during fiscal year 2005, 'c' is equal to 1.42;

''(X) during fiscal year 2006, 'c' is equal to 1.37;

''(XI) during fiscal year 2007, 'c' is equal to 1.32; and

''(XII) on or after October 1, 2007, 'c' is equal to 1.35.''.

(b) CONFORMING AMENDMENT RELATING TO DETERMINATION OF STANDARDIZED AMOUNT.—Section 1886(d)(2)(C)(i) (42 U.S.C. 1395ww(d)(2)(C)(i)) is amended—

(1) by striking ''1999 or'' and inserting ''1999,''; and

(2) by inserting '', or the Medicare Prescription Drug, Improvement, and Modernization Act of 2003'' after ''2000''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to discharges occurring on or after April 1, 2004.

SEC. 503. RECOGNITION OF NEW MEDICAL TECHNOLOGIES UNDER INPATIENT HOSPITAL PROSPECTIVE PAYMENT SYSTEM.

(a) IMPROVING TIMELINESS OF DATA COLLECTION.—Section 1886(d)(5)(K) (42 U.S.C. 1395ww(d)(5)(K)) is amended by adding at the end the following new clause:

''(vii) Under the mechanism under this subparagraph, the Secretary shall provide for the addition of new diagnosis and procedure codes in April 1 of each year, but the addition of such codes shall not require the Secretary to adjust the payment (or diagnosis-related group classification) under this subsection until the fiscal year that begins after such date.''.

(b) ELIGIBILITY STANDARD FOR TECHNOLOGY OUTLIERS.—

(1) ADJUSTMENT OF THRESHOLD.—Section 1886(d)(5)(K)(ii)(I) (42 U.S.C. 1395ww(d)(5)(K)(ii)(I)) is amended by inserting ''(applying a threshold specified by the Secretary that is the lesser of 75 percent of the standardized amount (increased to reflect the difference between cost and charges) or 75 percent of one standard deviation for the diagnosis-related group involved)'' after ''is inadequate''.

(2) PROCESS FOR PUBLIC INPUT.—Section 1886(d)(5)(K) (42 U.S.C. 1395ww(d)(5)(K)), as amended by subsection (a), is amended—

(A) in clause (i), by adding at the end the following: ''Such mechanism shall be modified to meet the requirements of clause (viii).''; and

(B) by adding at the end the following new clause:

''(viii) The mechanism established pursuant to clause (i) shall be adjusted to provide, before publication of a proposed rule, for public input regarding whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of individuals entitled to benefits under part A as follows:

''(I) The Secretary shall make public and periodically update a list of all the services and technologies for which an application for additional payment under this subparagraph is pending.

''(II) The Secretary shall accept comments, recommendations, and data from the public regarding whether the service or technology represents a substantial improvement.

''(III) The Secretary shall provide for a meeting at which organizations representing hospitals, physicians, such individuals, manufacturers, and any other interested party may present comments, recommendations, and data to the clinical staff of the Centers for Medicare & Medicaid Services before publication of a notice of proposed rulemaking regarding whether service or technology represents a substantial improvement.''.

(c) PREFERENCE FOR USE OF DRG ADJUSTMENT.—Section 1886(d)(5)(K) (42 U.S.C. 1395ww(d)(5)(K)), as amended by subsections (a) and (b), is amended by adding at the end the following new clause:

''(ix) Before establishing any add-on payment under this subparagraph with respect to a new technology, the Secretary shall seek to identify one or more diagnosis-related groups associated with such technology, based on similar clinical or anatomical characteristics and the cost of the technology. Within such groups the Secretary shall assign an eligible new technology into a diagnosis-related group where the average costs of care most closely approximate the costs of care of using the new technology. No add-on payment under this subparagraph shall be made with respect to such new technology and this clause shall not affect the application of paragraph (4)(C)(iii).''.

(d) ESTABLISHMENT OF NEW FUNDING FOR HOSPITAL INPATIENT TECHNOLOGY.—

(1) IN GENERAL.—Section 1886(d)(5)(K)(ii)(III) (42 U.S.C. 1395ww(d)(5)(K)(ii)(III)) is amended by striking ''subject to paragraph (4)(C)(iii),''.

(2) NOT BUDGET NEUTRAL.—There shall be no reduction or other adjustment in payments under section 1886 of the Social Security Act because an additional payment is provided under subsection (d)(5)(K)(ii)(III) of such section.

(e) EFFECTIVE DATE.—

(1) IN GENERAL.—The Secretary shall implement the amendments made by this section so that they apply to classification for fiscal years beginning with fiscal year 2005.

(2) RECONSIDERATIONS OF APPLICATIONS FOR FISCAL YEAR 2004 THAT ARE DENIED.—In the case of an application for a classification of a medical service or technology as a new medical service or technology under section 1886(d)(5)(K) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(K)) that was filed for fiscal year 2004 and that is denied—

(A) the Secretary shall automatically reconsider the application as an application for fiscal year 2005 under the amendments made by this section; and

(B) the maximum time period otherwise permitted for such classification of the service or technology shall be extended by 12 months.

SEC. 504. INCREASE IN FEDERAL RATE FOR HOSPITALS IN PUERTO RICO.

Section 1886(d)(9) (42 U.S.C. 1395ww(d)(9)) is amended—

(1) in subparagraph (A)—

(A) in clause (i), by striking ''for discharges beginning on or after October 1, 1997, 50 percent (and for discharges between October 1, 1987, and September 30, 1997, 75 percent)'' and inserting ''the applicable Puerto Rico percentage (specified in subparagraph (E))''; and

(B) in clause (ii), by striking ''for discharges beginning in a fiscal year beginning on or after October 1, 1997, 50 percent (and for discharges between October 1, 1987, and September 30, 1997, 25 percent)'' and inserting ''the applicable Federal percentage (specified in subparagraph (E))''; and

(2) by adding at the end the following new subparagraph:

''(E) For purposes of subparagraph (A), for discharges occurring—

''(i) on or after October 1, 1987, and before October 1, 1997, the applicable Puerto Rico percentage is 75 percent and the applicable Federal percentage is 25 percent;

''(ii) on or after October 1, 1997, and before April 1, 2004, the applicable Puerto Rico percentage is 50 percent and the applicable Federal percentage is 50 percent;

''(iii) on or after April 1, 2004, and before October 1, 2004, the applicable Puerto Rico percentage is 37.5 percent and the applicable Federal percentage is 62.5 percent; and

''(iv) on or after October 1, 2004, the applicable Puerto Rico percentage is 25 percent and the applicable Federal percentage is 75 percent.''.

SEC. 505. WAGE INDEX ADJUSTMENT RECLASSIFICATION REFORM.

(a) IN GENERAL.—Section 1886(d) (42 U.S.C. 1395ww(d)), as amended by section 406, is amended by adding at the end the following new paragraph:

''(13)(A) In order to recognize commuting patterns among geographic areas, the Secretary shall establish a process through application or otherwise for an increase of the wage index applied under paragraph (3)(E) for subsection (d) hospitals located in a qualifying county described in subparagraph (B) in the amount computed under subparagraph (D) based on out-migration of hospital employees who reside in that county to any higher wage index area.

''(B) The Secretary shall establish criteria for a qualifying county under this subparagraph based on the out-migration referred to in subparagraph (A) and differences in the area wage indices. Under such criteria the Secretary shall, utilizing such data as the Secretary determines to be appropriate, establish—

''(i) a threshold percentage, established by the Secretary, of the weighted average of the area wage index or indices for the higher wage index areas involved;

''(ii) a threshold (of not less than 10 percent) for minimum out-migration to a higher wage index area or areas; and

''(iii) a requirement that the average hourly wage of the hospitals in the qualifying county equals or exceeds the average hourly wage of all the hospitals in the area in which the qualifying county is located.

''(C) For purposes of this paragraph, the term 'higher wage index area' means, with respect to a county, an area with a wage index that exceeds that of the county.

''(D) The increase in the wage index under subparagraph (A) for a qualifying county shall be equal to the percentage of the hospital employees residing in the qualifying county who are employed in any higher wage index area multiplied by the sum of the products, for each higher wage index area of—

''(i) the difference between—

''(I) the wage index for such higher wage index area, and

''(II) the wage index of the qualifying county; and

''(ii) the number of hospital employees residing in the qualifying county who are employed in such higher wage index area divided by the total number of hospital employees residing in the qualifying county who are employed in any higher wage index area.

''(E) The process under this paragraph may be based upon the process used by the Medicare Geographic Classification Review Board under paragraph (10). As the Secretary determines to be appropriate to carry out such process, the Secretary may require hospitals (including subsection (d) hospitals and other hospitals) and critical access hospitals, as required under section 1866(a)(1)(T), to submit data regarding the location of residence, or the Secretary may use data from other sources.

''(F) A wage index increase under this paragraph shall be effective for a period of 3 fiscal years, except that the Secretary shall establish procedures under which a subsection (d) hospital may elect to waive the application of such wage index increase.

''(G) A hospital in a county that has a wage index increase under this paragraph for a period and that has not waived the application of such an increase under subparagraph (F) is not eligible for reclassification under paragraph (8) or (10) during that period.

''(H) Any increase in a wage index under this paragraph for a county shall not be taken into account for purposes of—

''(i) computing the wage index for portions of the wage index area (not including the county) in which the county is located; or

''(ii) applying any budget neutrality adjustment with respect to such index under paragraph (8)(D).

''(I) The thresholds described in subparagraph (B), data on hospital employees used under this paragraph, and any determination of the Secretary under the process described in subparagraph (E) shall be final and shall not be subject to judicial review.''.

(b) CONFORMING AMENDMENTS.—Section 1866(a)(1) (42 U.S.C. 1395cc(a)(1)) is amended—

(1) in subparagraph (R), by striking ''and'' at the end;

(2) in subparagraph (S), by striking the period at the end and inserting '', and''; and

(3) by inserting after subparagraph (S) the following new subparagraph:

''(T) in the case of hospitals and critical access hospitals, to furnish to the Secretary such data as the Secretary determines appropriate pursuant to subparagraph (E) of section 1886(d)(12) to carry out such section.''.

(c) EFFECTIVE DATE.—The amendments made by this section shall first apply to the wage index for discharges occurring on or after October 1, 2004. In initially implementing such amendments, the Secretary may modify the deadlines otherwise applicable under clauses (ii) and (iii)(I) of section 1886(d)(10)(C) of the Social Security Act (42 U.S.C. 1395ww(d)(10)(C)), for submission of, and actions on, applications relating to changes in hospital geographic reclassification.

SEC. 506. LIMITATION ON CHARGES FOR INPATIENT HOSPITAL CONTRACT HEALTH SERVICES PROVIDED TO INDIANS BY MEDICARE PARTICIPATING HOSPITALS.

(a) IN GENERAL.—Section 1866(a)(1) (42 U.S.C. 1395cc(a)(1)), as amended by section 505(b), is amended—

(1) in subparagraph (S), by striking ''and'' at the end;

(2) in subparagraph (T), by striking the period and inserting '', and''; and

(3) by inserting after subparagraph (T) the following new subparagraph:

''(U) in the case of hospitals which furnish inpatient hospital services for which payment may be made under this title, to be a participating provider of medical care both—

''(i) under the contract health services program funded by the Indian Health Service and operated by the Indian Health Service, an Indian tribe, or tribal organization (as those terms are defined in section 4 of the Indian Health Care Improvement Act), with respect to items and services that are covered under such program and furnished to an individual eligible for such items and services under such program; and

''(ii) under any program funded by the Indian Health Service and operated by an urban Indian organization with respect to the purchase of items and services for an eligible urban Indian (as those terms are defined in such section 4),

in accordance with regulations promulgated by the Secretary regarding admission practices, payment methodology, and rates of payment (including the acceptance of no more than such payment rate as payment in full for such items and services.''.

(b) EFFECTIVE DATE.—The amendments made by this section shall apply as of a date specified by the Secretary of Health and Human Services (but in no case later than 1 year after the date of enactment of this Act) to medicare participation agreements in effect (or entered into) on or after such date.

(c) PROMULGATION OF REGULATIONS.—The Secretary shall promulgate regulations to carry out the amendments made by subsection (a).

SEC. 507. CLARIFICATIONS TO CERTAIN EXCEPTIONS TO MEDICARE LIMITS ON PHYSICIAN REFERRALS.

(a) LIMITS ON PHYSICIAN REFERRALS.—

(1) OWNERSHIP AND INVESTMENT INTERESTS IN WHOLE HOSPITALS.—

(A) IN GENERAL.—Section 1877(d)(3) (42 U.S.C. 1395nn(d)(3)) is amended—

(i) by striking '', and'' at the end of subparagraph (A) and inserting a semicolon; and

(ii) by redesignating subparagraph (B) as subparagraph (C) and inserting after subparagraph (A) the following new subparagraph:

''(B) effective for the 18-month period beginning on the date of the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the hospital is not a specialty hospital (as defined in subsection (h)(7)); and''.

(B) DEFINITION.—Section 1877(h) (42 U.S.C. 1395nn(h)) is amended by adding at the end the following:

''(7) SPECIALTY HOSPITAL.—

''(A) IN GENERAL.—For purposes of this section, except as provided in subparagraph (B), the term 'specialty hospital' means a subsection (d) hospital (as defined in section 1886(d)(1)(B)) that is primarily or exclusively engaged in the care and treatment of one of the following categories:

''(i) Patients with a cardiac condition.

''(ii) Patients with an orthopedic condition.

''(iii) Patients receiving a surgical procedure.

''(iv) Any other specialized category of services that the Secretary designates as inconsistent with the purpose of permitting physician ownership and investment interests in a hospital under this section.

''(B) EXCEPTION.—For purposes of this section, the term 'specialty hospital' does not include any hospital—

''(i) determined by the Secretary—

''(I) to be in operation before November 18, 2003; or

''(II) under development as of such date;

''(ii) for which the number of physician investors at any time on or after such date is no greater than the number of such investors as of such date;

''(iii) for which the type of categories described in subparagraph (A) at any time on or after such date is no different than the type of such categories as of such date;

''(iv) for which any increase in the number of beds occurs only in the facilities on the main campus of the hospital and does not exceed 50 percent of the number of beds in the hospital as of November 18, 2003, or 5 beds, whichever is greater; and

''(v) that meets such other requirements as the Secretary may specify.''.

(2) OWNERSHIP AND INVESTMENT INTERESTS IN A RURAL PROVIDER.—Section 1877(d)(2) (42 U.S.C. 1395nn(d)(2)) is amended to read as follows:

''(2) RURAL PROVIDERS.—In the case of designated health services furnished in a rural area (as defined in section 1886(d)(2)(D)) by an entity, if—

''(A) substantially all of the designated health services furnished by the entity are furnished to individuals residing in such a rural area; and

''(B) effective for the 18-month period beginning on the date of the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the entity is not a specialty hospital (as defined in subsection (h)(7)).''.

(b) APPLICATION OF EXCEPTION FOR HOSPITALS UNDER DEVELOPMENT.—For purposes of section 1877(h)(7)(B)(i)(II) of the Social Security Act, as added by subsection (a)(1)(B), in determining whether a hospital is under development as of November 18, 2003, the Secretary shall consider—

(1) whether architectural plans have been completed, funding has been received, zoning requirements have been met, and necessary approvals from appropriate State agencies have been received; and

(2) any other evidence the Secretary determines would indicate whether a hospital is under development as of such date.

(c) STUDIES.—

(1) MEDPAC STUDY.—The Medicare Payment Advisory Commission, in consultation with the Comptroller General of the United States, shall conduct a study to determine—

(A) any differences in the costs of health care services furnished to patients by physician-owned specialty hospitals and the costs of such services furnished by local full-service community hospitals within specific diagnosis-related groups;

(B) the extent to which specialty hospitals, relative to local full-service community hospitals, treat patients in certain diagnosis-related groups within a category, such as cardiology, and an analysis of the selection;

(C) the financial impact of physician-owned specialty hospitals on local full-service community hospitals;

(D) how the current diagnosis-related group system should be updated to better reflect the cost of delivering care in a hospital setting; and

(E) the proportions of payments received, by type of payer, between the specialty hospitals and local full-service community hospitals.

(2) HHS STUDY.—The Secretary shall conduct a study of a representative sample of specialty hospitals—

(A) to determine the percentage of patients admitted to physician-owned specialty hospitals who are referred by physicians with an ownership interest;

(B) to determine the referral patterns of physician owners, including the percentage of patients they referred to physician-owned specialty hospitals and the percentage of patients they referred to local full-service community hospitals for the same condition;

(C) to compare the quality of care furnished in physician-owned specialty hospitals and in local full-service community hospitals for similar conditions and patient satisfaction with such care; and

(D) to assess the differences in uncompensated care, as defined by the Secretary, between the specialty hospital and local full-service community hospitals, and the relative value of any tax exemption available to such hospitals.

(3) REPORTS.—Not later than 15 months after the date of the enactment of this Act, the Commission and the Secretary, respectively, shall each submit to Congress a report on the studies conducted under paragraphs (1) and (2), respectively, and shall include any recommendations for legislation or administrative changes.

SEC. 508. 1-TIME APPEALS PROCESS FOR HOSPITAL WAGE INDEX CLASSIFICATION.

(a) ESTABLISHMENT OF PROCESS.—

(1) IN GENERAL.—The Secretary shall establish not later than January 1, 2004, by instruction or otherwise a process under which a hospital may appeal the wage index classification otherwise applicable to the hospital and select another area within the State (or, at the discretion of the Secretary, within a contiguous State) to which to be reclassified.

(2) PROCESS REQUIREMENTS.—The process established under paragraph (1) shall be consistent with the following:

(A) Such an appeal may be filed as soon as possible after the date of the enactment of this Act but shall be filed by not later than February 15, 2004.

(B) Such an appeal shall be heard by the Medicare Geographic Reclassification Review Board.

(C) There shall be no further administrative or judicial review of a decision of such Board.

(3) RECLASSIFICATION UPON SUCCESSFUL APPEAL.—If the Medicare Geographic Reclassification Review Board determines that the hospital is a qualifying hospital (as defined in subsection (c)), the hospital shall be reclassified to the area selected under paragraph (1). Such reclassification shall apply with respect to discharges occurring during the 3-year period beginning with April 1, 2004.

(4) INAPPLICABILITY OF CERTAIN PROVISIONS.—Except as the Secretary may provide, the provisions of paragraphs (8) and (10) of section 1886(d) of the Social Security Act (42 U.S.C. 1395ww(d)) shall not apply to an appeal under this section.

(b) APPLICATION OF RECLASSIFICATION.—In the case of an appeal decided in favor of a qualifying hospital under subsection (a), the wage index reclassification shall not affect the wage index computation for any area or for any other hospital and shall not be effected in a budget neutral manner. The provisions of this section shall not affect payment for discharges occurring after the end of the 3-year-period referred to in subsection (a).

(c) QUALIFYING HOSPITAL DEFINED.—For purposes of this section, the term ''qualifying hospital'' means a subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Social Security Act, 42 U.S.C. 1395ww(d)(1)(B)) that—

(1) does not qualify for a change in wage index classification under paragraph (8) or (10) of section 1886(d) of the Social Security Act (42 U.S.C. 1395ww(d)) on the basis of requirements relating to distance or commuting; and

(2) meets such other criteria, such as quality, as the Secretary may specify by instruction or otherwise.

The Secretary may modify the wage comparison guidelines promulgated under section 1886(d)(10)(D) of such Act (42 U.S.C. 1395ww(d)(10)(D)) in carrying out this section.

(d) WAGE INDEX CLASSIFICATION.—For purposes of this section, the term ''wage index classification'' means the geographic area in which it is classified for purposes of determining for a fiscal year the factor used to adjust the DRG prospective payment rate under section 1886(d) of the Social Security Act (42 U.S.C. 1395ww(d)) for area differences in hospital wage levels that applies to such hospital under paragraph (3)(E) of such section.

(e) LIMITATION ON EXPENDITURES.—The aggregate amount of additional expenditures resulting from the application of this section shall not exceed $900,000,000.

(f) TRANSITIONAL EXTENSION.—Any reclassification of a county or other area made by Act of Congress for purposes of making payments under section 1886(d) of the Social Security Act (42 U.S.C. 1395ww(d)) that expired on September 30, 2003, shall be deemed to be in effect during the period beginning on January 1, 2004, and ending on September 30, 2004.

Subtitle B—Other Provisions

SEC. 511. PAYMENT FOR COVERED SKILLED NURSING FACILITY SERVICES.

(a) ADJUSTMENT TO RUGS FOR AIDS RESIDENTS.—Paragraph (12) of section 1888(e) (42 U.S.C. 1395yy(e)) is amended to read as follows:

''(12) ADJUSTMENT FOR RESIDENTS WITH AIDS.—

''(A) IN GENERAL.—Subject to subparagraph (B), in the case of a resident of a skilled nursing facility who is afflicted with acquired immune deficiency syndrome (AIDS), the per diem amount of payment otherwise applicable (determined without regard to any increase under section 101 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, or under section 314(a) of Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000), shall be increased by 128 percent to reflect increased costs associated with such residents.

''(B) SUNSET.—Subparagraph (A) shall not apply on and after such date as the Secretary certifies that there is an appropriate adjustment in the case mix under paragraph (4)(G)(i) to compensate for the increased costs associated with residents described in such subparagraph.''.

(b) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to services furnished on or after October 1, 2004.

SEC. 512. COVERAGE OF HOSPICE CONSULTATION SERVICES.

(a) COVERAGE OF HOSPICE CONSULTATION SERVICES.—Section 1812(a) (42 U.S.C. 1395d(a)) is amended—

(1) by striking ''and'' at the end of paragraph (3);

(2) by striking the period at the end of paragraph (4) and inserting ''; and''; and

(3) by inserting after paragraph (4) the following new paragraph:

''(5) for individuals who are terminally ill, have not made an election under subsection (d)(1), and have not previously received services under this paragraph, services that are furnished by a physician (as defined in section 1861(r)(1)) who is either the medical director or an employee of a hospice program and that—

''(A) consist of—

''(i) an evaluation of the individual's need for pain and symptom management, including the individual's need for hospice care; and

''(ii) counseling the individual with respect to hospice care and other care options; and

''(B) may include advising the individual regarding advanced care planning.''.

(b) PAYMENT.—Section 1814(i) (42 U.S.C. 1395f(i)) is amended by adding at the end the following new paragraph:

''(4) The amount paid to a hospice program with respect to the services under section 1812(a)(5) for which payment may be made under this part shall be equal to an amount established for an office or other outpatient visit for evaluation and management associated with presenting problems of moderate severity and requiring medical decisionmaking of low complexity under the fee schedule established under section 1848(b), other than the portion of such amount attributable to the practice expense component.''.

(c) CONFORMING AMENDMENT.—Section 1861(dd)(2)(A)(i) (42 U.S.C. 1395x(dd)(2)(A)(i)) is amended by inserting before the comma at the end the following: ''and services described in section 1812(a)(5)''.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to services provided by a hospice program on or after January 1, 2005.

SEC. 513. STUDY ON PORTABLE DIAGNOSTIC ULTRASOUND SERVICES FOR BENEFICIARIES IN SKILLED NURSING FACILITIES.

(a) STUDY.—The Comptroller General of the United States shall conduct a study of portable diagnostic ultrasound services furnished to medicare beneficiaries in skilled nursing facilities. Such study shall consider the following:

(1) TYPES OF EQUIPMENT; TRAINING.—The types of portable diagnostic ultrasound services furnished to such beneficiaries, the types of portable ultrasound equipment used to furnish such services, and the technical skills, or training, or both, required for technicians to furnish such services.

(2) CLINICAL APPROPRIATENESS.—The clinical appropriateness of transporting portable diagnostic ultrasound diagnostic and technicians to patients in skilled nursing facilities as opposed to transporting such patients to a hospital or other facility that furnishes diagnostic ultrasound services.

(3) FINANCIAL IMPACT.—The financial impact if Medicare were make a separate payment for portable ultrasound diagnostic services, including the impact of separate payments—

(A) for transportation and technician services for residents during a resident in a part A stay, that would otherwise be paid for under the prospective payment system for covered skilled nursing facility services (under section 1888(e) of

the Social Security Act (42 U.S.C. 1395yy(e)); and

(B) for such services for residents in a skilled nursing facility after a part A stay.

(4) CREDENTIALING REQUIREMENTS.—Whether the Secretary should establish credentialing or other requirements for technicians that furnish diagnostic ultrasound services to medicare beneficiaries.

(b) REPORT.—Not later than 2 years after the date of the enactment of this Act, the Comptroller General shall submit to Congress a report on the study conducted under subsection (a), and shall include any recommendations for legislation or administrative change as the Comptroller General determines appropriate.

TITLE VI—PROVISIONS RELATING TO PART B

Subtitle A—Provisions Relating to Physicians' Services

SEC. 601. REVISION OF UPDATES FOR PHYSICIANS' SERVICES.

(a) UPDATE FOR 2004 AND 2005.—

(1) IN GENERAL.—Section 1848(d) (42 U.S.C. 1395w–4(d)) is amended by adding at the end the following new paragraph:

''(5) UPDATE FOR 2004 AND 2005.—The update to the single conversion factor established in paragraph (1)(C) for each of 2004 and 2005 shall be not less than 1.5 percent.''.

(2) CONFORMING AMENDMENT.—Paragraph (4)(B) of such section is amended, in the matter before clause (i), by inserting ''and paragraph (5)'' after ''subparagraph (D)''.

(3) NOT TREATED AS CHANGE IN LAW AND REGULATION IN SUSTAINABLE GROWTH RATE DETERMINATION.—The amendments made by this subsection shall not be treated as a change in law for purposes of applying section 1848(f)(2)(D) of the Social Security Act (42 U.S.C. 1395w–4(f)(2)(D)).

(b) USE OF 10-YEAR ROLLING AVERAGE IN COMPUTING GROSS DOMESTIC PRODUCT.—

(1) IN GENERAL.—Section 1848(f)(2)(C) (42 U.S.C. 1395w–4(f)(2)(C)) is amended—

(A) by striking ''projected'' and inserting ''annual average''; and

(B) by striking ''from the previous applicable period to the applicable period involved'' and inserting ''during the 10-year period ending with the applicable period involved''.

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to computations of the sustainable growth rate for years beginning with 2003.

SEC. 602. TREATMENT OF PHYSICIANS' SERVICES FURNISHED IN ALASKA.

Section 1848(e)(1) (42 U.S.C. 1395w–4(e)(1)), as amended by section 421, is amended—

(1) in subparagraph (A), by striking ''subparagraphs (B), (C), (E), and (F)'' and inserting ''subparagraphs (B), (C), (E), (F) and (G)''; and

(2) by adding at the end the following new subparagraph:

''(G) FLOOR FOR PRACTICE EXPENSE, MALPRACTICE, AND WORK GEOGRAPHIC INDICES FOR SERVICES FURNISHED IN ALASKA.—For purposes of payment for services furnished in Alaska on or after January 1, 2004, and before January 1, 2006, after calculating the practice expense, malpractice, and work geographic indices in clauses (i), (ii), and (iii) of subparagraph (A) and in subparagraph (B), the Secretary shall increase any such index to 1.67 if such index would otherwise be less than 1.67.''.

SEC. 603. INCLUSION OF PODIATRISTS, DENTISTS, AND OPTOMETRISTS UNDER PRIVATE CONTRACTING AUTHORITY.

Section 1802(b)(5)(B) (42 U.S.C. 1395a(b)(5)(B)) is amended by striking ''section 1861(r)(1)'' and inserting ''paragraphs (1), (2), (3), and (4) of section 1861(r)''.

SEC. 604. GAO STUDY ON ACCESS TO PHYSICIANS' SERVICES.

(a) STUDY.—The Comptroller General of the United States shall conduct a study on access of medicare beneficiaries to physicians' services under the medicare program. The study shall include—

(1) an assessment of the use by beneficiaries of such services through an analysis of claims submitted by physicians for such services under part B of the medicare program;

(2) an examination of changes in the use by beneficiaries of physicians' services over time; and

(3) an examination of the extent to which physicians are not accepting new medicare beneficiaries as patients.

(b) REPORT.—Not later than 18 months after the date of the enactment of this Act, the Comptroller General shall submit to Congress a report on the study conducted under subsection (a). The report shall include a determination whether—

(1) data from claims submitted by physicians under part B of the medicare program indicate potential access problems for medicare beneficiaries in certain geographic areas; and

(2) access by medicare beneficiaries to physicians' services may have improved, remained constant, or deteriorated over time.

SEC. 605. COLLABORATIVE DEMONSTRATION-BASED REVIEW OF PHYSICIAN PRACTICE EXPENSE GEOGRAPHIC ADJUSTMENT DATA.

(a) IN GENERAL.—Not later than January 1, 2005, the Secretary shall, in collaboration with State and other appropriate organizations representing physicians, and other appropriate persons, review and consider alternative data sources than those currently used in establishing the geographic index for the practice expense component under the medicare physician fee schedule under section 1848(e)(1)(A)(i) of the Social Security Act (42 U.S.C. 1395w–4(e)(1)(A)(i)).

(b) SITES.—The Secretary shall select two physician payment localities in which to carry out subsection (a). One locality shall include rural areas and at least one locality shall be a statewide locality that includes both urban and rural areas.

(c) REPORT AND RECOMMENDATIONS.—

(1) REPORT.—Not later than January 1, 2006, the Secretary shall submit to Congress a report on the review and consideration conducted under subsection (a). Such report shall include information on the alternative developed data sources considered by the Secretary under subsection (a), including the accuracy and validity of the data as measures of the elements of the geographic index for practice expenses under the medicare physician fee schedule as well as the feasibility of using such alternative data nationwide in lieu of current proxy data used in such index, and the estimated impacts of using such alternative data.

(2) RECOMMENDATIONS.—The report submitted under paragraph (1) shall contain recommendations on which data sources reviewed and considered under subsection (a) are appropriate for use in calculating the geographic index for practice expenses under the medicare physician fee schedule.

SEC. 606. MEDPAC REPORT ON PAYMENT FOR PHYSICIANS' SERVICES.

(a) PRACTICE EXPENSE COMPONENT.—Not later than 1 year after the date of the enactment of this Act, the Medicare Payment Advisory Commission shall submit to Congress a report on the effect of refinements to the practice expense component of payments for physicians' services, after the transition to a full resource-based payment system in 2002, under section 1848 of the Social Security Act (42 U.S.C. 1395w–4). Such report shall examine the following matters by physician specialty:

(1) The effect of such refinements on payment for physicians' services.

(2) The interaction of the practice expense component with other components of and adjustments to payment for physicians' services under such section.

(3) The appropriateness of the amount of compensation by reason of such refinements.

(4) The effect of such refinements on access to care by medicare beneficiaries to physicians' services.

(5) The effect of such refinements on physician participation under the medicare program.

(b) VOLUME OF PHYSICIANS' SERVICES.—Not later than 1 year after the date of the enactment of this Act, the Medicare Payment Advisory Commission shall submit to Congress a report on the extent to which increases in the volume of physicians' services under part B of the medicare program are a result of care that improves the health and well-being of medicare beneficiaries. The study shall include the following:

(1) An analysis of recent and historic growth in the components that the Secretary includes under the sustainable growth rate (under section 1848(f) of the Social Security Act (42 U.S.C. 1395w–4(f))).

(2) An examination of the relative growth of volume in physicians' services between medicare beneficiaries and other populations.

(3) An analysis of the degree to which new technology, including coverage determinations of the Centers for Medicare & Medicaid Services, has affected the volume of physicians' services.

(4) An examination of the impact on volume of demographic changes.

(5) An examination of shifts in the site of service or services that influence the number and intensity of services furnished in physicians' offices and the extent to which changes in reimbursement rates to other providers have effected these changes.

(6) An evaluation of the extent to which the Centers for Medicare & Medicaid Services takes into account the impact of law and regulations on the sustainable growth rate.

Subtitle B—Preventive Services

SEC. 611. COVERAGE OF AN INITIAL PREVENTIVE PHYSICAL EXAMINATION.

(a) COVERAGE.—Section 1861(s)(2) (42 U.S.C. 1395x(s)(2)) is amended—

(1) in subparagraph (U), by striking ''and'' at the end;

(2) in subparagraph (V)(iii), by inserting ''and'' at the end; and

(3) by adding at the end the following new subparagraph:

''(W) an initial preventive physical examination (as defined in subsection (ww));''.

(b) SERVICES DESCRIBED.—Section 1861 (42 U.S.C. 1395x) is amended by adding at the end the following new subsection:

''Initial Preventive Physical Examination

''(ww)(1) The term 'initial preventive physical examination' means physicians' services consisting of a physical examination (including measurement of height, weight, and blood pressure, and an electrocardiogram) with the goal of health promotion and disease detection and includes education, counseling, and referral with respect to screening and other preventive services described in paragraph (2), but does not include clinical laboratory tests.

''(2) The screening and other preventive services described in this paragraph include the following:

''(A) Pneumococcal, influenza, and hepatitis B vaccine and administration under subsection (s)(10).

''(B) Screening mammography as defined in subsection (jj).

''(C) Screening pap smear and screening pelvic exam as defined in subsection (nn).

''(D) Prostate cancer screening tests as defined in subsection (oo).

''(E) Colorectal cancer screening tests as defined in subsection (pp).

''(F) Diabetes outpatient self-management training services as defined in subsection (qq)(1).

''(G) Bone mass measurement as defined in subsection (rr).

''(H) Screening for glaucoma as defined in subsection (uu).

''(I) Medical nutrition therapy services as defined in subsection (vv).

''(J) Cardiovascular screening blood tests as defined in subsection (xx)(1).

''(K) Diabetes screening tests as defined in subsection (yy).''.

(c) PAYMENT AS PHYSICIANS' SERVICES.—Section 1848(j)(3) (42 U.S.C. 1395w–4(j)(3)) is amended by inserting ''(2)(W),'' after ''(2)(S),''.

(d) OTHER CONFORMING AMENDMENTS.—(1) Section 1862(a) (42 U.S.C. 1395y(a)), as amended by section 303(i)(3)(B), is amended—

(A) in paragraph (1)—

(i) by striking ''and'' at the end of subparagraph (I);

(ii) by striking the semicolon at the end of subparagraph (J) and inserting '', and''; and

(iii) by adding at the end the following new subparagraph:

''(K) in the case of an initial preventive physical examination, which is performed not later than 6 months after the date the individual's first coverage period begins under part B;''; a

(B) in paragraph (7), by striking ''or (H)'' and inserting ''(H), or (K)''.

(2) Clauses (i) and (ii) of section 1861(s)(2)(K) (42 U.S.C. 1395x(s)(2)(K)) are each amended by inserting ''and services described in subsection (ww)(1)'' after ''services which would be physicians' services''.

(e) EFFECTIVE DATE.—The amendments made by this section shall apply to services furnished on or after January 1, 2005, but only for individuals whose coverage period under part B begins on or after such date.

SEC. 612. COVERAGE OF CARDIOVASCULAR SCREENING BLOOD TESTS.

(a) COVERAGE.—Section 1861(s)(2) (42 U.S.C. 1395x(s)(2)), as amended by section 611(a), is amended—

(1) in subparagraph (V)(iii), by striking ''and'' at the end;

(2) in subparagraph (W), by inserting ''and'' at the end; and

(3) by adding at the end the following new subparagraph:

''(X) cardiovascular screening blood tests (as defined in subsection (xx)(1));''.

(b) SERVICES DESCRIBED.—Section 1861 (42 U.S.C. 1395x) is amended by adding at the end the following new subsection:

''Cardiovascular Screening Blood Test

''(xx)(1) The term 'cardiovascular screening blood test' means a blood test for the early detection of cardiovascular disease (or abnormalities associated with an elevated risk of cardiovascular disease) that tests for the following:

''(A) Cholesterol levels and other lipid or triglyceride levels.

''(B) Such other indications associated with the presence of, or an elevated risk for, cardiovascular disease as the Secretary may approve for all individuals (or for some individuals determined by the Secretary to be at risk for cardiovascular disease), including indications measured by noninvasive testing.

The Secretary may not approve an indication under subparagraph (B) for any individual unless a blood test for such is recommended by the United States Preventive Services Task Force.

''(2) The Secretary shall establish standards, in consultation with appropriate organizations, regarding the frequency for each type of cardiovascular screening blood tests, except that such frequency may not be more often than once every 2 years.''.

(c) FREQUENCY.—Section 1862(a)(1) (42 U.S.C. 1395y(a)(1)), as amended by section 611(d), is amended—

(1) by striking ''and'' at the end of subparagraph (J);

(2) by striking the semicolon at the end of subparagraph (K) and inserting '', and''; and

(3) by adding at the end the following new subparagraph:

''(L) in the case of cardiovascular screening blood tests (as defined in section 1861(xx)(1)), which are performed more frequently than is covered under section 1861(xx)(2);''.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to tests furnished on or after January 1, 2005.

SEC. 613. COVERAGE OF DIABETES SCREENING TESTS.

(a) COVERAGE.—Section 1861(s)(2) (42 U.S.C. 1395x(s)(2)), as amended by section 612(a), is amended—

(1) in subparagraph (W), by striking ''and'' at the end;

(2) in subparagraph (X), by adding ''and'' at the end; and

(3) by adding at the end the following new subparagraph:

''(Y) diabetes screening tests (as defined in subsection (yy));''.

(b) SERVICES DESCRIBED.—Section 1861 (42 U.S.C. 1395x), as amended by section 612(b), is amended by adding at the end the following new subsection:

''Diabetes Screening Tests

''(yy)(1) The term 'diabetes screening tests' means testing furnished to an individual at risk for diabetes (as defined in paragraph (2)) for the purpose of early detection of diabetes, including—

''(A) a fasting plasma glucose test; and

''(B) such other tests, and modifications to tests, as the Secretary determines appropriate, in consultation with appropriate organizations.

''(2) For purposes of paragraph (1), the term 'individual at risk for diabetes' means an individual who has any of the following risk factors for diabetes:

''(A) Hypertension.

''(B) Dyslipidemia.

''(C) Obesity, defined as a body mass index greater than or equal to 30 kg/m^2.

''(D) Previous identification of an elevated impaired fasting glucose.

''(E) Previous identification of impaired glucose tolerance.

''(F) A risk factor consisting of at least 2 of the following characteristics:

''(i) Overweight, defined as a body mass index greater than 25, but less than 30, kg/m^2.

''(ii) A family history of diabetes.

''(iii) A history of gestational diabetes mellitus or delivery of a baby weighing greater than 9 pounds.

''(iv) 65 years of age or older.

''(3) The Secretary shall establish standards, in consultation with appropriate organizations, regarding the frequency of diabetes screening tests, except that such frequency may not be more often than twice within the 12-month period following the date of the most recent diabetes screening test of that individual.''.

(c) FREQUENCY.—Section 1862(a)(1) (42 U.S.C. 1395y(a)(1)), as amended by section 612(c), is amended—

(1) by striking ''and'' at the end of subparagraph (K);

(2) by striking the semicolon at the end of subparagraph (L) and inserting '', and''; and

(3) by adding at the end the following new subparagraph:

''(M) in the case of a diabetes screening test (as defined in section 1861(yy)(1)), which is performed more frequently than is covered under section 1861(yy)(3);''.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to tests furnished on or after January 1, 2005.

SEC. 614. IMPROVED PAYMENT FOR CERTAIN MAMMOGRAPHY SERVICES.

(a) EXCLUSION FROM OPD FEE SCHEDULE.—Section 1833(t)(1)(B)(iv) (42 U.S.C. 1395l(t)(1)(B)(iv)) is amended by inserting before the period at the end the following: ''and does not include screening mammography (as defined in section 1861(jj)) and diagnostic mammography''.

(b) CONFORMING AMENDMENT.—Section 1833(a)(2)(E)(i) (42 U.S.C. 1395l(a)(2)(E)(i)) is amended by inserting ''and, for services furnished on or after January 1, 2005, diagnostic mammography'' after ''screening mammography''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply—

(1) in the case of screening mammography, to services furnished on or after the date of the enactment of this Act; and

(2) in the case of diagnostic mammography, to services furnished on or after January 1, 2005.

Subtitle C—Other Provisions

SEC. 621. HOSPITAL OUTPATIENT DEPARTMENT (HOPD) PAYMENT REFORM.

(a) PAYMENT FOR DRUGS.—

(1) SPECIAL RULES FOR CERTAIN DRUGS AND BIOLOGICALS.—Section 1833(t) (42 U.S.C. 1395l(t)), as amended by section 411(b), is amended by inserting after paragraph (13) the following new paragraphs:

''(14) DRUG APC PAYMENT RATES.—

''(A) IN GENERAL.—The amount of payment under this subsection for a specified covered outpatient drug (defined in subparagraph (B)) that is furnished as part of a covered OPD service (or group of services)—

''(i) in 2004, in the case of—

''(I) a sole source drug shall in no case be less than 88 percent, or exceed 95 percent, of the reference average wholesale price for the drug;

''(II) an innovator multiple source drug shall in no case exceed 68 percent of the reference average wholesale price for the drug; or

''(III) a noninnovator multiple source drug shall in no case exceed 46 percent of the reference average wholesale price for the drug;

''(ii) in 2005, in the case of—

''(I) a sole source drug shall in no case be less than 83 percent, or exceed 95 percent, of the reference average wholesale price for the drug;

''(II) an innovator multiple source drug shall in no case exceed 68 percent of the reference average wholesale price for the drug; or

''(III) a noninnovator multiple source drug shall in no case exceed 46 percent of the reference average wholesale price for the drug; or

''(iii) in a subsequent year, shall be equal, subject to subparagraph (E)—

''(I) to the average acquisition cost for the drug for that year (which, at the option of the Secretary, may vary by hospital group (as defined by the Secretary based on volume of covered OPD services or other relevant characteristics)), as determined by the Secretary taking into account the hospital acquisition cost survey data under subparagraph (D); or

''(II) if hospital acquisition cost data are not available, the average price for the drug in the year established under section 1842(o), section 1847A, or section 1847B, as the case may be, as calculated and adjusted by the Secretary as necessary for purposes of this paragraph.

''(B) SPECIFIED COVERED OUTPATIENT DRUG DEFINED.—

''(i) IN GENERAL.—In this paragraph, the term 'specified covered outpatient drug' means, subject to clause (ii), a covered outpatient drug (as defined in section 1927(k)(2)) for which a separate ambulatory payment classification group (APC) has been established and that is—

''(I) a radiopharmaceutical; or

''(II) a drug or biological for which payment was made under paragraph (6) (relating to pass-through payments) on or before December 31, 2002.

''(ii) EXCEPTION.—Such term does not include—

''(I) a drug or biological for which payment is first made on or after January 1, 2003, under paragraph (6);

''(II) a drug or biological for which a temporary HCPCS code has not been assigned; or

''(III) during 2004 and 2005, an orphan drug (as designated by the Secretary).

''(C) PAYMENT FOR DESIGNATED ORPHAN DRUGS DURING 2004 AND 2005.—The amount of payment under this subsection for an orphan drug designated by the Secretary under subparagraph

(B)(ii)(III) that is furnished as part of a covered OPD service (or group of services) during 2004 and 2005 shall equal such amount as the Secretary may specify.

''(D) ACQUISITION COST SURVEY FOR HOSPITAL OUTPATIENT DRUGS.—

''(i) ANNUAL GAO SURVEYS IN 2004 AND 2005.—

''(I) IN GENERAL.—The Comptroller General of the United States shall conduct a survey in each of 2004 and 2005 to determine the hospital acquisition cost for each specified covered outpatient drug. Not later than April 1, 2005, the Comptroller General shall furnish data from such surveys to the Secretary for use in setting the payment rates under subparagraph (A) for 2006.

''(II) RECOMMENDATIONS.—Upon the completion of such surveys, the Comptroller General shall recommend to the Secretary the frequency and methodology of subsequent surveys to be conducted by the Secretary under clause (ii).

''(ii) SUBSEQUENT SECRETARIAL SURVEYS.—The Secretary, taking into account such recommendations, shall conduct periodic subsequent surveys to determine the hospital acquisition cost for each specified covered outpatient drug for use in setting the payment rates under subparagraph (A).

''(iii) SURVEY REQUIREMENTS.—The surveys conducted under clauses (i) and (ii) shall have a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each specified covered outpatient drug. With respect to the surveys conducted under clause (i), the Comptroller General shall report to Congress on the justification for the size of the sample used in order to assure the validity of such estimates.

''(iv) DIFFERENTIATION IN COST.—In conducting surveys under clause (i), the Comptroller General shall determine and report to Congress if there is (and the extent of any) variation in hospital acquisition costs for drugs among hospitals based on the volume of covered OPD services performed by such hospitals or other relevant characteristics of such hospitals (as defined by the Comptroller General).

''(v) COMMENT ON PROPOSED RATES.—Not later than 30 days after the date the Secretary promulgated proposed rules setting forth the payment rates under subparagraph (A) for 2006, the Comptroller General shall evaluate such proposed rates and submit to Congress a report regarding the appropriateness of such rates based on the surveys the Comptroller General has conducted under clause (i).

''(E) ADJUSTMENT IN PAYMENT RATES FOR OVERHEAD COSTS.—

''(i) MEDPAC REPORT ON DRUG APC DESIGN.—The Medicare Payment Advisory Commission shall submit to the Secretary, not later than July 1, 2005, a report on adjustment of payment for ambulatory payment classifications for specified covered outpatient drugs to take into account overhead and related expenses, such as pharmacy services and handling costs. Such report shall include—

''(I) a description and analysis of the data available with regard to such expenses;

''(II) a recommendation as to whether such a payment adjustment should be made; and

''(III) if such adjustment should be made, a recommendation regarding the methodology for making such an adjustment.

''(ii) ADJUSTMENT AUTHORIZED.—The Secretary may adjust the weights for ambulatory payment classifications for specified covered outpatient drugs to take into account the recommendations contained in the report submitted under clause (i).

''(F) CLASSES OF DRUGS.—For purposes of this paragraph:

''(i) SOLE SOURCE DRUGS.—The term 'sole source drug' means—

''(I) a biological product (as defined under section 1861(t)(1)); or

''(II) a single source drug (as defined in section 1927(k)(7)(A)(iv)).

''(ii) INNOVATOR MULTIPLE SOURCE DRUGS.—The term 'innovator multiple source drug' has the meaning given such term in section 1927(k)(7)(A)(ii).

''(iii) NONINNOVATOR MULTIPLE SOURCE DRUGS.—The term 'noninnovator multiple source drug' has the meaning given such term in section 1927(k)(7)(A)(iii).

''(G) REFERENCE AVERAGE WHOLESALE PRICE.—The term 'reference average wholesale price' means, with respect to a specified covered outpatient drug, the average wholesale price for the drug as determined under section 1842(o) as of May 1, 2003.

''(H) INAPPLICABILITY OF EXPENDITURES IN DETERMINING CONVERSION, WEIGHTING, AND OTHER ADJUSTMENT FACTORS.—Additional expenditures resulting from this paragraph shall not be taken into account in establishing the conversion, weighting, and other adjustment factors for 2004 and 2005 under paragraph (9), but shall be taken into account for subsequent years.

''(15) PAYMENT FOR NEW DRUGS AND BIOLOGICALS UNTIL HCPCS CODE ASSIGNED.—With respect to payment under this part for an outpatient drug or biological that is covered under this part and is furnished as part of covered OPD services for which a HCPCS code has not been assigned, the amount provided for payment for such drug or biological under this part shall be equal to 95 percent of the average wholesale price for the drug or biological.''.

(2) REDUCTION IN THRESHOLD FOR SEPARATE APCS FOR DRUGS.—Section 1833(t)(16), as redesignated section 411(b), is amended by adding at the end the following new subparagraph:

''(B) THRESHOLD FOR ESTABLISHMENT OF SEPARATE APCS FOR DRUGS.—The Secretary shall reduce the threshold for the establishment of separate ambulatory payment classification groups (APCs) with respect to drugs or biologicals to $50 per administration for drugs and biologicals furnished in 2005 and 2006.''.

(3) EXCLUSION OF SEPARATE DRUG APCS FROM OUTLIER PAYMENTS.—Section 1833(t)(5) is amended by adding at the end the following new subparagraph:

''(E) EXCLUSION OF SEPARATE DRUG AND BIOLOGICAL APCS FROM OUTLIER PAYMENTS.—No additional payment shall be made under subparagraph (A) in the case of ambulatory payment classification groups established separately for drugs or biologicals.''.

(4) PAYMENT FOR PASS THROUGH DRUGS.—Section 1833(t)(6)(D)(i) (42 U.S.C. 1395l(t)(6)(D)(i)) is amended by inserting after ''under section 1842(o)'' the following: ''(or if the drug or biological is covered under a competitive acquisition contract under section 1847B, an amount determined by the Secretary equal to the average price for the drug or biological for all competitive acquisition areas and year established under such section as calculated and adjusted by the Secretary for purposes of this paragraph)''.

(5) CONFORMING AMENDMENT TO BUDGET NEUTRALITY REQUIREMENT.—Section 1833(t)(9)(B) (42 U.S.C. 1395l(t)(9)(B)) is amended by adding at the end the following: ''In determining adjustments under the preceding sentence for 2004 and 2005, the Secretary shall not take into account under this subparagraph or paragraph (2)(E) any expenditures that would not have been made but for the application of paragraph (14).''.

(6) EFFECTIVE DATE.—The amendments made by this subsection shall apply to items and services furnished on or after January 1, 2004.

(b) SPECIAL PAYMENT FOR BRACHYTHERAPY.—

(1) IN GENERAL.—Section 1833(t)(16), as redesignated by section 411(b) and as amended by subsection (a)(2), is amended by adding at the end the following new subparagraph:

''(C) PAYMENT FOR DEVICES OF BRACHYTHERAPY AT CHARGES ADJUSTED TO COST.—Notwithstanding the preceding provisions of this subsection, for a device of brachytherapy consisting of a seed or seeds (or radioactive source) furnished on or after January 1, 2004, and before January 1, 2007, the payment basis for the device under this subsection shall be equal to the hospital's charges for each device furnished, adjusted to cost. Charges for such devices shall not be included in determining any outlier payment under this subsection.''.

(2) SPECIFICATION OF GROUPS FOR BRACHYTHERAPY DEVICES.—Section 1833(t)(2) (42 U.S.C. 1395l(t)(2)) is amended—

(A) in subparagraph (F), by striking ''and'' at the end;

(B) in subparagraph (G), by striking the period at the end and inserting ''; and''; and

(C) by adding at the end the following new subparagraph:

''(H) with respect to devices of brachytherapy consisting of a seed or seeds (or radioactive source), the Secretary shall create additional groups of covered OPD services that classify such devices separately from the other services (or group of services) paid for under this subsection in a manner reflecting the number, isotope, and radioactive intensity of such devices furnished, including separate groups for palladium-103 and iodine-125 devices.''.

(3) GAO REPORT.—The Comptroller General of the United States shall conduct a study to determine appropriate payment amounts under section 1833(t)(16)(C) of the Social Security Act, as added by paragraph (1), for devices of brachytherapy. Not later than January 1, 2005, the Comptroller General shall submit to Congress and the Secretary a report on the study conducted under this paragraph, and shall include specific recommendations for appropriate payments for such devices.

SEC. 622. LIMITATION OF APPLICATION OF FUNCTIONAL EQUIVALENCE STANDARD.

Section 1833(t)(6) (42 U.S.C. 1395l(t)(6)) is amended by adding at the end the following new subparagraph:

''(F) LIMITATION OF APPLICATION OF FUNCTIONAL EQUIVALENCE STANDARD.—

''(i) IN GENERAL.—The Secretary may not publish regulations that apply a functional equivalence standard to a drug or biological under this paragraph.

''(ii) APPLICATION.—Clause (i) shall apply to the application of a functional equivalence standard to a drug or biological on or after the date of enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 unless—

''(I) such application was being made to such drug or biological prior to such date of enactment; and

''(II) the Secretary applies such standard to such drug or biological only for the purpose of determining eligibility of such drug or biological for additional payments under this paragraph and not for the purpose of any other payments under this title.

''(iii) RULE OF CONSTRUCTION.—Nothing in this subparagraph shall be construed to effect the Secretary's authority to deem a particular drug to be identical to another drug if the 2 products are pharmaceutically equivalent and bioequivalent, as determined by the Commissioner of Food and Drugs.''.

SEC. 623. PAYMENT FOR RENAL DIALYSIS SERVICES.

(a) INCREASE IN RENAL DIALYSIS COMPOSITE RATE FOR SERVICES FURNISHED.—The last sentence of section 1881(b)(7) (42 U.S.C. 1395rr(b)(7)) is amended—

(1) by striking ''and'' before ''for such services'' the second place it appears;

(2) by inserting ''and before January 1, 2005,'' after ''January 1, 2001,''; and

(3) by inserting before the period at the end the following: '', and for such services furnished on or after January 1, 2005, by 1.6 percent above such composite rate payment amounts for such services furnished on December 31, 2004''.

(b) RESTORING COMPOSITE RATE EXCEPTIONS FOR PEDIATRIC FACILITIES.—

(1) IN GENERAL.—Section 422(a)(2) of BIPA is amended—

(A) in subparagraph (A), by striking ''and (C)'' and inserting '', (C), and (D)'';

(B) in subparagraph (B), by striking ''In the case'' and inserting ''Subject to subparagraph (D), in the case''; and

(C) by adding at the end the following new subparagraph:

''(D) INAPPLICABILITY TO PEDIATRIC FACILITIES.—Subparagraphs (A) and (B) shall not apply, as of October 1, 2002, to pediatric facilities that do not have an exception rate described in subparagraph (C) in effect on such date. For purposes of this subparagraph, the term 'pediatric facility' means a renal facility at least 50 percent of whose patients are individuals under 18 years of age.''.

(2) CONFORMING AMENDMENT.—The fourth sentence of section 1881(b)(7) (42 U.S.C. 1395rr(b)(7)) is amended by striking ''The Secretary'' and inserting ''Subject to section 422(a)(2) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, the Secretary''.

(c) INSPECTOR GENERAL STUDIES ON ESRD DRUGS.—

(1) IN GENERAL.—The Inspector General of the Department of Health and Human Services shall conduct two studies with respect to drugs and biologicals (including erythropoietin) furnished to end-stage renal disease patients under the medicare program which are separately billed by end stage renal disease facilities.

(2) STUDIES ON ESRD DRUGS.—

(A) EXISTING DRUGS.—The first study under paragraph (1) shall be conducted with respect to such drugs and biologicals for which a billing code exists prior to January 1, 2004.

(B) NEW DRUGS.—The second study under paragraph (1) shall be conducted with respect to such drugs and biologicals for which a billing code does not exist prior to January 1, 2004.

(3) MATTERS STUDIED.—Under each study conducted under paragraph (1), the Inspector General shall—

(A) determine the difference between the amount of payment made to end stage renal disease facilities under title XVIII of the Social Security Act for such drugs and biologicals and the acquisition costs of such facilities for such drugs and biologicals and which are separately billed by end stage renal disease facilities, and

(B) estimate the rates of growth of expenditures for such drugs and biologicals billed by such facilities.

(4) REPORTS.—

(A) EXISTING ESRD DRUGS.—Not later than April 1, 2004, the Inspector General shall report to the Secretary on the study described in paragraph (2)(A).

(B) NEW ESRD DRUGS.—Not later than April 1, 2006, the Inspector General shall report to the Secretary on the study described in paragraph (2)(B).

(d) BASIC CASE-MIX ADJUSTED COMPOSITE RATE FOR RENAL DIALYSIS FACILITY SERVICES.—(1) Section 1881(b) (42 U.S.C. 1395rr(b)) is amended by adding at the end the following new paragraphs:

''(12)(A) In lieu of payment under paragraph (7) beginning with services furnished on January 1, 2005, the Secretary shall establish a basic case-mix adjusted prospective payment system for dialysis services furnished by providers of services and renal dialysis facilities in a year to individuals in a facility and to such individuals at home. The case-mix under such system shall be for a limited number of patient characteristics.

''(B) The system described in subparagraph (A) shall include—

''(i) the services comprising the composite rate established under paragraph (7); and

''(ii) the difference between payment amounts under this title for separately billed drugs and biologicals (including erythropoietin) and acquisition costs of such drugs and biologicals, as determined by the Inspector General reports to the Secretary as required by section 623(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003—

''(I) beginning with 2005, for such drugs and biologicals for which a billing code exists prior to January 1, 2004; and

''(II) beginning with 2007, for such drugs and biologicals for which a billing code does not exist prior to January 1, 2004,

adjusted to 2005, or 2007, respectively, as determined to be appropriate by the Secretary.

''(C)(i) In applying subparagraph (B)(ii) for 2005, such payment amounts under this title shall be determined using the methodology specified in paragraph (13)(A)(i).

''(ii) For 2006, the Secretary shall provide for an adjustment to the payments under clause (i) to reflect the difference between the payment amounts using the methodology under paragraph (13)(A)(i) and the payment amount determined using the methodology applied by the Secretary under paragraph (13)(A)(iii) of such paragraph, as estimated by the Secretary.

''(D) The Secretary shall adjust the payment rates under such system by a geographic index as the Secretary determines to be appropriate. If the Secretary applies a geographic index under this paragraph that differs from the index applied under paragraph (7) the Secretary shall phase-in the application of the index under this paragraph over a multiyear period.

''(E)(i) Such system shall be designed to result in the same aggregate amount of expenditures for such services, as estimated by the Secretary, as would have been made for 2005 if this paragraph did not apply.

''(ii) The adjustment made under subparagraph (B)(ii)(II) shall be done in a manner to result in the same aggregate amount of expenditures after such adjustment as would otherwise have been made for such services for 2006 or 2007, respectively, as estimated by the Secretary, if this paragraph did not apply.

''(F) Beginning with 2006, the Secretary shall annually increase the basic case-mix adjusted payment amounts established under this paragraph, by an amount determined by—

''(i) applying the estimated growth in expenditures for drugs and biologicals (including erythropoietin) that are separately billable to the component of the basic case-mix adjusted system described in subparagraph (B)(ii); and

''(ii) converting the amount determined in clause (i) to an increase applicable to the basic case-mix adjusted payment amounts established under subparagraph (B).

Nothing in this paragraph shall be construed as providing for an update to the composite rate component of the basic case-mix adjusted system under subparagraph (B).

''(G) There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of the case-mix system, relative weights, payment amounts, the geographic adjustment factor, or the update for the system established under this paragraph, or the determination of the difference between medicare payment amounts and acquisition costs for separately billed drugs and biologicals (including erythropoietin) under this paragraph and paragraph (13).

''(13)(A) The payment amounts under this title for separately billed drugs and biologicals furnished in a year, beginning with 2004, are as follows:

''(i) For such drugs and biologicals (other than erythropoietin) furnished in 2004, the amount determined under section 1842(o)(1)(A)(v) for the drug or biological.

''(ii) For such drugs and biologicals (including erythropoietin) furnished in 2005, the acquisition cost of the drug or biological, as determined by the Inspector General reports to the Secretary as required by section 623(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Insofar as the Inspector General has not determined the acquisition cost with respect to a drug or biological, the Secretary shall determine the payment amount for such drug or biological.

''(iii) For such drugs and biologicals (including erythropoietin) furnished in 2006 and subsequent years, such acquisition cost or the amount determined under section 1847A for the drug or biological, as the Secretary may specify.

''(B)(i) Drugs and biologicals (including erythropoietin) which were separately billed under this subsection on the day before the date of the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 shall continue to be separately billed on and after such date.

''(ii) Nothing in this paragraph, section 1842(o), section 1847A, or section 1847B shall be construed as requiring or authorizing the bundling of payment for drugs and biologicals into the basic case-mix adjusted payment system under this paragraph.''.

(2) Paragraph (7) of such section is amended in the first sentence by striking ''The Secretary'' and inserting ''Subject to paragraph (12), the Secretary''.

(3) Paragraph (11)(B) of such section is amended by inserting ''subject to paragraphs (12) and (13)'' before ''payment for such item''.

(e) DEMONSTRATION OF BUNDLED CASE-MIX ADJUSTED PAYMENT SYSTEM FOR ESRD SERVICES.—

(1) IN GENERAL.—The Secretary shall establish a demonstration project of the use of a fully case-mix adjusted payment system for end stage renal disease services under section 1881 of the Social Security Act (42 U.S.C. 1395rr) for patient characteristics identified in the report under subsection (f) that bundles into such payment rates amounts for—

(A) drugs and biologicals (including erythropoietin) furnished to end stage renal disease patients under the medicare program which are separately billed by end stage renal disease facilities (as of the date of the enactment of this Act); and

(B) clinical laboratory tests related to such drugs and biologicals.

(2) FACILITIES INCLUDED IN THE DEMONSTRATION.—In conducting the demonstration under this subsection, the Secretary shall ensure the participation of a sufficient number of providers of dialysis services and renal dialysis facilities, but in no case to exceed 500. In selecting such providers and facilities, the Secretary shall ensure that the following types of providers are included in the demonstration:

(A) Urban providers and facilities.

(B) Rural providers and facilities.

(C) Not-for-profit providers and facilities.

(D) For-profit providers and facilities.

(E) Independent providers and facilities.

(F) Specialty providers and facilities, including pediatric providers and facilities and small providers and facilities.

(3) TEMPORARY ADD-ON PAYMENT FOR DIALYSIS SERVICES FURNISHED UNDER THE DEMONSTRATION.—

(A) IN GENERAL.—During the period of the demonstration project, the Secretary shall increase payment rates that would otherwise apply under section 1881(b) of such Act (42 U.S.C. 1395rr(b)) by 1.6 percent for dialysis services furnished in facilities in the demonstration site.

(B) RULES OF CONSTRUCTION.—Nothing in this subsection shall be construed as—

(i) as an annual update under section 1881(b) of the Social Security Act (42 U.S.C. 1395rr(b));

(ii) as increasing the baseline for payments under such section; or

(iii) requiring the budget neutral implementation of the demonstration project under this subsection.

(4) 3-YEAR PERIOD.—The Secretary shall conduct the demonstration under this subsection for the 3-year period beginning on January 1, 2006.

(5) USE OF ADVISORY BOARD.—

(A) IN GENERAL.—In carrying out the demonstration under this subsection, the Secretary shall establish an advisory board comprised of representatives described in subparagraph (B) to

provide advice and recommendations with respect to the establishment and operation of such demonstration.

(B) REPRESENTATIVES.—Representatives referred to in subparagraph (A) include representatives of the following:

(i) Patient organizations.

(ii) Individuals with expertise in end stage renal dialysis services, such as clinicians, economists, and researchers.

(iii) The Medicare Payment Advisory Commission, established under section 1805 of the Social Security Act (42 U.S.C. 1395b–6).

(iv) The National Institutes of Health.

(v) Network organizations under section 1881(c) of the Social Security Act (42 U.S.C. 1395rr(c)).

(vi) Medicare contractors to monitor quality of care.

(vii) Providers of services and renal dialysis facilities furnishing end stage renal disease services.

(C) TERMINATION OF ADVISORY PANEL.—The advisory panel shall terminate on December 31, 2008.

(6) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated, in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund, $5,000,000 in fiscal year 2006 to conduct the demonstration under this subsection.

(f) REPORT ON A BUNDLED PROSPECTIVE PAYMENT SYSTEM FOR END STAGE RENAL DISEASE SERVICES.—

(1) REPORT.—

(A) IN GENERAL.—Not later than October 1, 2005, the Secretary shall submit to Congress a report detailing the elements and features for the design and implementation of a bundled prospective payment system for services furnished by end stage renal disease facilities including, to the maximum extent feasible, bundling of drugs, clinical laboratory tests, and other items that are separately billed by such facilities. The report shall include a description of the methodology to be used for the establishment of payment rates, including components of the new system described in paragraph (2).

(B) RECOMMENDATIONS.—The Secretary shall include in such report recommendations on elements, features, and methodology for a bundled prospective payment system or other issues related to such system as the Secretary determines to be appropriate.

(2) ELEMENTS AND FEATURES OF A BUNDLED PROSPECTIVE PAYMENT SYSTEM.—The report required under paragraph (1) shall include the following elements and features of a bundled prospective payment system:

(A) BUNDLE OF ITEMS AND SERVICES.—A description of the bundle of items and services to be included under the prospective payment system.

(B) CASE MIX.—A description of the case-mix adjustment to account for the relative resource use of different types of patients.

(C) WAGE INDEX.—A description of an adjustment to account for geographic differences in wages.

(D) RURAL AREAS.—The appropriateness of establishing a specific payment adjustment to account for additional costs incurred by rural facilities.

(E) OTHER ADJUSTMENTS.—Such other adjustments as may be necessary to reflect the variation in costs incurred by facilities in caring for patients with end stage renal disease.

(F) UPDATE FRAMEWORK.—A methodology for appropriate updates under the prospective payment system.

(G) ADDITIONAL RECOMMENDATIONS.—Such other matters as the Secretary determines to be appropriate.

SEC. 624. 2-YEAR MORATORIUM ON THERAPY CAPS; PROVISIONS RELATING TO REPORTS.

(a) ADDITIONAL MORATORIUM ON THERAPY CAPS.—

(1) 2004 AND 2005.—Section 1833(g)(4) (42 U.S.C. 1395l(g)(4)) is amended by striking ''and 2002'' and inserting ''2002, 2004, and 2005''.

(2) REMAINDER OF 2003.—For the period beginning on the date of the enactment of this Act and ending of December 31, 2003, the Secretary shall not apply the provisions of paragraphs (1), (2), and (3) of section 1833(g) to expenses incurred with respect to services described in such paragraphs during such period. Nothing in the preceding sentence shall be construed as affecting the application of such paragraphs by the Secretary before the date of the enactment of this Act.

(b) PROMPT SUBMISSION OF OVERDUE REPORTS ON PAYMENT AND UTILIZATION OF OUTPATIENT THERAPY SERVICES.—Not later than March 31, 2004, the Secretary shall submit to Congress the reports required under section 4541(d)(2) of the Balanced Budget Act of 1997 (Public Law 105–33; 111 Stat. 457) (relating to alternatives to a single annual dollar cap on outpatient therapy) and under section 221(d) of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (Appendix F, 113 Stat. 1501A–352), as enacted into law by section 1000(a)(6) of Public Law 106–113 (relating to utilization patterns for outpatient therapy).

(c) GAO REPORT IDENTIFYING CONDITIONS AND DISEASES JUSTIFYING WAIVER OF THERAPY CAP.—

(1) STUDY.—The Comptroller General of the United States shall identify conditions or diseases that may justify waiving the application of the therapy caps under section 1833(g) of the Social Security Act (42 U.S.C. 1395l(g)) with respect to such conditions or diseases.

(2) REPORT TO CONGRESS.—Not later than October 1, 2004, the Comptroller General shall submit to Congress a report on the conditions and diseases identified under paragraph (1), and shall include a recommendation of criteria, with respect to such conditions and disease, under which a waiver of the therapy caps would apply.

SEC. 625. WAIVER OF PART B LATE ENROLLMENT PENALTY FOR CERTAIN MILITARY RETIREES; SPECIAL ENROLLMENT PERIOD.

(a) WAIVER OF PENALTY.—

(1) IN GENERAL.—Section 1839(b) (42 U.S.C. 1395r(b)) is amended by adding at the end the following new sentence: ''No increase in the premium shall be effected for a month in the case of an individual who enrolls under this part during 2001, 2002, 2003, or 2004 and who demonstrates to the Secretary before December 31, 2004, that the individual is a covered beneficiary (as defined in section 1072(5) of title 10, United States Code). The Secretary of Health and Human Services shall consult with the Secretary of Defense in identifying individuals described in the previous sentence.''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to premiums for months beginning with January 2004. The Secretary shall establish a method for providing rebates of premium penalties paid for months on or after January 2004 for which a penalty does not apply under such amendment but for which a penalty was previously collected.

(b) MEDICARE PART B SPECIAL ENROLLMENT PERIOD.—

(1) IN GENERAL.—In the case of any individual who, as of the date of the enactment of this Act, is eligible to enroll but is not enrolled under part B of title XVIII of the Social Security Act and is a covered beneficiary (as defined in section 1072(5) of title 10, United States Code), the Secretary of Health and Human Services shall provide for a special enrollment period during which the individual may enroll under such part. Such period shall begin as soon as possible after the date of the enactment of this Act and shall end on December 31, 2004.

(2) COVERAGE PERIOD.—In the case of an individual who enrolls during the special enrollment period provided under paragraph (1), the coverage period under part B of title XVIII of the Social Security Act shall begin on the first day of the month following the month in which the individual enrolls.

SEC. 626. PAYMENT FOR SERVICES FURNISHED IN AMBULATORY SURGICAL CENTERS.

(a) REDUCTIONS IN PAYMENT UPDATES.—Section 1833(i)(2)(C) (42 U.S.C. 1395l(i)(2)(C)) is amended to read as follows:

''(C)(i) Notwithstanding the second sentence of each of subparagraphs (A) and (B), except as otherwise specified in clauses (ii), (iii), and (iv), if the Secretary has not updated amounts established under such subparagraphs or under subparagraph (D), with respect to facility services furnished during a fiscal year (beginning with fiscal year 1986 or a calendar year (beginning with 2006)), such amounts shall be increased by the percentage increase in the Consumer Price Index for all urban consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved.

''(ii) In each of the fiscal years 1998 through 2002, the increase under this subparagraph shall be reduced (but not below zero) by 2.0 percentage points.

''(iii) In fiscal year 2004, beginning with April 1, 2004, the increase under this subparagraph shall be the Consumer Price Index for all urban consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with March 31, 2003, minus 3.0 percentage points.

''(iv) In fiscal year 2005, the last quarter of calendar year 2005, and each of calendar years 2006 through 2009, the increase under this subparagraph shall be 0 percent.''.

(b) REPEAL OF SURVEY REQUIREMENT AND IMPLEMENTATION OF NEW SYSTEM.—Section 1833(i)(2) (42 U.S.C. 1395l(i)(2)) is amended—

(1) in subparagraph (A)—

(A) in the matter preceding clause (i), by striking ''The'' and inserting ''For services furnished prior to the implementation of the system described in subparagraph (D), the''; and

(B) in clause (i), by striking ''taken not later than January 1, 1995, and every 5 years thereafter,''; and

(2) by adding at the end the following new subparagraph:

''(D)(i) Taking into account the recommendations in the report under section 626(d) of Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the Secretary shall implement a revised payment system for payment of surgical services furnished in ambulatory surgical centers.

''(ii) In the year the system described in clause (i) is implemented, such system shall be designed to result in the same aggregate amount of expenditures for such services as would be made if this subparagraph did not apply, as estimated by the Secretary.

''(iii) The Secretary shall implement the system described in clause (i) for periods in a manner so that it is first effective beginning on or after January 1, 2006, and not later than January 1, 2008.

''(iv) There shall be no administrative or judicial review under section 1869, 1878, or otherwise, of the classification system, the relative weights, payment amounts, and the geographic adjustment factor, if any, under this subparagraph.''.

(c) CONFORMING AMENDMENT.—Section 1833(a)(1) (42 U.S.C. 1395l(a)(1)) is amended by adding the following new subparagraph:

''(G) with respect to facility services furnished in connection with a surgical procedure specified pursuant to subsection (i)(1)(A) and furnished to an individual in an ambulatory surgical center described in such subsection, for services furnished beginning with the implementation date of a revised payment system for such services in such facilities specified in subsection (i)(2)(D), the amounts paid shall be 80 percent of the lesser of the actual charge for the services or

the amount determined by the Secretary under such revised payment system,''.

(d) GAO STUDY OF AMBULATORY SURGICAL CENTER PAYMENTS.—

(1) STUDY.—

(A) IN GENERAL.—The Comptroller General of the United States shall conduct a study that compares the relative costs of procedures furnished in ambulatory surgical centers to the relative costs of procedures furnished in hospital outpatient departments under section 1833(t) of the Social Security Act (42 U.S.C. 1395l(t)). The study shall also examine how accurately ambulatory payment categories reflect procedures furnished in ambulatory surgical centers.

(B) CONSIDERATION OF ASC DATA.—In conducting the study under paragraph (1), the Comptroller General shall consider data submitted by ambulatory surgical centers regarding the matters described in clauses (i) through (iii) of paragraph (2)(B).

(2) REPORT AND RECOMMENDATIONS.—

(A) REPORT.—Not later than January 1, 2005, the Comptroller General shall submit to Congress a report on the study conducted under paragraph (1).

(B) RECOMMENDATIONS.—The report submitted under subparagraph (A) shall include recommendations on the following matters:

(i) The appropriateness of using the groups of covered services and relative weights established under the outpatient prospective payment system as the basis of payment for ambulatory surgical centers.

(ii) If the relative weights under such hospital outpatient prospective payment system are appropriate for such purpose—

(I) whether the payment rates for ambulatory surgical centers should be based on a uniform percentage of the payment rates or weights under such outpatient system; or

(II) whether the payment rates for ambulatory surgical centers should vary, or the weights should be revised, based on specific procedures or types of services (such as ophthalmology and pain management services).

(iii) Whether a geographic adjustment should be used for payment of services furnished in ambulatory surgical centers, and if so, the labor and nonlabor shares of such payment.

SEC. 627. PAYMENT FOR CERTAIN SHOES AND INSERTS UNDER THE FEE SCHEDULE FOR ORTHOTICS AND PROSTHETICS.

(a) IN GENERAL.—Section 1833(o) (42 U.S.C. 1395l(o)) is amended—

(1) in paragraph (1)(B), by striking ''no more than the limits established under paragraph (2)'' and inserting ''no more than the amount of payment applicable under paragraph (2)''; and

(2) in paragraph (2), to read as follows:

''(2)(A) Except as provided by the Secretary under subparagraphs (B) and (C), the amount of payment under this paragraph for custom molded shoes, extra-depth shoes, and inserts shall be the amount determined for such items by the Secretary under section 1834(h).

''(B) The Secretary may establish payment amounts for shoes and inserts that are lower than the amount established under section 1834(h) if the Secretary finds that shoes and inserts of an appropriate quality are readily available at or below the amount established under such section.

''(C) In accordance with procedures established by the Secretary, an individual entitled to benefits with respect to shoes described in section 1861(s)(12) may substitute modification of such shoes instead of obtaining one (or more, as specified by the Secretary) pair of inserts (other than the original pair of inserts with respect to such shoes). In such case, the Secretary shall substitute, for the payment amount established under section 1834(h), a payment amount that the Secretary estimates will assure that there is no net increase in expenditures under this subsection as a result of this subparagraph.''.

(b) CONFORMING AMENDMENTS.—(1) Section 1834(h)(4)(C) (42 U.S.C. 1395m(h)(4)(C)) is amended by inserting ''(and includes shoes described in section 1861(s)(12))'' after ''in section 1861(s)(9)''.

(2) Section 1842(s)(2) (42 U.S.C. 1395u(s)(2)) is amended by striking subparagraph (C).

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to items furnished on or after January 1, 2005.

SEC. 628. PAYMENT FOR CLINICAL DIAGNOSTIC LABORATORY TESTS.

Section 1833(h)(2)(A)(ii)(IV) (42 U.S.C. 1395l(h)(2)(A)(ii)(IV)) is amended by striking ''and 1998 through 2002'' and inserting '', 1998 through 2002, and 2004 through 2008''.

SEC. 629. INDEXING PART B DEDUCTIBLE TO INFLATION.

The first sentence of section 1833(b) (42 U.S.C. 1395l(b)) is amended by striking ''and $100 for 1991 and subsequent years'' and inserting the following: '', $100 for 1991 through 2004, $110 for 2005, and for a subsequent year the amount of such deductible for the previous year increased by the annual percentage increase in the monthly actuarial rate under section 1839(a)(1) ending with such subsequent year (rounded to the nearest $1)''.

SEC. 630. 5-YEAR AUTHORIZATION OF REIMBURSEMENT FOR ALL MEDICARE PART B SERVICES FURNISHED BY CERTAIN INDIAN HOSPITALS AND CLINICS.

Section 1880(e)(1)(A) (42 U.S.C. 1395qq(e)(1)(A)) is amended by inserting ''(and for items and services furnished during the 5-year period beginning on January 1, 2005, all items and services for which payment may be made under part B)'' after ''for services described in paragraph (2)''.

Subtitle D—Additional Demonstrations, Studies, and Other Provisions

SEC. 641. DEMONSTRATION PROJECT FOR COVERAGE OF CERTAIN PRESCRIPTION DRUGS AND BIOLOGICALS.

(a) DEMONSTRATION PROJECT.—The Secretary shall conduct a demonstration project under part B of title XVIII of the Social Security Act under which payment is made for drugs or biologicals that are prescribed as replacements for drugs and biologicals described in section 1861(s)(2)(A) or 1861(s)(2)(Q) of such Act (42 U.S.C. 1395x(s)(2)(A), 1395x(s)(2)(Q)), or both, for which payment is made under such part. Such project shall provide for cost-sharing applicable with respect to such drugs or biologicals in the same manner as cost-sharing applies with respect to part D drugs under standard prescription drug coverage (as defined in section 1860D–2(b) of the Social Security Act, as added by section 101(a)).

(b) DEMONSTRATION PROJECT SITES.—The project established under this section shall be conducted in sites selected by the Secretary.

(c) DURATION.—The Secretary shall conduct the demonstration project for the 2-year period beginning on the date that is 90 days after the date of the enactment of this Act, but in no case may the project extend beyond December 31, 2005.

(d) LIMITATION.—Under the demonstration project over the duration of the project, the Secretary may not provide—

(1) coverage for more than 50,000 patients; and

(2) more than $500,000,000 in funding.

(e) REPORT.—Not later than July 1, 2006, the Secretary shall submit to Congress a report on the project. The report shall include an evaluation of patient access to care and patient outcomes under the project, as well as an analysis of the cost effectiveness of the project, including an evaluation of the costs savings (if any) to the medicare program attributable to reduced physicians' services and hospital outpatient departments services for administration of the biological.

SEC. 642. EXTENSION OF COVERAGE OF INTRAVENOUS IMMUNE GLOBULIN (IVIG) FOR THE TREATMENT OF PRIMARY IMMUNE DEFICIENCY DISEASES IN THE HOME.

(a) IN GENERAL.—Section 1861 (42 U.S.C. 1395x), as amended by sections 611(a) and 612(a) is amended—

(1) in subsection (s)(2)—

(A) by striking ''and'' at the end of subparagraph (X);

(B) by adding ''and'' at the end of subparagraph (Y); and

(C) by adding at the end the following new subparagraph:

''(Z) intravenous immune globulin for the treatment of primary immune deficiency diseases in the home (as defined in subsection (zz));''; and

(2) by adding at the end the following new subsection:

''Intravenous Immune Globulin

''(zz) The term 'intravenous immune globulin' means an approved pooled plasma derivative for the treatment in the patient's home of a patient with a diagnosed primary immune deficiency disease, but not including items or services related to the administration of the derivative, if a physician determines administration of the derivative in the patient's home is medically appropriate.''.

(b) PAYMENT AS A DRUG OR BIOLOGICAL.—Section 1833(a)(1)(S) (42 U.S.C. 1395l(a)(1)(S)) is amended by inserting ''(including intravenous immune globulin (as defined in section 1861(zz)))'' after ''with respect to drugs and biologicals''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to items furnished administered on or after January 1, 2004.

SEC. 643. MEDPAC STUDY OF COVERAGE OF SURGICAL FIRST ASSISTING SERVICES OF CERTIFIED REGISTERED NURSE FIRST ASSISTANTS.

(a) STUDY.—The Medicare Payment Advisory Commission (in this section referred to as the ''Commission'') shall conduct a study on the feasibility and advisability of providing for payment under part B of title XVIII of the Social Security Act for surgical first assisting services furnished by a certified registered nurse first assistant to medicare beneficiaries.

(b) REPORT.—Not later than January 1, 2005, the Commission shall submit to Congress a report on the study conducted under subsection (a) together with recommendations for such legislation or administrative action as the Commission determines to be appropriate.

(c) DEFINITIONS.—In this section:

(1) SURGICAL FIRST ASSISTING SERVICES.—The term ''surgical first assisting services'' means services consisting of first assisting a physician with surgery and related preoperative, intraoperative, and postoperative care (as determined by the Secretary) furnished by a certified registered nurse first assistant (as defined in paragraph (2)) which the certified registered nurse first assistant is legally authorized to perform by the State in which the services are performed.

(2) CERTIFIED REGISTERED NURSE FIRST ASSISTANT.—The term ''certified registered nurse first assistant'' means an individual who—

(A) is a registered nurse and is licensed to practice nursing in the State in which the surgical first assisting services are performed;

(B) has completed a minimum of 2,000 hours of first assisting a physician with surgery and related preoperative, intraoperative, and postoperative care; and

(C) is certified as a registered nurse first assistant by an organization recognized by the Secretary.

SEC. 644. MEDPAC STUDY OF PAYMENT FOR CARDIO-THORACIC SURGEONS.

(a) STUDY.—The Medicare Payment Advisory Commission (in this section referred to as the ''Commission'') shall conduct a study on the

practice expense relative values established by the Secretary of Health and Human Services under the medicare physician fee schedule under section 1848 of the Social Security Act (42 U.S.C. 1395w–4) for physicians in the specialties of thoracic and cardiac surgery to determine whether such values adequately take into account the attendant costs that such physicians incur in providing clinical staff for patient care in hospitals.

(b) REPORT.—Not later than January 1, 2005, the Commission shall submit to Congress a report on the study conducted under subsection (a) together with recommendations for such legislation or administrative action as the Commission determines to be appropriate.

SEC. 645. STUDIES RELATING TO VISION IMPAIRMENTS.

(a) COVERAGE OF OUTPATIENT VISION SERVICES FURNISHED BY VISION REHABILITATION PROFESSIONALS UNDER PART B.—

(1) STUDY.—The Secretary shall conduct a study to determine the feasibility and advisability of providing for payment for vision rehabilitation services furnished by vision rehabilitation professionals.

(2) REPORT.—Not later than January 1, 2005, the Secretary shall submit to Congress a report on the study conducted under paragraph (1) together with recommendations for such legislation or administrative action as the Secretary determines to be appropriate.

(3) VISION REHABILITATION PROFESSIONAL DEFINED.—In this subsection, the term ''vision rehabilitation professional'' means an orientation and mobility specialist, a rehabilitation teacher, or a low vision therapist.

(b) REPORT ON APPROPRIATENESS OF A DEMONSTRATION PROJECT TO TEST FEASIBILITY OF USING PPO NETWORKS TO REDUCE COSTS OF ACQUIRING EYEGLASSES FOR MEDICARE BENEFICIARIES AFTER CATARACT SURGERY.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall submit to Congress a report on the feasibility of establishing a two-year demonstration project under which the Secretary enters into arrangements with vision care preferred provider organization networks to furnish and pay for conventional eyeglasses subsequent to each cataract surgery with insertion of an intraocular lens on behalf of Medicare beneficiaries. In such report, the Secretary shall include an estimate of potential cost savings to the Medicare program through the use of such networks, taking into consideration quality of service and beneficiary access to services offered by vision care preferred provider organization networks.

SEC. 646. MEDICARE HEALTH CARE QUALITY DEMONSTRATION PROGRAMS.

Title XVIII (42 U.S.C. 1395 et seq.) is amended by inserting after section 1866B the following new section:

''HEALTH CARE QUALITY DEMONSTRATION PROGRAM

''SEC. 1866C. (a) DEFINITIONS.—In this section:

''(1) BENEFICIARY.—The term 'beneficiary' means an individual who is entitled to benefits under part A and enrolled under part B, including any individual who is enrolled in a Medicare Advantage plan under part C.

''(2) HEALTH CARE GROUP.—

''(A) IN GENERAL.—The term 'health care group' means—

''(i) a group of physicians that is organized at least in part for the purpose of providing physician's services under this title;

''(ii) an integrated health care delivery system that delivers care through coordinated hospitals, clinics, home health agencies, ambulatory surgery centers, skilled nursing facilities, rehabilitation facilities and clinics, and employed, independent, or contracted physicians; or

''(iii) an organization representing regional coalitions of groups or systems described in clause (i) or (ii).

''(B) INCLUSION.—As the Secretary determines appropriate, a health care group may include a hospital or any other individual or entity furnishing items or services for which payment may be made under this title that is affiliated with the health care group under an arrangement structured so that such hospital, individual, or entity participates in a demonstration project under this section.

''(3) PHYSICIAN.—Except as otherwise provided for by the Secretary, the term 'physician' means any individual who furnishes services that may be paid for as physicians' services under this title.

''(b) DEMONSTRATION PROJECTS.—The Secretary shall establish a 5-year demonstration program under which the Secretary shall approve demonstration projects that examine health delivery factors that encourage the delivery of improved quality in patient care, including—

''(1) the provision of incentives to improve the safety of care provided to beneficiaries;

''(2) the appropriate use of best practice guidelines by providers and services by beneficiaries;

''(3) reduced scientific uncertainty in the delivery of care through the examination of variations in the utilization and allocation of services, and outcomes measurement and research;

''(4) encourage shared decision making between providers and patients;

''(5) the provision of incentives for improving the quality and safety of care and achieving the efficient allocation of resources;

''(6) the appropriate use of culturally and ethnically sensitive health care delivery; and

''(7) the financial effects on the health care marketplace of altering the incentives for care delivery and changing the allocation of resources.

''(c) ADMINISTRATION BY CONTRACT.—

''(1) IN GENERAL.—Except as otherwise provided in this section, the Secretary may administer the demonstration program established under this section in a manner that is similar to the manner in which the demonstration program established under section 1866A is administered in accordance with section 1866B.

''(2) ALTERNATIVE PAYMENT SYSTEMS.—A health care group that receives assistance under this section may, with respect to the demonstration project to be carried out with such assistance, include proposals for the use of alternative payment systems for items and services provided to beneficiaries by the group that are designed to—

''(A) encourage the delivery of high quality care while accomplishing the objectives described in subsection (b); and

''(B) streamline documentation and reporting requirements otherwise required under this title.

''(3) BENEFITS.—A health care group that receives assistance under this section may, with respect to the demonstration project to be carried out with such assistance, include modifications to the package of benefits available under the original medicare fee-for-service program under parts A and B or the package of benefits available through a Medicare Advantage plan under part C. The criteria employed under the demonstration program under this section to evaluate outcomes and determine best practice guidelines and incentives shall not be used as a basis for the denial of medicare benefits under the demonstration program to patients against their wishes (or if the patient is incompetent, against the wishes of the patient's surrogate) on the basis of the patient's age or expected length of life or of the patient's present or predicted disability, degree of medical dependency, or quality of life.

''(d) ELIGIBILITY CRITERIA.—To be eligible to receive assistance under this section, an entity shall—

''(1) be a health care group;

''(2) meet quality standards established by the Secretary, including—

''(A) the implementation of continuous quality improvement mechanisms that are aimed at integrating community-based support services, primary care, and referral care;

''(B) the implementation of activities to increase the delivery of effective care to beneficiaries;

''(C) encouraging patient participation in preference-based decisions;

''(D) the implementation of activities to encourage the coordination and integration of medical service delivery; and

''(E) the implementation of activities to measure and document the financial impact on the health care marketplace of altering the incentives of health care delivery and changing the allocation of resources; and

''(3) meet such other requirements as the Secretary may establish.

''(e) WAIVER AUTHORITY.—The Secretary may waive such requirements of titles XI and XVIII as may be necessary to carry out the purposes of the demonstration program established under this section.

''(f) BUDGET NEUTRALITY.—With respect to the 5-year period of the demonstration program under subsection (b), the aggregate expenditures under this title for such period shall not exceed the aggregate expenditures that would have been expended under this title if the program established under this section had not been implemented.

''(g) NOTICE REQUIREMENTS.—In the case of an individual that receives health care items or services under a demonstration program carried out under this section, the Secretary shall ensure that such individual is notified of any waivers of coverage or payment rules that are applicable to such individual under this title as a result of the participation of the individual in such program.

''(h) PARTICIPATION AND SUPPORT BY FEDERAL AGENCIES.—In carrying out the demonstration program under this section, the Secretary may direct—

''(1) the Director of the National Institutes of Health to expand the efforts of the Institutes to evaluate current medical technologies and improve the foundation for evidence-based practice;

''(2) the Administrator of the Agency for Healthcare Research and Quality to, where possible and appropriate, use the program under this section as a laboratory for the study of quality improvement strategies and to evaluate, monitor, and disseminate information relevant to such program; and

''(3) the Administrator of the Centers for Medicare & Medicaid Services and the Administrator of the Center for Medicare Choices to support linkages of relevant medicare data to registry information from participating health care groups for the beneficiary populations served by the participating groups, for analysis supporting the purposes of the demonstration program, consistent with the applicable provisions of the Health Insurance Portability and Accountability Act of 1996.''.

SEC. 647. MEDPAC STUDY ON DIRECT ACCESS TO PHYSICAL THERAPY SERVICES.

(a) STUDY.—The Medicare Payment Advisory Commission (in this section referred to as the ''Commission'') shall conduct a study on the feasibility and advisability of allowing medicare fee-for-service beneficiaries direct access to outpatient physical therapy services and physical therapy services furnished as comprehensive rehabilitation facility services.

(b) REPORT.—Not later than January 1, 2005, the Commission shall submit to Congress a report on the study conducted under subsection (a) together with recommendations for such legislation or administrative action as the Commission determines to be appropriate.

(c) DIRECT ACCESS DEFINED.—The term ''direct access'' means, with respect to outpatient physical therapy services and physical therapy services furnished as comprehensive outpatient

rehabilitation facility services, coverage of and payment for such services in accordance with the provisions of title XVIII of the Social Security Act, except that sections 1835(a)(2), 1861(p), and 1861(cc) of such Act (42 U.S.C. 1395n(a)(2), 1395x(p), and 1395x(cc), respectively) shall be applied—

(1) without regard to any requirement that—

(A) an individual be under the care of (or referred by) a physician; or

(B) services be provided under the supervision of a physician; and

(2) by allowing a physician or a qualified physical therapist to satisfy any requirement for—

(A) certification and recertification; and

(B) establishment and periodic review of a plan of care.

SEC. 648. DEMONSTRATION PROJECT FOR CONSUMER-DIRECTED CHRONIC OUTPATIENT SERVICES.

(a) ESTABLISHMENT.—

(1) IN GENERAL.—Subject to the succeeding provisions of this section, the Secretary shall establish demonstration projects (in this section referred to as ''demonstration projects'') under which the Secretary shall evaluate methods that improve the quality of care provided to individuals with chronic conditions and that reduce expenditures that would otherwise be made under the medicare program on behalf of such individuals for such chronic conditions, such methods to include permitting those beneficiaries to direct their own health care needs and services.

(2) INDIVIDUALS WITH CHRONIC CONDITIONS DEFINED.—In this section, the term ''individuals with chronic conditions'' means an individual entitled to benefits under part A of title XVIII of the Social Security Act, and enrolled under part B of such title, but who is not enrolled under part C of such title who is diagnosed as having one or more chronic conditions (as defined by the Secretary), such as diabetes.

(b) DESIGN OF PROJECTS.—

(1) EVALUATION BEFORE IMPLEMENTATION OF PROJECT.—

(A) IN GENERAL.—In establishing the demonstration projects under this section, the Secretary shall evaluate best practices employed by group health plans and practices under State plans for medical assistance under the medicaid program under title XIX of the Social Security Act, as well as best practices in the private sector or other areas, of methods that permit patients to self-direct the provision of personal care services. The Secretary shall evaluate such practices for a 1-year period and, based on such evaluation, shall design the demonstration project.

(B) REQUIREMENT FOR ESTIMATE OF BUDGET NEUTRAL COSTS.—As part of the evaluation under subparagraph (A), the Secretary shall evaluate the costs of furnishing care under the projects. The Secretary may not implement the demonstration projects under this section unless the Secretary determines that the costs of providing care to individuals with chronic conditions under the project will not exceed the costs, in the aggregate, of furnishing care to such individuals under title XVIII of the Social Security Act, that would otherwise be paid without regard to the demonstration projects for the period of the project.

(2) SCOPE OF SERVICES.—The Secretary shall determine the appropriate scope of personal care services that would apply under the demonstration projects.

(c) VOLUNTARY PARTICIPATION.—Participation of providers of services and suppliers, and of individuals with chronic conditions, in the demonstration projects shall be voluntary.

(d) DEMONSTRATION PROJECTS SITES.—Not later than 2 years after the date of the enactment of this Act, the Secretary shall conduct a demonstration project in at least one area that the Secretary determines has a population of individuals entitled to benefits under part A of title XVIII of the Social Security Act, and enrolled under part B of such title, with a rate of incidence of diabetes that significantly exceeds the national average rate of all areas.

(e) EVALUATION AND REPORT.—

(1) EVALUATIONS.—The Secretary shall conduct evaluations of the clinical and cost effectiveness of the demonstration projects.

(2) REPORTS.—Not later than 2 years after the commencement of the demonstration projects, and biannually thereafter, the Secretary shall submit to Congress a report on the evaluation, and shall include in the report the following:

(A) An analysis of the patient outcomes and costs of furnishing care to the individuals with chronic conditions participating in the projects as compared to such outcomes and costs to other individuals for the same health conditions.

(B) Evaluation of patient satisfaction under the demonstration projects.

(C) Such recommendations regarding the extension, expansion, or termination of the projects as the Secretary determines appropriate.

(f) WAIVER AUTHORITY.—The Secretary shall waive compliance with the requirements of title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) to such extent and for such period as the Secretary determines is necessary to conduct demonstration projects.

(g) AUTHORIZATION OF APPROPRIATIONS.—(1) Payments for the costs of carrying out the demonstration project under this section shall be made from the Federal Supplementary Medical Insurance Trust Fund under section 1841 of such Act (42 U.S.C. 1395t).

(2) There are authorized to be appropriated from such Trust Fund such sums as may be necessary for the Secretary to enter into contracts with appropriate organizations for the deign, implementation, and evaluation of the demonstration project.

(3) In no case may expenditures under this section exceed the aggregate expenditures that would otherwise have been made for the provision of personal care services.

SEC. 649. MEDICARE CARE MANAGEMENT PERFORMANCE DEMONSTRATION.

(a) ESTABLISHMENT.—

(1) IN GENERAL.—The Secretary shall establish a pay-for-performance demonstration program with physicians to meet the needs of eligible beneficiaries through the adoption and use of health information technology and evidence-based outcomes measures for—

(A) promoting continuity of care;

(B) helping stabilize medical conditions;

(C) preventing or minimizing acute exacerbations of chronic conditions; and

(D) reducing adverse health outcomes, such as adverse drug interactions related to polypharmacy.

(2) SITES.—The Secretary shall designate no more than 4 sites at which to conduct the demonstration program under this section, of which—

(A) 2 shall be in an urban area;

(B) 1 shall be in a rural area; and

(C) 1 shall be in a State with a medical school with a Department of Geriatrics that manages rural outreach sites and is capable of managing patients with multiple chronic conditions, one of which is dementia.

(3) DURATION.—The Secretary shall conduct the demonstration program under this section for a 3-year period.

(4) CONSULTATION.—In carrying out the demonstration program under this section, the Secretary shall consult with private sector and non-profit groups that are undertaking similar efforts to improve quality and reduce avoidable hospitalizations for chronically ill patients.

(b) PARTICIPATION.—

(1) IN GENERAL.—A physician who provides care for a minimum number of eligible beneficiaries (as specified by the Secretary) may participate in the demonstration program under this section if such physician agrees, to phase-in over the course of the 3-year demonstration period and with the assistance provided under subsection (d)(2)—

(A) the use of health information technology to manage the clinical care of eligible beneficiaries consistent with paragraph (3); and

(B) the electronic reporting of clinical quality and outcomes measures in accordance with requirements established by the Secretary under the demonstration program.

(2) SPECIAL RULE.—In the case of the sites referred to in subparagraphs (B) and (C) of subsection (a)(2), a physician who provides care for a minimum number of beneficiaries with two or more chronic conditions, including dementia (as specified by the Secretary), may participate in the program under this section if such physician agrees to the requirements in subparagraphs (A) and (B) of paragraph (1).

(3) PRACTICE STANDARDS.—Each physician participating in the demonstration program under this section must demonstrate the ability—

(A) to assess each eligible beneficiary for conditions other than chronic conditions, such as impaired cognitive ability and co-morbidities, for the purposes of developing care management requirements;

(B) to serve as the primary contact of eligible beneficiaries in accessing items and services for which payment may be made under the medicare program;

(C) to establish and maintain health care information system for such beneficiaries;

(D) to promote continuity of care across providers and settings;

(E) to use evidence-based guidelines and meet such clinical quality and outcome measures as the Secretary shall require;

(F) to promote self-care through the provision of patient education and support for patients or, where appropriate, family caregivers;

(G) when appropriate, to refer such beneficiaries to community service organizations; and

(H) to meet such other complex care management requirements as the Secretary may specify.

The guidelines and measures required under subparagraph (E) shall be designed to take into account beneficiaries with multiple chronic conditions.

(c) PAYMENT METHODOLOGY.—Under the demonstration program under this section the Secretary shall pay a per beneficiary amount to each participating physician who meets or exceeds specific performance standards established by the Secretary with respect to the clinical quality and outcome measures reported under subsection (b)(1)(B). Such amount may vary based on different levels of performance or improvement.

(d) ADMINISTRATION.—

(1) USE OF QUALITY IMPROVEMENT ORGANIZATIONS.—The Secretary shall contract with quality improvement organizations or such other entities as the Secretary deems appropriate to enroll physicians and evaluate their performance under the demonstration program under this section.

(2) TECHNICAL ASSISTANCE.—The Secretary shall require in such contracts that the contractor be responsible for technical assistance and education as needed to physicians enrolled in the demonstration program under this section for the purpose of aiding their adoption of health information technology, meeting practice standards, and implementing required clinical and outcomes measures.

(e) FUNDING.—

(1) IN GENERAL.—The Secretary shall provide for the transfer from the Federal Supplementary Medical Insurance Trust Fund established under section 1841 of the Social Security Act (42 U.S.C. 1395t) of such funds as are necessary for the costs of carrying out the demonstration program under this section.

(2) BUDGET NEUTRALITY.—In conducting the demonstration program under this section, the

Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration program under this section was not implemented.

(f) WAIVER AUTHORITY.—The Secretary may waive such requirements of titles XI and XVIII of the Social Security Act (42 U.S.C. 1301 et seq.; 1395 et seq.) as may be necessary for the purpose of carrying out the demonstration program under this section.

(g) REPORT.—Not later than 12 months after the date of completion of the demonstration program under this section, the Secretary shall submit to Congress a report on such program, together with recommendations for such legislation and administrative action as the Secretary determines to be appropriate.

(h) DEFINITIONS.—In this section:

(1) ELIGIBLE BENEFICIARY.—The term ''eligible beneficiary'' means any individual who—

(A) is entitled to benefits under part A and enrolled for benefits under part B of title XVIII of the Social Security Act and is not enrolled in a plan under part C of such title; and

(B) has one or more chronic medical conditions specified by the Secretary (one of which may be cognitive impairment).

(2) HEALTH INFORMATION TECHNOLOGY.—The term ''health information technology'' means email communication, clinical alerts and reminders, and other information technology that meets such functionality, interoperability, and other standards as prescribed by the Secretary.

SEC. 650. GAO STUDY AND REPORT ON THE PROPAGATION OF CONCIERGE CARE.

(a) STUDY.—

(1) IN GENERAL.—The Comptroller General of the United States shall conduct a study on concierge care (as defined in paragraph (2)) to determine the extent to which such care—

(A) is used by medicare beneficiaries (as defined in section 1802(b)(5)(A) of the Social Security Act (42 U.S.C. 1395a(b)(5)(A))); and

(B) has impacted upon the access of medicare beneficiaries (as so defined) to items and services for which reimbursement is provided under the medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.).

(2) CONCIERGE CARE.—In this section, the term ''concierge care'' means an arrangement under which, as a prerequisite for the provision of a health care item or service to an individual, a physician, practitioner (as described in section 1842(b)(18)(C) of the Social Security Act (42 U.S.C. 1395u(b)(18)(C))), or other individual—

(A) charges a membership fee or another incidental fee to an individual desiring to receive the health care item or service from such physician, practitioner, or other individual; or

(B) requires the individual desiring to receive the health care item or service from such physician, practitioner, or other individual to purchase an item or service.

(b) REPORT.—Not later than the date that is 12 months after the date of enactment of this Act, the Comptroller General of the United States shall submit to Congress a report on the study conducted under subsection (a)(1) together with such recommendations for legislative or administrative action as the Comptroller General determines to be appropriate.

SEC. 651. DEMONSTRATION OF COVERAGE OF CHIROPRACTIC SERVICES UNDER MEDICARE.

(a) DEFINITIONS.—In this section:

(1) CHIROPRACTIC SERVICES.—The term ''chiropractic services'' has the meaning given that term by the Secretary for purposes of the demonstration projects, but shall include, at a minimum—

(A) care for neuromusculoskeletal conditions typical among eligible beneficiaries; and

(B) diagnostic and other services that a chiropractor is legally authorized to perform by the State or jurisdiction in which such treatment is provided.

(2) DEMONSTRATION PROJECT.—The term ''demonstration project'' means a demonstration project established by the Secretary under subsection (b)(1).

(3) ELIGIBLE BENEFICIARY.—The term ''eligible beneficiary'' means an individual who is enrolled under part B of the medicare program.

(4) MEDICARE PROGRAM.—The term ''medicare program'' means the health benefits program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.).

(b) DEMONSTRATION OF COVERAGE OF CHIROPRACTIC SERVICES UNDER MEDICARE.—

(1) ESTABLISHMENT.—The Secretary shall establish demonstration projects in accordance with the provisions of this section for the purpose of evaluating the feasibility and advisability of covering chiropractic services under the medicare program (in addition to the coverage provided for services consisting of treatment by means of manual manipulation of the spine to correct a subluxation described in section 1861(r)(5) of the Social Security Act (42 U.S.C. 1395x(r)(5))).

(2) NO PHYSICIAN APPROVAL REQUIRED.—In establishing the demonstration projects, the Secretary shall ensure that an eligible beneficiary who participates in a demonstration project, including an eligible beneficiary who is enrolled for coverage under a Medicare+Choice plan (or, on and after January 1, 2006, under a Medicare Advantage plan), is not required to receive approval from a physician or other health care provider in order to receive a chiropractic service under a demonstration project.

(3) CONSULTATION.—In establishing the demonstration projects, the Secretary shall consult with chiropractors, organizations representing chiropractors, eligible beneficiaries, and organizations representing eligible beneficiaries.

(4) PARTICIPATION.—Any eligible beneficiary may participate in the demonstration projects on a voluntary basis.

(c) CONDUCT OF DEMONSTRATION PROJECTS.—

(1) DEMONSTRATION SITES.—

(A) SELECTION OF DEMONSTRATION SITES.—The Secretary shall conduct demonstration projects at 4 demonstration sites.

(B) GEOGRAPHIC DIVERSITY.—Of the sites described in subparagraph (A)—

(i) 2 shall be in rural areas; and

(ii) 2 shall be in urban areas.

(C) SITES LOCATED IN HPSAS.—At least 1 site described in clause (i) of subparagraph (B) and at least 1 site described in clause (ii) of such subparagraph shall be located in an area that is designated under section 332(a)(1)(A) of the Public Health Service Act (42 U.S.C. 254e(a)(1)(A)) as a health professional shortage area.

(2) IMPLEMENTATION; DURATION.—

(A) IMPLEMENTATION.—The Secretary shall not implement the demonstration projects before October 1, 2004.

(B) DURATION.—The Secretary shall complete the demonstration projects by the date that is 2 years after the date on which the first demonstration project is implemented.

(d) EVALUATION AND REPORT.—

(1) EVALUATION.—The Secretary shall conduct an evaluation of the demonstration projects—

(A) to determine whether eligible beneficiaries who use chiropractic services use a lesser overall amount of items and services for which payment is made under the medicare program than eligible beneficiaries who do not use such services;

(B) to determine the cost of providing payment for chiropractic services under the medicare program;

(C) to determine the satisfaction of eligible beneficiaries participating in the demonstration projects and the quality of care received by such beneficiaries; and

(D) to evaluate such other matters as the Secretary determines is appropriate.

(2) REPORT.—Not later than the date that is 1 year after the date on which the demonstration projects conclude, the Secretary shall submit to Congress a report on the evaluation conducted under paragraph (1) together with such recommendations for legislation or administrative action as the Secretary determines is appropriate.

(e) WAIVER OF MEDICARE REQUIREMENTS.—The Secretary shall waive compliance with such requirements of the medicare program to the extent and for the period the Secretary finds necessary to conduct the demonstration projects.

(f) FUNDING.—

(1) DEMONSTRATION PROJECTS.—

(A) IN GENERAL.—Subject to subparagraph (B) and paragraph (2), the Secretary shall provide for the transfer from the Federal Supplementary Insurance Trust Fund under section 1841 of the Social Security Act (42 U.S.C. 1395t) of such funds as are necessary for the costs of carrying out the demonstration projects under this section.

(B) LIMITATION.—In conducting the demonstration projects under this section, the Secretary shall ensure that the aggregate payments made by the Secretary under the medicare program do not exceed the amount which the Secretary would have paid under the medicare program if the demonstration projects under this section were not implemented.

(2) EVALUATION AND REPORT.—There are authorized to be appropriated such sums as are necessary for the purpose of developing and submitting the report to Congress under subsection (d).

TITLE VII—PROVISIONS RELATING TO PARTS A AND B

Subtitle A—Home Health Services

SEC. 701. UPDATE IN HOME HEALTH SERVICES.

(a) CHANGE TO CALENDAR YEAR UPDATE.—Section 1895(b) (42 U.S.C. 1395fff(b)(3)) is amended—

(1) in paragraph (3)(B)(i)—

(A) by striking ''each fiscal year (beginning with fiscal year 2002)'' and inserting ''fiscal year 2002 and for fiscal year 2003 and for each subsequent year (beginning with 2004)''; and

(B) by inserting ''or year'' after ''the fiscal year'';

(2) in paragraph (3)(B)(ii)—

(A) in subclause (I), by striking ''or'' at the end;

(B) by redesignating subclause (II) as subclause (III);

(C) in subclause (III), as so redesignated, by striking ''any subsequent fiscal year'' and inserting ''2004 and any subsequent year''; and

(D) by inserting after subclause (I) the following new subclause:

''(II) for the last calendar quarter of 2003 and the first calendar quarter of 2004, the home health market basket percentage increase; or'';

(3) in paragraph (3)(B)(iii), by inserting ''or year'' after ''fiscal year'' each place it appears; and

(4) in paragraph (3)(B)(iv)—

(A) by inserting ''or year'' after ''fiscal year'' each place it appears; and

(B) by inserting ''or years'' after ''fiscal years''; and

(5) in paragraph (5), by inserting ''or year'' after ''fiscal year''.

(b) ADJUSTMENT TO UPDATES FOR 2004, 2005, AND 2006.—Section 1895(b)(3)(B)(ii) (42 U.S.C. 1395fff(b)(3)(B)(ii)), as amended by subsection (a)(2), is amended—

(1) by striking ''or'' at the end of subclause (II);

(2) by redesignating subclause (III) as subclause (IV);

(3) in subclause (IV), as so redesignated, by striking ''2004'' and inserting ''2007''; and

(4) by inserting after subclause (II) the following new subclause:

''(III) the last 3 calendar quarters of 2004, and each of 2005 and 2006 the home health market basket percentage increase minus 0.8 percentage points; or''.

SEC. 702. DEMONSTRATION PROJECT TO CLARIFY THE DEFINITION OF HOMEBOUND.

(a) DEMONSTRATION PROJECT.—Not later than 180 days after the date of the enactment of this

Act, the Secretary shall conduct a 2-year demonstration project under part B of title XVIII of the Social Security Act under which medicare beneficiaries with chronic conditions described in subsection (b) are deemed to be homebound for purposes of receiving home health services under the medicare program.

(b) MEDICARE BENEFICIARY DESCRIBED.—For purposes of subsection (a), a medicare beneficiary is eligible to be deemed to be homebound, without regard to the purpose, frequency, or duration of absences from the home, if—

(1) the beneficiary has been certified by one physician as an individual who has a permanent and severe, disabling condition that is not expected to improve;

(2) the beneficiary is dependent upon assistance from another individual with at least 3 out of the 5 activities of daily living for the rest of the beneficiary's life;

(3) the beneficiary requires skilled nursing services for the rest of the beneficiary's life and the skilled nursing is more than medication management;

(4) an attendant is required to visit the beneficiary on a daily basis to monitor and treat the beneficiary's medical condition or to assist the beneficiary with activities of daily living;

(5) the beneficiary requires technological assistance or the assistance of another person to leave the home; and

(6) the beneficiary does not regularly work in a paid position full-time or part-time outside the home.

(c) DEMONSTRATION PROJECT SITES.—The demonstration project established under this section shall be conducted in 3 States selected by the Secretary to represent the Northeast, Midwest, and Western regions of the United States.

(d) LIMITATION ON NUMBER OF PARTICIPANTS.—The aggregate number of such beneficiaries that may participate in the project may not exceed 15,000.

(e) DATA.—The Secretary shall collect such data on the demonstration project with respect to the provision of home health services to medicare beneficiaries that relates to quality of care, patient outcomes, and additional costs, if any, to the medicare program.

(f) REPORT TO CONGRESS.—Not later than 1 year after the date of the completion of the demonstration project under this section, the Secretary shall submit to Congress a report on the project using the data collected under subsection (e). The report shall include the following:

(1) An examination of whether the provision of home health services to medicare beneficiaries under the project has had any of the following effects:

(A) Has adversely affected the provision of home health services under the medicare program.

(B) Has directly caused an increase of expenditures under the medicare program for the provision of such services that is directly attributable to such clarification.

(2) The specific data evidencing the amount of any increase in expenditures that is directly attributable to the demonstration project (expressed both in absolute dollar terms and as a percentage) above expenditures that would otherwise have been incurred for home health services under the medicare program.

(3) Specific recommendations to exempt permanently and severely disabled homebound beneficiaries from restrictions on the length, frequency, and purpose of their absences from the home to qualify for home health services without incurring additional costs to the medicare program.

(g) WAIVER AUTHORITY.—The Secretary shall waive compliance with the requirements of title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) to such extent and for such period as the Secretary determines is necessary to conduct demonstration projects.

(h) CONSTRUCTION.—Nothing in this section shall be construed as waiving any applicable civil monetary penalty, criminal penalty, or other remedy available to the Secretary under title XI or title XVIII of the Social Security Act for acts prohibited under such titles, including penalties for false certifications for purposes of receipt of items or services under the medicare program.

(i) AUTHORIZATION OF APPROPRIATIONS.—Payments for the costs of carrying out the demonstration project under this section shall be made from the Federal Supplementary Medical Insurance Trust Fund under section 1841 of such Act (42 U.S.C. 1395t).

(j) DEFINITIONS.—In this section:

(1) MEDICARE BENEFICIARY.—The term ''medicare beneficiary'' means an individual who is enrolled under part B of title XVIII of the Social Security Act.

(2) HOME HEALTH SERVICES.—The term ''home health services'' has the meaning given such term in section 1861(m) of the Social Security Act (42 U.S.C. 1395x(m)).

(3) ACTIVITIES OF DAILY LIVING DEFINED.—The term ''activities of daily living'' means eating, toileting, transferring, bathing, and dressing.

SEC. 703. DEMONSTRATION PROJECT FOR MEDICAL ADULT DAY-CARE SERVICES.

(a) ESTABLISHMENT.—Subject to the succeeding provisions of this section, the Secretary shall establish a demonstration project (in this section referred to as the ''demonstration project'') under which the Secretary shall, as part of a plan of an episode of care for home health services established for a medicare beneficiary, permit a home health agency, directly or under arrangements with a medical adult day-care facility, to provide medical adult day-care services as a substitute for a portion of home health services that would otherwise be provided in the beneficiary's home.

(b) PAYMENT.—

(1) IN GENERAL.—Subject to paragraph (2), the amount of payment for an episode of care for home health services, a portion of which consists of substitute medical adult day-care services, under the demonstration project shall be made at a rate equal to 95 percent of the amount that would otherwise apply for such home health services under section 1895 of the Social Security Act (42 U.S.C. 1395fff). In no case may a home health agency, or a medical adult day-care facility under arrangements with a home health agency, separately charge a beneficiary for medical adult day-care services furnished under the plan of care.

(2) ADJUSTMENT IN CASE OF OVERUTILIZATION OF SUBSTITUTE ADULT DAY-CARE SERVICES TO ENSURE BUDGET NEUTRALITY.—The Secretary shall monitor the expenditures under the demonstration project and under title XVIII of the Social Security Act for home health services. If the Secretary estimates that the total expenditures under the demonstration project and under such title XVIII for home health services for a period determined by the Secretary exceed expenditures that would have been made under such title XVIII for home health services for such period if the demonstration project had not been conducted, the Secretary shall adjust the rate of payment to medical adult day-care facilities under paragraph (1) in order to eliminate such excess.

(c) DEMONSTRATION PROJECT SITES.—The demonstration project established under this section shall be conducted in not more than 5 sites in States selected by the Secretary that license or certify providers of services that furnish medical adult day-care services.

(d) DURATION.—The Secretary shall conduct the demonstration project for a period of 3 years.

(e) VOLUNTARY PARTICIPATION.—Participation of medicare beneficiaries in the demonstration project shall be voluntary. The total number of such beneficiaries that may participate in the project at any given time may not exceed 15,000.

(f) PREFERENCE IN SELECTING AGENCIES.—In selecting home health agencies to participate under the demonstration project, the Secretary shall give preference to those agencies that are currently licensed or certified through common ownership and control to furnish medical adult day-care services.

(g) WAIVER AUTHORITY.—The Secretary may waive such requirements of title XVIII of the Social Security Act as may be necessary for the purposes of carrying out the demonstration project, other than waiving the requirement that an individual be homebound in order to be eligible for benefits for home health services.

(h) EVALUATION AND REPORT.—The Secretary shall conduct an evaluation of the clinical and cost-effectiveness of the demonstration project. Not later than 6 months after the completion of the project, the Secretary shall submit to Congress a report on the evaluation, and shall include in the report the following:

(1) An analysis of the patient outcomes and costs of furnishing care to the medicare beneficiaries participating in the project as compared to such outcomes and costs to beneficiaries receiving only home health services for the same health conditions.

(2) Such recommendations regarding the extension, expansion, or termination of the project as the Secretary determines appropriate.

(i) DEFINITIONS.—In this section:

(1) HOME HEALTH AGENCY.—The term ''home health agency'' has the meaning given such term in section 1861(o) of the Social Security Act (42 U.S.C. 1395x(o)).

(2) MEDICAL ADULT DAY-CARE FACILITY.—The term ''medical adult day-care facility'' means a facility that—

(A) has been licensed or certified by a State to furnish medical adult day-care services in the State for a continuous 2-year period;

(B) is engaged in providing skilled nursing services and other therapeutic services directly or under arrangement with a home health agency;

(C) is licensed and certified by the State in which it operates or meets such standards established by the Secretary to assure quality of care and such other requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the facility; and

(D) provides medical adult day-care services.

(3) MEDICAL ADULT DAY-CARE SERVICES.—The term ''medical adult day-care services'' means—

(A) home health service items and services described in paragraphs (1) through (7) of section 1861(m) furnished in a medical adult day-care facility;

(B) a program of supervised activities furnished in a group setting in the facility that—

(i) meet such criteria as the Secretary determines appropriate; and

(ii) is designed to promote physical and mental health of the individuals; and

(C) such other services as the Secretary may specify.

(4) MEDICARE BENEFICIARY.—The term ''medicare beneficiary'' means an individual entitled to benefits under part A of this title, enrolled under part B of this title, or both.

SEC. 704. TEMPORARY SUSPENSION OF OASIS REQUIREMENT FOR COLLECTION OF DATA ON NON-MEDICARE AND NON-MEDICAID PATIENTS.

(a) IN GENERAL.—During the period described in subsection (b), the Secretary may not require, under section 4602(e) of the Balanced Budget Act of 1997 (Public Law 105–33; 111 Stat. 467) or otherwise under OASIS, a home health agency to gather or submit information that relates to an individual who is not eligible for benefits under either title XVIII or title XIX of the Social Security Act (such information in this section referred to as ''non-medicare/medicaid OASIS information'').

(b) PERIOD OF SUSPENSION.—The period described in this subsection—

(1) begins on the date of the enactment of this Act; and

(2) ends on the last day of the second month beginning after the date as of which the Secretary has published final regulations regarding the collection and use by the Centers for Medicare & Medicaid Services of non-medicare/medicaid OASIS information following the submission of the report required under subsection (c).

(c) REPORT.—

(1) STUDY.—The Secretary shall conduct a study on how non-medicare/medicaid OASIS information is and can be used by large home health agencies. Such study shall examine—

(A) whether there are unique benefits from the analysis of such information that cannot be derived from other information available to, or collected by, such agencies; and

(B) the value of collecting such information by small home health agencies compared to the administrative burden related to such collection.

In conducting the study the Secretary shall obtain recommendations from quality assessment experts in the use of such information and the necessity of small, as well as large, home health agencies collecting such information.

(2) REPORT.—The Secretary shall submit to Congress a report on the study conducted under paragraph (1) by not later than 18 months after the date of the enactment of this Act.

(d) CONSTRUCTION.—Nothing in this section shall be construed as preventing home health agencies from collecting non-medicare/medicaid OASIS information for their own use.

SEC. 705. MEDPAC STUDY ON MEDICARE MARGINS OF HOME HEALTH AGENCIES.

(a) STUDY.—The Medicare Payment Advisory Commission shall conduct a study of payment margins of home health agencies under the home health prospective payment system under section 1895 of the Social Security Act (42 U.S.C. 1395fff). Such study shall examine whether systematic differences in payment margins are related to differences in case mix (as measured by home health resource groups (HHRGs)) among such agencies. The study shall use the partial or full-year cost reports filed by home health agencies.

(b) REPORT.—Not later than 2 years after the date of the enactment of this Act, the Commission shall submit to Congress a report on the study under subsection (a).

SEC. 706. COVERAGE OF RELIGIOUS NONMEDICAL HEALTH CARE INSTITUTION SERVICES FURNISHED IN THE HOME.

(a) IN GENERAL.—Section 1821(a) (42 U.S.C. 1395i–5(a)) is amended—

(1) in the matter preceding paragraph (1), by inserting ''and for home health services furnished an individual by a religious nonmedical health care institution'' after ''religious nonmedical health care institution''; and

(2) in paragraph (2)—

(A) by striking ''or extended care services'' and inserting '', extended care services, or home health services''; and

(B) by inserting '', or receiving services from a home health agency,'' after ''skilled nursing facility''.

(b) DEFINITION.—Section 1861 (42 U.S.C. 1395x), as amended by section 642, is amended by adding at the end the following new section:

''Extended Care in Religious Nonmedical Health Care Institutions

''(aaa)(1) The term 'home health agency' also includes a religious nonmedical health care institution (as defined in subsection (ss)(1)), but only with respect to items and services ordinarily furnished by such an institution to individuals in their homes, and that are comparable to items and services furnished to individuals by a home health agency that is not religious nonmedical health care institution.

''(2)(A) Subject to subparagraphs (B), payment may be made with respect to services provided by such an institution only to such extent and under such conditions, limitations, and requirements (in addition to or in lieu of the conditions, limitations, and requirements otherwise applicable) as may be provided in regulations consistent with section 1821.

''(B) Notwithstanding any other provision of this title, payment may not be made under subparagraph (A)—

''(i) in a year insofar as such payments exceed $700,000; and

''(ii) after December 31, 2006.''.

Subtitle B—Graduate Medical Education

SEC. 711. EXTENSION OF UPDATE LIMITATION ON HIGH COST PROGRAMS.

Section 1886(h)(2)(D)(iv) (42 U.S.C. 1395ww(h)(2)(D)(iv)) is amended—

(1) in subclause (I)—

(A) by inserting ''AND 2004 THROUGH 2013'' after ''AND 2002''; and

(B) by inserting ''or during the period beginning with fiscal year 2004 and ending with fiscal year 2013'' after ''during fiscal year 2001 or fiscal year 2002''; and

(2) in subclause (II)—

(A) by striking ''fiscal year 2004, or fiscal year 2005,'' and

(B) by striking ''For a'' and inserting ''For the''.

SEC. 712. EXCEPTION TO INITIAL RESIDENCY PERIOD FOR GERIATRIC RESIDENCY OR FELLOWSHIP PROGRAMS.

(a) CLARIFICATION OF CONGRESSIONAL INTENT.—Congress intended section 1886(h)(5)(F)(ii) of the Social Security Act (42 U.S.C. 1395ww(h)(5)(F)(ii)), as added by section 9202 of the Consolidated Omnibus Budget Reconciliation Act of 1985 (Public Law 99–272), to provide an exception to the initial residency period for geriatric residency or fellowship programs such that, where a particular approved geriatric training program requires a resident to complete 2 years of training to initially become board eligible in the geriatric specialty, the 2 years spent in the geriatric training program are treated as part of the resident's initial residency period, but are not counted against any limitation on the initial residency period.

(b) INTERIM FINAL REGULATORY AUTHORITY AND EFFECTIVE DATE.—The Secretary shall promulgate interim final regulations consistent with the congressional intent expressed in this section after notice and pending opportunity for public comment to be effective for cost reporting periods beginning on or after October 1, 2003.

SEC. 713. TREATMENT OF VOLUNTEER SUPERVISION.

(a) MORATORIUM ON CHANGES IN TREATMENT.—During the 1-year period beginning on January 1, 2004, for purposes of applying subsections (d)(5)(B) and (h) of section 1886 of the Social Security Act (42 U.S.C. 1395ww), the Secretary shall allow all hospitals to count residents in osteopathic and allopathic family practice programs in existence as of January 1, 2002, who are training at non-hospital sites, without regard to the financial arrangement between the hospital and the teaching physician practicing in the non-hospital site to which the resident has been assigned.

(b) STUDY AND REPORT.—

(1) STUDY.—The Inspector General of the Department of Health and Human Services shall conduct a study of the appropriateness of alternative payment methodologies under such sections for the costs of training residents in non-hospital settings.

(2) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Inspector General shall submit to Congress a report on the study conducted under paragraph (1), together with such recommendations as the Inspector General determines appropriate.

Subtitle C—Chronic Care Improvement

SEC. 721. VOLUNTARY CHRONIC CARE IMPROVEMENT UNDER TRADITIONAL FEE-FOR-SERVICE.

(a) IN GENERAL.—Title XVIII is amended by inserting after section 1806 the following new section:

''CHRONIC CARE IMPROVEMENT

''SEC. 1807. (a) IMPLEMENTATION OF CHRONIC CARE IMPROVEMENT PROGRAMS.—

''(1) IN GENERAL.—The Secretary shall provide for the phased-in development, testing, evaluation, and implementation of chronic care improvement programs in accordance with this section. Each such program shall be designed to improve clinical quality and beneficiary satisfaction and achieve spending targets with respect to expenditures under this title for targeted beneficiaries with one or more threshold conditions.

''(2) DEFINITIONS.—For purposes of this section:

''(A) CHRONIC CARE IMPROVEMENT PROGRAM.—The term 'chronic care improvement program' means a program described in paragraph (1) that is offered under an agreement under subsection (b) or (c).

''(B) CHRONIC CARE IMPROVEMENT ORGANIZATION.—The term 'chronic care improvement organization' means an entity that has entered into an agreement under subsection (b) or (c) to provide, directly or through contracts with subcontractors, a chronic care improvement program under this section. Such an entity may be a disease management organization, health insurer, integrated delivery system, physician group practice, a consortium of such entities, or any other legal entity that the Secretary determines appropriate to carry out a chronic care improvement program under this section.

''(C) CARE MANAGEMENT PLAN.—The term 'care management plan' means a plan established under subsection (d) for a participant in a chronic care improvement program.

''(D) THRESHOLD CONDITION.—The term 'threshold condition' means a chronic condition, such as congestive heart failure, diabetes, chronic obstructive pulmonary disease (COPD), or other diseases or conditions, as selected by the Secretary as appropriate for the establishment of a chronic care improvement program.

''(E) TARGETED BENEFICIARY.—The term 'targeted beneficiary' means, with respect to a chronic care improvement program, an individual who—

''(i) is entitled to benefits under part A and enrolled under part B, but not enrolled in a plan under part C;

''(ii) has one or more threshold conditions covered under such program; and

''(iii) has been identified under subsection (d)(1) as a potential participant in such program.

''(3) CONSTRUCTION.—Nothing in this section shall be construed as—

''(A) expanding the amount, duration, or scope of benefits under this title;

''(B) providing an entitlement to participate in a chronic care improvement program under this section;

''(C) providing for any hearing or appeal rights under section 1869, 1878, or otherwise, with respect to a chronic care improvement program under this section; or

''(D) providing benefits under a chronic care improvement program for which a claim may be submitted to the Secretary by any provider of services or supplier (as defined in section 1861(d)).

''(b) DEVELOPMENTAL PHASE (PHASE I).—

''(1) IN GENERAL.—In carrying out this section, the Secretary shall enter into agreements consistent with subsection (f) with chronic care improvement organizations for the development, testing, and evaluation of chronic care improvement programs using randomized controlled trials. The first such agreement shall be entered into not later than 12 months after the date of the enactment of this section.

''(2) AGREEMENT PERIOD.—The period of an agreement under this subsection shall be for 3 years.

''(3) MINIMUM PARTICIPATION.—

''(A) IN GENERAL.—The Secretary shall enter into agreements under this subsection in a manner so that chronic care improvement programs offered under this section are offered in geographic areas that, in the aggregate, consist of

areas in which at least 10 percent of the aggregate number of medicare beneficiaries reside.

''(B) MEDICARE BENEFICIARY DEFINED.—In this paragraph, the term 'medicare beneficiary' means an individual who is entitled to benefits under part A, enrolled under part B, or both, and who resides in the United States.

''(4) SITE SELECTION.—In selecting geographic areas in which agreements are entered into under this subsection, the Secretary shall ensure that each chronic care improvement program is conducted in a geographic area in which at least 10,000 targeted beneficiaries reside among other individuals entitled to benefits under part A, enrolled under part B, or both to serve as a control population.

''(5) INDEPENDENT EVALUATIONS OF PHASE I PROGRAMS.—The Secretary shall contract for an independent evaluation of the programs conducted under this subsection. Such evaluation shall be done by a contractor with knowledge of chronic care management programs and demonstrated experience in the evaluation of such programs. Each evaluation shall include an assessment of the following factors of the programs:

''(A) Quality improvement measures, such as adherence to evidence-based guidelines and rehospitalization rates.

''(B) Beneficiary and provider satisfaction.

''(C) Health outcomes.

''(D) Financial outcomes, including any cost savings to the program under this title.

''(c) EXPANDED IMPLEMENTATION PHASE (PHASE II).—

''(1) IN GENERAL.—With respect to chronic care improvement programs conducted under subsection (b), if the Secretary finds that the results of the independent evaluation conducted under subsection (b)(6) indicate that the conditions specified in paragraph (2) have been met by a program (or components of such program), the Secretary shall enter into agreements consistent with subsection (f) to expand the implementation of the program (or components) to additional geographic areas not covered under the program as conducted under subsection (b), which may include the implementation of the program on a national basis. Such expansion shall begin not earlier than 2 years after the program is implemented under subsection (b) and not later than 6 months after the date of completion of such program.

''(2) CONDITIONS FOR EXPANSION OF PROGRAMS.—The conditions specified in this paragraph are, with respect to a chronic care improvement program conducted under subsection (b) for a threshold condition, that the program is expected to—

''(A) improve the clinical quality of care;

''(B) improve beneficiary satisfaction; and

''(C) achieve targets for savings to the program under this title specified by the Secretary in the agreement within a range determined to be appropriate by the Secretary, subject to the application of budget neutrality with respect to the program and not taking into account any payments by the organization under the agreement under the program for risk under subsection (f)(3)(B).

''(3) INDEPENDENT EVALUATIONS OF PHASE II PROGRAMS.—The Secretary shall carry out evaluations of programs expanded under this subsection as the Secretary determines appropriate. Such evaluations shall be carried out in the similar manner as is provided under subsection (b)(5).

''(d) IDENTIFICATION AND ENROLLMENT OF PROSPECTIVE PROGRAM PARTICIPANTS.—

''(1) IDENTIFICATION OF PROSPECTIVE PROGRAM PARTICIPANTS.—The Secretary shall establish a method for identifying targeted beneficiaries who may benefit from participation in a chronic care improvement program.

''(2) INITIAL CONTACT BY SECRETARY.—The Secretary shall communicate with each targeted beneficiary concerning participation in a chronic care improvement program. Such communication may be made by the Secretary and shall include information on the following:

''(A) A description of the advantages to the beneficiary in participating in a program.

''(B) Notification that the organization offering a program may contact the beneficiary directly concerning such participation.

''(C) Notification that participation in a program is voluntary.

''(D) A description of the method for the beneficiary to participate or for declining to participate and the method for obtaining additional information concerning such participation.

''(3) VOLUNTARY PARTICIPATION.—A targeted beneficiary may participate in a chronic care improvement program on a voluntary basis and may terminate participation at any time.

''(e) CHRONIC CARE IMPROVEMENT PROGRAMS.—

''(1) IN GENERAL.—Each chronic care improvement program shall—

''(A) have a process to screen each targeted beneficiary for conditions other than threshold conditions, such as impaired cognitive ability and co-morbidities, for the purposes of developing an individualized, goal-oriented care management plan under paragraph (2);

''(B) provide each targeted beneficiary participating in the program with such plan; and

''(C) carry out such plan and other chronic care improvement activities in accordance with paragraph (3).

''(2) ELEMENTS OF CARE MANAGEMENT PLANS.—A care management plan for a targeted beneficiary shall be developed with the beneficiary and shall, to the extent appropriate, include the following:

''(A) A designated point of contact responsible for communications with the beneficiary and for facilitating communications with other health care providers under the plan.

''(B) Self-care education for the beneficiary (through approaches such as disease management or medical nutrition therapy) and education for primary caregivers and family members.

''(C) Education for physicians and other providers and collaboration to enhance communication of relevant clinical information.

''(D) The use of monitoring technologies that enable patient guidance through the exchange of pertinent clinical information, such as vital signs, symptomatic information, and health self-assessment.

''(E) The provision of information about hospice care, pain and palliative care, and end-of-life care.

''(3) CONDUCT OF PROGRAMS.—In carrying out paragraph (1)(C) with respect to a participant, the chronic care improvement organization shall—

''(A) guide the participant in managing the participant's health (including all co-morbidities, relevant health care services, and pharmaceutical needs) and in performing activities as specified under the elements of the care management plan of the participant;

''(B) use decision-support tools such as evidence-based practice guidelines or other criteria as determined by the Secretary; and

''(C) develop a clinical information database to track and monitor each participant across settings and to evaluate outcomes.

''(4) ADDITIONAL RESPONSIBILITIES.—

''(A) OUTCOMES REPORT.—Each chronic care improvement organization offering a chronic care improvement program shall monitor and report to the Secretary, in a manner specified by the Secretary, on health care quality, cost, and outcomes.

''(B) ADDITIONAL REQUIREMENTS.—Each such organization and program shall comply with such additional requirements as the Secretary may specify.

''(5) ACCREDITATION.—The Secretary may provide that chronic care improvement programs and chronic care improvement organizations that are accredited by qualified organizations (as defined by the Secretary) may be deemed to meet such requirements under this section as the Secretary may specify.

''(f) TERMS OF AGREEMENTS.—

''(1) TERMS AND CONDITIONS.—

''(A) IN GENERAL.—An agreement under this section with a chronic care improvement organization shall contain such terms and conditions as the Secretary may specify consistent with this section.

''(B) CLINICAL, QUALITY IMPROVEMENT, AND FINANCIAL REQUIREMENTS.—The Secretary may not enter into an agreement with such an organization under this section for the operation of a chronic care improvement program unless—

''(i) the program and organization meet the requirements of subsection (e) and such clinical, quality improvement, financial, and other requirements as the Secretary deems to be appropriate for the targeted beneficiaries to be served; and

''(ii) the organization demonstrates to the satisfaction of the Secretary that the organization is able to assume financial risk for performance under the agreement (as applied under paragraph (3)(B)) with respect to payments made to the organization under such agreement through available reserves, reinsurance, withholds, or such other means as the Secretary determines appropriate.

''(2) MANNER OF PAYMENT.—Subject to paragraph (3)(B), the payment under an agreement under—

''(A) subsection (b) shall be computed on a per-member per-month basis; or

''(B) subsection (c) may be on a per-member per-month basis or such other basis as the Secretary and organization may agree.

''(3) APPLICATION OF PERFORMANCE STANDARDS.—

''(A) SPECIFICATION OF PERFORMANCE STANDARDS.—Each agreement under this section with a chronic care improvement organization shall specify performance standards for each of the factors specified in subsection (c)(2), including clinical quality and spending targets under this title, against which the performance of the chronic care improvement organization under the agreement is measured.

''(B) ADJUSTMENT OF PAYMENT BASED ON PERFORMANCE.—

''(i) IN GENERAL.—Each such agreement shall provide for adjustments in payment rates to an organization under the agreement insofar as the Secretary determines that the organization failed to meet the performance standards specified in the agreement under subparagraph (A).

''(ii) FINANCIAL RISK FOR PERFORMANCE.—In the case of an agreement under subsection (b) or (c), the agreement shall provide for a full recovery for any amount by which the fees paid to the organization under the agreement exceed the estimated savings to the programs under this title attributable to implementation of such agreement.

''(4) BUDGET NEUTRAL PAYMENT CONDITION.—Under this section, the Secretary shall ensure that the aggregate sum of medicare program benefit expenditures for beneficiaries participating in chronic care improvement programs and funds paid to chronic care improvement organizations under this section, shall not exceed the medicare program benefit expenditures that the Secretary estimates would have been made for such targeted beneficiaries in the absence of such programs.

''(g) FUNDING.—(1) Subject to paragraph (2), there are appropriated to the Secretary, in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund, such sums as may be necessary to provide for agreements with chronic care improvement programs under this section.

''(2) In no case shall the funding under this section exceed $100,000,000 in aggregate increased expenditures under this title (after taking into account any savings attributable to the

operation of this section) over the 3-fiscal-year period beginning on October 1, 2003.''.

(b) REPORTS.—The Secretary shall submit to Congress reports on the operation of section 1807 of the Social Security Act, as added by subsection (a), as follows:

(1) Not later than 2 years after the date of the implementation of such section, the Secretary shall submit to Congress an interim report on the scope of implementation of the programs under subsection (b) of such section, the design of the programs, and preliminary cost and quality findings with respect to those programs based on the following measures of the programs:

(A) Quality improvement measures, such as adherence to evidence-based guidelines and rehospitalization rates.

(B) Beneficiary and provider satisfaction.

(C) Health outcomes.

(D) Financial outcomes.

(2) Not later than 3 years and 6 months after the date of the implementation of such section the Secretary shall submit to Congress an update to the report required under paragraph (1) on the results of such programs.

(3) The Secretary shall submit to Congress 2 additional biennial reports on the chronic care improvement programs conducted under such section. The first such report shall be submitted not later than 2 years after the report is submitted under paragraph (2). Each such report shall include information on—

(A) the scope of implementation (in terms of both regions and chronic conditions) of the chronic care improvement programs;

(B) the design of the programs; and

(C) the improvements in health outcomes and financial efficiencies that result from such implementation.

SEC. 722. MEDICARE ADVANTAGE QUALITY IMPROVEMENT PROGRAMS.

(a) IN GENERAL.—Section 1852(e) (42 U.S.C. 1395w–22(e)) is amended—

(1) in the heading, by striking ''ASSURANCE'' and inserting ''IMPROVEMENT'';

(2) by amending paragraphs (1) through (3) to read as follows:

''(1) IN GENERAL.—Each MA organization shall have an ongoing quality improvement program for the purpose of improving the quality of care provided to enrollees in each MA plan offered by such organization (other than an MA private fee-for-service plan or an MSA plan).

''(2) CHRONIC CARE IMPROVEMENT PROGRAMS.—As part of the quality improvement program under paragraph (1), each MA organization shall have a chronic care improvement program. Each chronic care improvement program shall have a method for monitoring and identifying enrollees with multiple or sufficiently severe chronic conditions that meet criteria established by the organization for participation under the program.

''(3) DATA.—

''(A) COLLECTION, ANALYSIS, AND REPORTING.—

''(i) IN GENERAL.—Except as provided in clauses (ii) and (iii) with respect to plans described in such clauses and subject to subparagraph (B), as part of the quality improvement program under paragraph (1), each MA organization shall provide for the collection, analysis, and reporting of data that permits the measurement of health outcomes and other indices of quality.

''(ii) APPLICATION TO MA REGIONAL PLANS.—The Secretary shall establish as appropriate by regulation requirements for the collection, analysis, and reporting of data that permits the measurement of health outcomes and other indices of quality for MA organizations with respect to MA regional plans. Such requirements may not exceed the requirements under this subparagraph with respect to MA local plans that are preferred provider organization plans.

''(iii) APPLICATION TO PREFERRED PROVIDER ORGANIZATIONS.—Clause (i) shall apply to MA organizations with respect to MA local plans that are preferred provider organization plans only insofar as services are furnished by providers or services, physicians, and other health care practitioners and suppliers that have contracts with such organization to furnish services under such plans.

''(iv) DEFINITION OF PREFERRED PROVIDER ORGANIZATION PLAN.—In this subparagraph, the term 'preferred provider organization plan' means an MA plan that—

''(I) has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan;

''(II) provides for reimbursement for all covered benefits regardless of whether such benefits are provided within such network of providers; and

''(III) is offered by an organization that is not licensed or organized under State law as a health maintenance organization.

''(B) LIMITATIONS.—

''(i) TYPES OF DATA.—The Secretary shall not collect under subparagraph (A) data on quality, outcomes, and beneficiary satisfaction to facilitate consumer choice and program administration other than the types of data that were collected by the Secretary as of November 1, 2003.

''(ii) CHANGES IN TYPES OF DATA.—Subject to subclause (iii), the Secretary may only change the types of data that are required to be submitted under subparagraph (A) after submitting to Congress a report on the reasons for such changes that was prepared in consultation with MA organizations and private accrediting bodies.

''(iii) CONSTRUCTION.—Nothing in the subsection shall be construed as restricting the ability of the Secretary to carry out the duties under section 1851(d)(4)(D).'';

(3) in paragraph (4)(B)—

(A) by amending clause (i) to read as follows:

''(i) Paragraphs (1) through (3) of this subsection (relating to quality improvement programs).''; and

(B) by adding at the end the following new clause:

''(vii) The requirements described in section 1860D–4(j), to the extent such requirements apply under section 1860D–21(c).''; and

(4) by striking paragraph (5).

(b) CONFORMING AMENDMENT.—Section 1852(c)(1)(I) (42 U.S.C. 1395w–22(c)(1)(I)) is amended to read as follows:

''(I) QUALITY IMPROVEMENT PROGRAM.—A description of the organization's quality improvement program under subsection (e).''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to contract years beginning on and after January 1, 2006.

SEC. 723. CHRONICALLY ILL MEDICARE BENEFICIARY RESEARCH, DATA, DEMONSTRATION STRATEGY.

(a) DEVELOPMENT OF PLAN.—Not later than 6 months after the date of the enactment of this Act, the Secretary shall develop a plan to improve quality of care and reduce the cost of care for chronically ill medicare beneficiaries.

(b) PLAN REQUIREMENTS.—The plan will utilize existing data and identify data gaps, develop research initiatives, and propose intervention demonstration programs to provide better health care for chronically ill medicare beneficiaries. The plan shall—

(1) integrate existing data sets including, the Medicare Current Beneficiary Survey (MCBS), Minimum Data Set (MDS), Outcome and Assessment Information Set (OASIS), data from Quality Improvement Organizations (QIO), and claims data;

(2) identify any new data needs and a methodology to address new data needs;

(3) plan for the collection of such data in a data warehouse; and

(4) develop a research agenda using such data.

(c) CONSULTATION.—In developing the plan under this section, the Secretary shall consult with experts in the fields of care for the chronically ill (including clinicians).

(d) IMPLEMENTATION.—Not later than 2 years after the date of the enactment of this Act, the Secretary shall implement the plan developed under this section. The Secretary may contract with appropriate entities to implement such plan.

(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Secretary such sums as may be necessary in fiscal years 2004 and 2005 to carry out this section.

Subtitle D—Other Provisions

SEC. 731. IMPROVEMENTS IN NATIONAL AND LOCAL COVERAGE DETERMINATION PROCESS TO RESPOND TO CHANGES IN TECHNOLOGY.

(a) NATIONAL AND LOCAL COVERAGE DETERMINATION PROCESS.—

(1) IN GENERAL.—Section 1862 (42 U.S.C. 1395y), as amended by sections 948 and 950, is amended—

(A) in the third sentence of subsection (a), by inserting ''consistent with subsection (l)'' after ''the Secretary shall ensure''; and

(B) by adding at the end the following new subsection:

''(l) NATIONAL AND LOCAL COVERAGE DETERMINATION PROCESS.—

''(1) FACTORS AND EVIDENCE USED IN MAKING NATIONAL COVERAGE DETERMINATIONS.—The Secretary shall make available to the public the factors considered in making national coverage determinations of whether an item or service is reasonable and necessary. The Secretary shall develop guidance documents to carry out this paragraph in a manner similar to the development of guidance documents under section 701(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)).

''(2) TIMEFRAME FOR DECISIONS ON REQUESTS FOR NATIONAL COVERAGE DETERMINATIONS.—In the case of a request for a national coverage determination that—

''(A) does not require a technology assessment from an outside entity or deliberation from the Medicare Coverage Advisory Committee, the decision on the request shall be made not later than 6 months after the date of the request; or

''(B) requires such an assessment or deliberation and in which a clinical trial is not requested, the decision on the request shall be made not later than 9 months after the date of the request.

''(3) PROCESS FOR PUBLIC COMMENT IN NATIONAL COVERAGE DETERMINATIONS.—

''(A) PERIOD FOR PROPOSED DECISION.—Not later than the end of the 6-month period (or 9-month period for requests described in paragraph (2)(B)) that begins on the date a request for a national coverage determination is made, the Secretary shall make a draft of proposed decision on the request available to the public through the Internet website of the Centers for Medicare & Medicaid Services or other appropriate means.

''(B) 30-DAY PERIOD FOR PUBLIC COMMENT.—Beginning on the date the Secretary makes a draft of the proposed decision available under subparagraph (A), the Secretary shall provide a 30-day period for public comment on such draft.

''(C) 60-DAY PERIOD FOR FINAL DECISION.—Not later than 60 days after the conclusion of the 30-day period referred to under subparagraph (B), the Secretary shall—

''(i) make a final decision on the request;

''(ii) include in such final decision summaries of the public comments received and responses to such comments;

''(iii) make available to the public the clinical evidence and other data used in making such a decision when the decision differs from the recommendations of the Medicare Coverage Advisory Committee; and

''(iv) in the case of a final decision under clause (i) to grant the request for the national

coverage determination, the Secretary shall assign a temporary or permanent code (whether existing or unclassified) and implement the coding change.

''(4) CONSULTATION WITH OUTSIDE EXPERTS IN CERTAIN NATIONAL COVERAGE DETERMINATIONS.—With respect to a request for a national coverage determination for which there is not a review by the Medicare Coverage Advisory Committee, the Secretary shall consult with appropriate outside clinical experts.

''(5) LOCAL COVERAGE DETERMINATION PROCESS.—

''(A) PLAN TO PROMOTE CONSISTENCY OF COVERAGE DETERMINATIONS.—The Secretary shall develop a plan to evaluate new local coverage determinations to determine which determinations should be adopted nationally and to what extent greater consistency can be achieved among local coverage determinations.

''(B) CONSULTATION.—The Secretary shall require the fiscal intermediaries or carriers providing services within the same area to consult on all new local coverage determinations within the area.

''(C) DISSEMINATION OF INFORMATION.—The Secretary should serve as a center to disseminate information on local coverage determinations among fiscal intermediaries and carriers to reduce duplication of effort.

''(6) NATIONAL AND LOCAL COVERAGE DETERMINATION DEFINED.—For purposes of this subsection—

''(A) NATIONAL COVERAGE DETERMINATION.—The term 'national coverage determination' means a determination by the Secretary with respect to whether or not a particular item or service is covered nationally under this title.

''(B) LOCAL COVERAGE DETERMINATION.—The term 'local coverage determination' has the meaning given that in section 1869(f)(2)(B).''.

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to national coverage determinations as of January 1, 2004, and section 1862(l)(5) of the Social Security Act, as added by such paragraph, shall apply to local coverage determinations made on or after July 1, 2004.

(b) MEDICARE COVERAGE OF ROUTINE COSTS ASSOCIATED WITH CERTAIN CLINICAL TRIALS OF CATEGORY A DEVICES.—

(1) IN GENERAL.—Section 1862 (42 U.S.C. 1395y), as amended by subsection (a), is amended by adding at the end the following new subsection:

''(m) COVERAGE OF ROUTINE COSTS ASSOCIATED WITH CERTAIN CLINICAL TRIALS OF CATEGORY A DEVICES.—

''(1) IN GENERAL.—In the case of an individual entitled to benefits under part A, or enrolled under part B, or both who participates in a category A clinical trial, the Secretary shall not exclude under subsection (a)(1) payment for coverage of routine costs of care (as defined by the Secretary) furnished to such individual in the trial.

''(2) CATEGORY A CLINICAL TRIAL.—For purposes of paragraph (1), a 'category A clinical trial' means a trial of a medical device if—

''(A) the trial is of an experimental/investigational (category A) medical device (as defined in regulations under section 405.201(b) of title 42, Code of Federal Regulations (as in effect as of September 1, 2003));

''(B) the trial meets criteria established by the Secretary to ensure that the trial conforms to appropriate scientific and ethical standards; and

''(C) in the case of a trial initiated before January 1, 2010, the device involved in the trial has been determined by the Secretary to be intended for use in the diagnosis, monitoring, or treatment of an immediately life-threatening disease or condition.''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to routine costs incurred on and after January 1, 2005, and, as of such date, section 411.15(o) of title 42, Code of Federal Regulations, is superseded to the extent inconsistent with section 1862(m) of the Social Security Act, as added by such paragraph.

(3) RULE OF CONSTRUCTION.—Nothing in the amendment made by paragraph (1) shall be construed as applying to, or affecting, coverage or payment for a nonexperimental/investigational (category B) device.

(c) ISSUANCE OF TEMPORARY NATIONAL CODES.—Not later than July 1, 2004, the Secretary shall implement revised procedures for the issuance of temporary national HCPCS codes under part B of title XVIII of the Social Security Act.

SEC. 732. EXTENSION OF TREATMENT OF CERTAIN PHYSICIAN PATHOLOGY SERVICES UNDER MEDICARE.

Section 542(c) of BIPA (114 Stat. 2763A–551) is amended by inserting '', and for services furnished during 2005 and 2006'' before the period at the end.

SEC. 733. PAYMENT FOR PANCREATIC ISLET CELL INVESTIGATIONAL TRANSPLANTS FOR MEDICARE BENEFICIARIES IN CLINICAL TRIALS.

(a) CLINICAL TRIAL.—

(1) IN GENERAL.—The Secretary, acting through the National Institute of Diabetes and Digestive and Kidney Disorders, shall conduct a clinical investigation of pancreatic islet cell transplantation which includes medicare beneficiaries.

(2) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Secretary such sums as may be necessary to conduct the clinical investigation under paragraph (1).

(b) MEDICARE PAYMENT.—Not earlier than October 1, 2004, the Secretary shall pay for the routine costs as well as transplantation and appropriate related items and services (as described in subsection (c)) in the case of medicare beneficiaries who are participating in a clinical trial described in subsection (a) as if such transplantation were covered under title XVIII of such Act and as would be paid under part A or part B of such title for such beneficiary.

(c) SCOPE OF PAYMENT.—For purposes of subsection (b):

(1) The term ''routine costs'' means reasonable and necessary routine patient care costs (as defined in the Centers for Medicare & Medicaid Services Coverage Issues Manual, section 30–1), including immunosuppressive drugs and other followup care.

(2) The term ''transplantation and appropriate related items and services'' means items and services related to the acquisition and delivery of the pancreatic islet cell transplantation, notwithstanding any national noncoverage determination contained in the Centers for Medicare & Medicaid Services Coverage Issues Manual.

(3) The term ''medicare beneficiary'' means an individual who is entitled to benefits under part A of title XVIII of the Social Security Act, or enrolled under part B of such title, or both.

(d) CONSTRUCTION.—The provisions of this section shall not be construed—

(1) to permit payment for partial pancreatic tissue or islet cell transplantation under title XVIII of the Social Security Act other than payment as described in subsection (b); or

(2) as authorizing or requiring coverage or payment conveying—

(A) benefits under part A of such title to a beneficiary not entitled to such part A; or

(B) benefits under part B of such title to a beneficiary not enrolled in such part B.

SEC. 734. RESTORATION OF MEDICARE TRUST FUNDS.

(a) DEFINITIONS.—In this section:

(1) CLERICAL ERROR.—The term ''clerical error'' means a failure that occurs on or after April 15, 2001, to have transferred the correct amount from the general fund of the Treasury to a Trust Fund.

(2) TRUST FUND.—The term ''Trust Fund'' means the Federal Hospital Insurance Trust Fund established under section 1817 of the Social Security Act (42 U.S.C. 1395i) and the Federal Supplementary Medical Insurance Trust Fund established under section 1841 of such Act (42 U.S.C. 1395t).

(b) CORRECTION OF TRUST FUND HOLDINGS.—

(1) IN GENERAL.—The Secretary of the Treasury shall take the actions described in paragraph (2) with respect to the Trust Fund with the goal being that, after such actions are taken, the holdings of the Trust Fund will replicate, to the extent practicable in the judgment of the Secretary of the Treasury, in consultation with the Secretary, the holdings that would have been held by the Trust Fund if the clerical error involved had not occurred.

(2) OBLIGATIONS ISSUED AND REDEEMED.—The Secretary of the Treasury shall—

(A) issue to the Trust Fund obligations under chapter 31 of title 31, United States Code, that bear issue dates, interest rates, and maturity dates that are the same as those for the obligations that—

(i) would have been issued to the Trust Fund if the clerical error involved had not occurred; or

(ii) were issued to the Trust Fund and were redeemed by reason of the clerical error involved; and

(B) redeem from the Trust Fund obligations that would have been redeemed from the Trust Fund if the clerical error involved had not occurred.

(c) APPROPRIATION.—There is appropriated to the Trust Fund, out of any money in the Treasury not otherwise appropriated, an amount determined by the Secretary of the Treasury, in consultation with the Secretary, to be equal to the interest income lost by the Trust Fund through the date on which the appropriation is being made as a result of the clerical error involved.

(d) CONGRESSIONAL NOTICE.—In the case of a clerical error that occurs after April 15, 2001, the Secretary of the Treasury, before taking action to correct the error under this section, shall notify the appropriate committees of Congress concerning such error and the actions to be taken under this section in response to such error.

(e) DEADLINE.—With respect to the clerical error that occurred on April 15, 2001, not later than 120 days after the date of the enactment of this Act—

(1) the Secretary of the Treasury shall take the actions under subsection (b)(1); and

(2) the appropriation under subsection (c) shall be made.

SEC. 735. MODIFICATIONS TO MEDICARE PAYMENT ADVISORY COMMISSION (MEDPAC).

(a) EXAMINATION OF BUDGET CONSEQUENCES.—Section 1805(b) (42 U.S.C. 1395b–6(b)) is amended by adding at the end the following new paragraph:

''(8) EXAMINATION OF BUDGET CONSEQUENCES.—Before making any recommendations, the Commission shall examine the budget consequences of such recommendations, directly or through consultation with appropriate expert entities.''.

(b) CONSIDERATION OF EFFICIENT PROVISION OF SERVICES.—Section 1805(b)(2)(B)(i) (42 U.S.C. 1395b–6(b)(2)(B)(i)) is amended by inserting ''the efficient provision of'' after ''expenditures for''.

(c) APPLICATION OF DISCLOSURE REQUIREMENTS.—

(1) IN GENERAL.—Section 1805(c)(2)(D) (42 U.S.C. 1395b–6(c)(2)(D)) is amended by adding at the end the following: ''Members of the Commission shall be treated as employees of Congress for purposes of applying title I of the Ethics in Government Act of 1978 (Public Law 95–521).''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on January 1, 2004.

(d) ADDITIONAL REPORTS.—

(1) DATA NEEDS AND SOURCES.—The Medicare Payment Advisory Commission shall conduct a

study, and submit a report to Congress by not later than June 1, 2004, on the need for current data, and sources of current data available, to determine the solvency and financial circumstances of hospitals and other medicare providers of services.

(2) USE OF TAX-RELATED RETURNS.—Using return information provided under Form 990 of the Internal Revenue Service, the Commission shall submit to Congress, by not later than June 1, 2004, a report on the following:

(A) Investments, endowments, and fundraising of hospitals participating under the medicare program and related foundations.

(B) Access to capital financing for private and for not-for-profit hospitals.

(e) REPRESENTATION OF EXPERTS IN PRESCRIPTION DRUGS.—

(1) IN GENERAL.—Section 1805(c)(2)(B) (42 U.S.C. 1395b–6(c)(2)(B)) is amended by inserting ''experts in the area of pharmaco-economics or prescription drug benefit programs,'' after ''other health professionals,''.

(2) APPOINTMENT.—The Comptroller General of the United States shall ensure that the membership of the Commission complies with the amendment made by paragraph (1) with respect to appointments made on or after the date of the enactment of this Act.

SEC. 736. TECHNICAL AMENDMENTS.

(a) PART A.—(1) Section 1814(a) (42 U.S.C. 1395f(a)) is amended—

(A) by striking the seventh sentence, as added by section 322(a)(1) of BIPA (114 Stat. 2763A–501); and

(B) in paragraph (7)(A)—

(i) in clause (i), by inserting before the comma at the end the following: ''based on the physician's or medical director's clinical judgment regarding the normal course of the individual's illness''; and

(ii) in clause (ii), by inserting before the semicolon at the end the following: ''based on such clinical judgment''.

(2) Section 1814(b) (42 U.S.C. 1395f(b)), in the matter preceding paragraph (1), is amended by inserting a comma after ''1813''.

(3) Section 1815(e)(1)(B) (42 U.S.C. 1395g(e)(1)(B)), in the matter preceding clause (i), is amended by striking ''of hospital'' and inserting ''of a hospital''.

(4) Section 1816(c)(2)(B)(ii) (42 U.S.C. 1395h(c)(2)(B)(ii)) is amended—

(A) by striking ''and'' at the end of subclause (III); and

(B) by striking the period at the end of subclause (IV) and inserting '', and''.

(5) Section 1817(k)(3)(A) (42 U.S.C. 1395i(k)(3)(A)) is amended—

(A) in clause (i)(I), by striking the comma at the end and inserting a semicolon; and

(B) in clause (ii), by striking ''the Medicare and medicaid programs'' and inserting ''the programs under this title and title XIX''.

(6) Section 1817(k)(6)(B) (42 U.S.C. 1395i(k)(6)(B)) is amended by striking ''Medicare program under title XVIII'' and inserting ''program under this title''.

(7) Section 1818 (42 U.S.C. 1395i–2) is amended—

(A) in subsection (d)(6)(A) is amended by inserting ''of such Code'' after ''3111(b)''; and

(B) in subsection (g)(2)(B) is amended by striking ''subsection (b).'' and inserting ''subsection (b)''.

(8) Section 1819 (42 U.S.C. 1395i–3) is amended—

(A) in subsection (b)(4)(C)(i), by striking ''at least at least'' and inserting ''at least'';

(B) in subsection (d)(1)(A), by striking ''physical mental'' and inserting ''physical, mental''; and

(C) in subsection (f)(2)(B)(iii), by moving the last sentence 2 ems to the left.

(9) Section 1886(b)(3)(I)(i)(I) (42 U.S.C. 1395ww(b)(3)(I)(i)(I)) is amended by striking ''the the'' and inserting ''the''.

(10) The heading of subsection (mm) of section 1861 (42 U.S.C. 1395x) is amended to read as follows:

''Critical Access Hospital; Critical Access Hospital Services''.

(11) Paragraphs (1) and (2) of section 1861(tt) (42 U.S.C. 1395x(tt)) are each amended by striking ''rural primary care'' and inserting ''critical access''.

(12) Section 1865(b)(3)(B) (42 U.S.C. 1395bb(b)(3)(B)) is amended by striking ''section 1819 and 1861(j)'' and inserting ''sections 1819 and 1861(j)''.

(13) Section 1866(b)(2) (42 U.S.C. 1395cc(b)(2)) is amended by moving subparagraph (D) 2 ems to the left.

(14) Section 1867 (42 U.S.C. 1395dd) is amended—

(A) in the matter following clause (ii) of subsection (d)(1)(B), by striking ''is is'' and inserting ''is'';

(B) in subsection (e)(1)(B), by striking ''a pregnant women'' and inserting ''a pregnant woman''; and

(C) in subsection (e)(2), by striking ''means hospital'' and inserting ''means a hospital''.

(15) Section 1886(g)(3)(B) (42 U.S.C. 1395ww(g)(3)(B)) is amended by striking ''(as defined in subsection (d)(5)(D)(iii)'' and inserting ''(as defined in subsection (d)(5)(D)(iii))''.

(b) PART B.—(1) Section 1833(h)(5)(D) (42 U.S.C. 1395l(h)(5)(D)) is amended by striking ''clinic,,'' and inserting ''clinic,''.

(2) Section 1833(t)(3)(C)(ii) (42 U.S.C. 1395l(t)(3)(C)(ii)) is amended by striking ''clause (iii)'' and inserting ''clause (iv)''.

(3) Section 1861(v)(1)(S)(ii)(III) (42 U.S.C. 1395x(v)(1)(S)(ii)(III)) is amended by striking ''(as defined in section 1886(d)(5)(D)(iii)'' and inserting ''(as defined in section 1886(d)(5)(D)(iii))''.

(4) Section 1834(b)(4)(D)(iv) (42 U.S.C. 1395m(b)(4)(D)(iv)) is amended by striking ''clauses (vi)'' and inserting ''clause (vi)''.

(5) Section 1834(m)(4)(C)(ii)(III) (42 U.S.C. 1395m(m)(4)(C)(ii)(III)) is amended by striking ''1861(aa)(s)'' and inserting ''1861(aa)(2)''.

(6) Section 1838(a)(1) (42 U.S.C. 1395q(a)(1)) is amended by inserting a comma after ''1966''.

(7) The second sentence of section 1839(a)(4) (42 U.S.C. 1395r(a)(4)) is amended by striking ''which will'' and inserting ''will''.

(8) Section 1842(c)(2)(B)(ii) (42 U.S.C. 1395u(c)(2)(B)(ii)) is amended—

(A) by striking ''and'' at the end of subclause (III); and

(B) by striking the period at the end of subclause (IV) and inserting '', and''.

(9) Section 1842(i)(2) (42 U.S.C. 1395u(i)(2)) is amended by striking ''services, a physician'' and inserting ''services, to a physician''.

(10) Section 1848(i)(3)(A) (42 U.S.C. 1395w–4(i)(3)(A)) is amended by striking ''a comparable services'' and inserting ''comparable services''.

(11) Section 1861(s)(2)(K)(i) (42 U.S.C. 1395x(s)(2)(K)(i)) is amended by striking ''; and but'' and inserting '', but''.

(12) Section 1861(aa)(1)(B) (42 U.S.C. 1395x(aa)(1)(B)) is amended by striking ''‚,'' and inserting a comma.

(13) Section 128(b)(2) of BIPA (114 Stat. 2763A–480) is amended by striking ''Not later that'' and inserting ''Not later than'' each place it appears.

(c) PARTS A AND B.—(1) Section 1812(a)(3) (42 U.S.C. 1395d(a)(3)) is amended—

(A) by striking ''for individuals not'' and inserting ''in the case of individuals not''; and

(B) by striking ''for individuals so'' and inserting ''in the case of individuals so''.

(2)(A) Section 1814(a) (42 U.S.C. 1395f(a)) is amended in the sixth sentence by striking ''leave home,'' and inserting ''leave home and''.

(B) Section 1835(a) (42 U.S.C. 1395n(a)) is amended in the seventh sentence by striking ''leave home,'' and inserting ''leave home and''.

(3) Section 1891(d)(1) (42 U.S.C. 1395bbb(d)(1)) is amended by striking ''subsection (c)(2)(C)(I)'' and inserting ''subsection (c)(2)(C)(i)(I)''.

(4) Section 1861(v) (42 U.S.C. 1395x(v)) is amended by moving paragraph (8) (including clauses (i) through (v) of such paragraph) 2 ems to the left.

(5) Section 1866B(b)(7)(D) (42 U.S.C. 1395cc–2(b)(7)(D)) is amended by striking ''(c)(2)(A)(ii)'' and inserting ''(c)(2)(B)''.

(6) Section 1886(h)(3)(D)(ii)(III) (42 U.S.C. 1395ww(h)(3)(D)(ii)(III)) is amended by striking ''and'' after the comma at the end.

(7) Section 1893(a) (42 U.S.C. 1395ddd(a)) is amended by striking ''Medicare program'' and inserting ''medicare program''.

(8) Section 1896(b)(4) (42 U.S.C. 1395ggg(b)(4)) is amended by striking ''701(f)'' and inserting ''712(f)''.

(d) PART C.—(1) Section 1853 (42 U.S.C. 1395w–23), as amended by section 607 of BIPA (114 Stat. 2763A–558), is amended—

(A) in subsection (a)(3)(C)(ii), by striking ''clause (iii)'' and inserting ''clause (iv)'';

(B) in subsection (a)(3)(C), by redesignating the clause (iii) added by such section 607 as clause (iv); and

(C) in subsection (c)(5), by striking ''(a)(3)(C)(iii)'' and inserting ''(a)(3)(C)(iv)''.

(2) Section 1876 (42 U.S.C. 1395mm) is amended—

(A) in subsection (c)(2)(B), by striking ''signifcant'' and inserting ''significant''; and

(B) in subsection (j)(2), by striking ''this setion'' and inserting ''this section''.

(e) MEDIGAP.—Section 1882 (42 U.S.C. 1395ss) is amended—

(1) in subsection (d)(3)(A)(i)(II), by striking ''plan a medicare supplemental policy'' and inserting ''plan, a medicare supplemental policy'';

(2) in subsection (d)(3)(B)(iii)(II), by striking ''to the best of the issuer or seller's knowledge'' and inserting ''to the best of the issuer's or seller's knowledge'';

(3) in subsection (g)(2)(A), by striking ''medicare supplement policies'' and inserting ''medicare supplemental policies'';

(4) in subsection (p)(2)(B), by striking '', and'' and inserting ''; and''; and

(5) in subsection (s)(3)(A)(iii), by striking ''pre-existing'' and inserting ''preexisting''.

TITLE VIII—COST CONTAINMENT

Subtitle A—Cost Containment

SEC. 801. INCLUSION IN ANNUAL REPORT OF MEDICARE TRUSTEES OF INFORMATION ON STATUS OF MEDICARE TRUST FUNDS.

(a) DETERMINATIONS OF EXCESS GENERAL REVENUE MEDICARE FUNDING.—

(1) IN GENERAL.—The Board of Trustees of each medicare trust fund shall include in the annual reports submitted under subsection (b)(2) of sections 1817 and 1841 of the Social Security Act (42 U.S.C. 1395i and 1395t)—

(A) the information described in subsection (b); and

(B) a determination as to whether there is projected to be excess general revenue medicare funding (as defined in subsection (c)) for the fiscal year in which the report is submitted or for any of the succeeding 6 fiscal years.

(2) MEDICARE FUNDING WARNING.—For purposes of section 1105(h) of title 31, United States Code, and this subtitle, an affirmative determination under paragraph (1)(B) in 2 consecutive annual reports shall be treated as a medicare funding warning in the year in which the second such report is made.

(3) 7-FISCAL-YEAR REPORTING PERIOD.—For purposes of this subtitle, the term ''7-fiscal-year reporting period'' means, with respect to a year in which an annual report described in paragraph (1) is made, the period of 7 consecutive fiscal years beginning with the fiscal year in which the report is submitted.

(b) INFORMATION.—The information described in this subsection for an annual report in a year is as follows:

(1) PROJECTIONS OF GROWTH OF GENERAL REVENUE SPENDING.—A statement of the general revenue medicare funding as a percentage of the total medicare outlays for each of the following:

(A) Each fiscal year within the 7-fiscal-year reporting period.

(B) Previous fiscal years and as of 10, 50, and 75 years after such year.

(2) COMPARISON WITH OTHER GROWTH TRENDS.—A comparison of the trend of such percentages with the annual growth rate in the following:

(A) The gross domestic product.

(B) Private health costs.

(C) National health expenditures.

(D) Other appropriate measures.

(3) PART D SPENDING.—Expenditures, including trends in expenditures, under part D of title XVIII of the Social Security Act, as added by section 101.

(4) COMBINED MEDICARE TRUST FUND ANALYSIS.—A financial analysis of the combined medicare trust funds if general revenue medicare funding were limited to the percentage specified in subsection (c)(1)(B) of total medicare outlays.

(c) DEFINITIONS.—For purposes of this section:

(1) EXCESS GENERAL REVENUE MEDICARE FUNDING.—The term ''excess general revenue medicare funding'' means, with respect to a fiscal year, that—

(A) general revenue medicare funding (as defined in paragraph (2)), expressed as a percentage of total medicare outlays (as defined in paragraph (4)) for the fiscal year; exceeds

(B) 45 percent.

(2) GENERAL REVENUE MEDICARE FUNDING.—The term ''general revenue medicare funding'' means for a year—

(A) the total medicare outlays (as defined in paragraph (4)) for the year; minus

(B) the dedicated medicare financing sources (as defined in paragraph (3)) for the year.

(3) DEDICATED MEDICARE FINANCING SOURCES.—The term ''dedicated medicare financing sources'' means the following:

(A) HOSPITAL INSURANCE TAX.—Amounts appropriated to the Hospital Insurance Trust Fund under the third sentence of section 1817(a) of the Social Security Act (42 U.S.C. 1395i(a)) and amounts transferred to such Trust Fund under section 7(c)(2) of the Railroad Retirement Act of 1974 (45 U.S.C. 231f(c)(2)).

(B) TAXATION OF CERTAIN OASDI BENEFITS.—Amounts appropriated to the Hospital Insurance Trust Fund under section 121(e)(1)(B) of the Social Security Amendments of 1983 (Public Law 98–21), as inserted by section 13215(c) of the Omnibus Budget Reconciliation Act of 1993 (Public Law 103–66).

(C) STATE TRANSFERS.—The State share of amounts paid to the Federal Government by a State under section 1843 of the Social Security Act (42 U.S.C. 1395v) or pursuant to section 1935(c) of such Act.

(D) PREMIUMS.—The following premiums:

(i) PART A.—Premiums paid by non-Federal sources under sections 1818 and section 1818A (42 U.S.C. 1395i–2 and 1395i–2a) of such Act.

(ii) PART B.—Premiums paid by non-Federal sources under section 1839 of such Act (42 U.S.C. 1395r), including any adjustments in premiums under such section.

(iii) PART D.—Monthly beneficiary premiums paid under part D of title XVIII of such Act, as added by section 101, and MA monthly prescription drug beneficiary premiums paid under part C of such title insofar as they are attributable to basic prescription drug coverage.

Premiums under clauses (ii) and (iii) shall be determined without regard to any reduction in such premiums attributable to a beneficiary rebate under section 1854(b)(1)(C) of such title, as amended by section 222(b)(1), and premiums under clause (iii) are deemed to include any amounts paid under section 1860D–13(b) of such title, as added by section 101.

(E) GIFTS.—Amounts received by the medicare trust funds under section 201(i) of the Social Security Act (42 U.S.C. 401(i)).

(4) TOTAL MEDICARE OUTLAYS.—The term ''total medicare outlays'' means total outlays from the medicare trust funds and shall—

(A) include payments made to plans under part C of title XVIII of the Social Security Act that are attributable to any rebates under section 1854(b)(1)(C) of such Act (42 U.S.C. 1395w–24(b)(1)(C)), as amended by section 222(b)(1);

(B) include administrative expenditures made in carrying out title XVIII of such Act and Federal outlays under section 1935(b) of such Act, as added by section 103(a)(2); and

(C) offset outlays by the amount of fraud and abuse collections insofar as they are applied or deposited into a medicare trust fund.

(5) MEDICARE TRUST FUND.—The term ''medicare trust fund'' means—

(A) the Federal Hospital Insurance Trust Fund established under section 1817 of the Social Security Act (42 U.S.C. 1395i); and

(B) the Federal Supplementary Medical Insurance Trust Fund established under section 1841 of such Act (42 U.S.C. 1395t), including the Medicare Prescription Drug Account under such Trust Fund.

(d) CONFORMING AMENDMENTS.—

(1) FEDERAL HOSPITAL INSURANCE TRUST FUND.—Section 1817(b)(2) (42 U.S.C. 1395i(b)(2)) is amended by adding at the end the following: ''Each report provided under paragraph (2) beginning with the report in 2005 shall include the information specified in section 801(a) of Medicare Prescription Drug, Improvement, and Modernization Act of 2003.''.

(2) FEDERAL SUPPLEMENTARY MEDICAL INSURANCE TRUST FUND.—Section 1841(b)(2) (42 U.S.C. 1395t(b)(2)) is amended by adding at the end the following: ''Each report provided under paragraph (2) beginning with the report in 2005 shall include the information specified in section 801(a) of Medicare Prescription Drug, Improvement, and Modernization Act of 2003.''.

(e) NOTICE OF MEDICARE FUNDING WARNING.—Whenever any report described in subsection (a) contains a determination that for any fiscal year within the 7-fiscal-year reporting period there will be excess general revenue medicare funding, Congress and the President should address the matter under existing rules and procedures.

SEC. 802. PRESIDENTIAL SUBMISSION OF LEGISLATION.

(a) IN GENERAL.—Section 1105 of title 31, United States Code, is amended by adding at the end the following new subsection:

''(h)(1) If there is a medicare funding warning under section 801(a)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 made in a year, the President shall submit to Congress, within the 15-day period beginning on the date of the budget submission to Congress under subsection (a) for the succeeding year, proposed legislation to respond to such warning.

''(2) Paragraph (1) does not apply if, during the year in which the warning is made, legislation is enacted which eliminates excess general revenue medicare funding (as defined in section 801(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003) for the 7-fiscal-year reporting period, as certified by the Board of Trustees of each medicare trust fund (as defined in section 801(c)(5) of such Act) not later than 30 days after the date of the enactment of such legislation.''.

(b) SENSE OF CONGRESS.—It is the sense of Congress that legislation submitted pursuant to section 1105(h) of title 31, United States Code, in a year should be designed to eliminate excess general revenue medicare funding (as defined in section 801(c)) for the 7-fiscal-year period that begins in such year.

SEC. 803. PROCEDURES IN THE HOUSE OF REPRESENTATIVES.

(a) INTRODUCTION AND REFERRAL OF PRESIDENT'S LEGISLATIVE PROPOSAL.—

(1) INTRODUCTION.—In the case of a legislative proposal submitted by the President pursuant to section 1105(h) of title 31, United States Code, within the 15-day period specified in paragraph (1) of such section, the Majority Leader of the House of Representatives (or his designee) and the Minority Leader of the House of Representatives (or his designee) shall introduce such proposal (by request), the title of which is as follows: ''A bill to respond to a medicare funding warning.'' Such bill shall be introduced within 3 legislative days after Congress receives such proposal.

(2) REFERRAL.—Any legislation introduced pursuant to paragraph (1) shall be referred to the appropriate committees of the House of Representatives.

(b) DIRECTION TO THE APPROPRIATE HOUSE COMMITTEES.—

(1) IN GENERAL.—In the House, in any year during which the President is required to submit proposed legislation to Congress under section 1105(h) of title 31, United States Code, the appropriate committees shall report medicare funding legislation by not later than June 30 of such year.

(2) MEDICARE FUNDING LEGISLATION.—For purposes of this section, the term ''medicare funding legislation'' means—

(A) legislation introduced pursuant to subsection (a)(1), but only if the legislative proposal upon which the legislation is based was submitted within the 15-day period referred to in such subsection; or

(B) any bill the title of which is as follows: ''A bill to respond to a medicare funding warning.''.

(3) CERTIFICATION.—With respect to any medicare funding legislation or any amendment to such legislation to respond to a medicare funding warning, the chairman of the Committee on the Budget of the House shall certify—

(A) whether or not such legislation eliminates excess general revenue medicare funding (as defined in section 801(c)) for each fiscal year in the 7-fiscal-year reporting period; and

(B) with respect to such an amendment, whether the legislation, as amended, would eliminate excess general revenue medicare funding (as defined in section 801(c)) for each fiscal year in such 7-fiscal-year reporting period.

(c) FALLBACK PROCEDURE FOR FLOOR CONSIDERATION IF THE HOUSE FAILS TO VOTE ON FINAL PASSAGE BY JULY 30.—

(1) After July 30 of any year during which the President is required to submit proposed legislation to Congress under section 1105(h) of title 31, United States Code, unless the House of Representatives has voted on final passage of any medicare funding legislation for which there is an affirmative certification under subsection (b)(3)(A), then, after the expiration of not less than 30 calendar days (and concurrently 5 legislative days), it is in order to move to discharge any committee to which medicare funding legislation which has such a certification and which has been referred to such committee for 30 calendar days from further consideration of the legislation.

(2) A motion to discharge may be made only by an individual favoring the legislation, may be made only if supported by one-fifth of the total membership of the House (a quorum being present), and is highly privileged in the House. Debate thereon shall be limited to not more than one hour, the time to be divided in the House equally between those favoring and those opposing the motion. An amendment to the motion is not in order, and it is not in order to move to reconsider the vote by which the motion is agreed to or disagreed to.

(3) Only one motion to discharge a particular committee may be adopted under this subsection in any session of a Congress.

(4) Notwithstanding paragraph (1), it shall not be in order to move to discharge a committee from further consideration of medicare funding legislation pursuant to this subsection during a session of a Congress if, during the previous session of the Congress, the House passed medicare funding legislation for which there is an affirmative certification under subsection (b)(3)(A).

(d) FLOOR CONSIDERATION IN THE HOUSE OF DISCHARGED LEGISLATION.—

(1) In the House, not later than 3 legislative days after any committee has been discharged from further consideration of legislation under subsection (c), the Speaker shall resolve the House into the Committee of the Whole for consideration of the legislation.

(2) The first reading of the legislation shall be dispensed with. All points of order against consideration of the legislation are waived. General debate shall be confined to the legislation and shall not exceed five hours, which shall be divided equally between those favoring and those opposing the legislation. After general debate the legislation shall be considered for amendment under the five-minute rule. During consideration of the legislation, no amendments shall be in order in the House or in the Committee of the Whole except those for which there has been an affirmative certification under subsection (b)(3)(B). All points of order against consideration of any such amendment in the Committee of the Whole are waived. The legislation, together with any amendments which shall be in order, shall be considered as read. During the consideration of the bill for amendment, the Chairman of the Committee of the Whole may accord priority in recognition on the basis of whether the Member offering an amendment has caused it to be printed in the portion of the Congressional Record designated for that purpose in clause 8 of Rule XVIII of the Rules of the House of Representatives. Debate on any amendment shall not exceed one hour, which shall be divided equally between those favoring and those opposing the amendment, and no pro forma amendments shall be offered during the debate. The total time for debate on all amendments shall not exceed 10 hours. At the conclusion of consideration of the legislation for amendment, the Committee shall rise and report the legislation to the House with such amendments as may have been adopted. The previous question shall be considered as ordered on the legislation and amendments thereto to final passage without intervening motion except one motion to recommit with or without instructions. If the Committee of the Whole rises and reports that it has come to no resolution on the bill, then on the next legislative day the House shall, immediately after the third daily order of business under clause 1 of Rule XIV of the Rules of the House of Representatives, resolve into the Committee of the Whole for further consideration of the bill.

(3) All appeals from the decisions of the Chair relating to the application of the Rules of the House of Representatives to the procedure relating to any such legislation shall be decided without debate.

(4) Except to the extent specifically provided in the preceding provisions of this subsection, consideration of any such legislation and amendments thereto (or any conference report thereon) shall be governed by the Rules of the House of Representatives applicable to other bills and resolutions, amendments, and conference reports in similar circumstances.

(e) LEGISLATIVE DAY DEFINED.—As used in this section, the term ''legislative day'' means a day on which the House of Representatives is in session.

(f) RESTRICTION ON WAIVER.—In the House, the provisions of this section may be waived only by a rule or order proposing only to waive such provisions.

(g) RULEMAKING POWER.—The provisions of this section are enacted by the Congress—

(1) as an exercise of the rulemaking power of the House of Representatives and, as such, shall be considered as part of the rules of that House and shall supersede other rules only to the extent that they are inconsistent therewith; and

(2) with full recognition of the constitutional right of that House to change the rules (so far as they relate to the procedures of that House) at any time, in the same manner, and to the same extent as in the case of any other rule of that House.

SEC. 804. PROCEDURES IN THE SENATE.

(a) INTRODUCTION AND REFERRAL OF PRESIDENT'S LEGISLATIVE PROPOSAL.—

(1) INTRODUCTION.—In the case of a legislative proposal submitted by the President pursuant to section 1105(h) of title 31, United States Code, within the 15-day period specified in paragraph (1) of such section, the Majority Leader and Minority Leader of the Senate (or their designees) shall introduce such proposal (by request), the title of which is as follows: ''A bill to respond to a medicare funding warning.'' Such bill shall be introduced within 3 days of session after Congress receives such proposal.

(2) REFERRAL.—Any legislation introduced pursuant to paragraph (1) shall be referred to the Committee on Finance.

(b) MEDICARE FUNDING LEGISLATION.—For purposes of this section, the term ''medicare funding legislation'' means—

(1) legislation introduced pursuant to subsection (a)(1), but only if the legislative proposal upon which the legislation is based was submitted within the 15-day period referred to in such subsection; or

(2) any bill the title of which is as follows: ''A bill to respond to a medicare funding warning.''.

(c) QUALIFICATION FOR SPECIAL PROCEDURES.—

(1) IN GENERAL.—The special procedures set forth in subsections (d) and (e) shall apply to medicare funding legislation, as described in subsection (b), only if the legislation—

(A) is medicare funding legislation that is passed by the House of Representatives; or

(B) contains matter within the jurisdiction of the Committee on Finance in the Senate.

(2) FAILURE TO QUALIFY FOR SPECIAL PROCEDURES.—If the medicare funding legislation does not satisfy paragraph (1), then the legislation shall be considered under the ordinary procedures of the Standing Rules of the Senate.

(d) DISCHARGE.—

(1) IN GENERAL.—If the Committee on Finance has not reported medicare funding legislation described in subsection (c)(1) by June 30 of a year in which the President is required to submit medicare funding legislation to Congress under section 1105(h) of title 31, United States Code, then any Senator may move to discharge the Committee of any single medicare funding legislation measure. Only one such motion shall be in order in any session of Congress.

(2) DEBATE LIMITS.—Debate in the Senate on any such motion to discharge, and all appeals in connection therewith, shall be limited to not more than 2 hours. The time shall be equally divided between, and controlled by, the maker of the motion and the Majority Leader, or their designees, except that in the event the Majority Leader is in favor of such motion, the time in opposition thereto shall be controlled by the Minority Leader or the Minority Leader's designee. A point of order under this subsection may be made at any time. It is not in order to move to proceed to another measure or matter while such motion (or the motion to reconsider such motion) is pending.

(3) AMENDMENTS.—No amendment to the motion to discharge shall be in order.

(4) EXCEPTION IF CERTIFIED LEGISLATION ENACTED.—Notwithstanding paragraph (1), it shall not be in order to discharge the Committee from further consideration of medicare funding legislation pursuant to this subsection during a session of a Congress if the chairman of the Committee on the Budget of the Senate certifies that medicare funding legislation has been enacted that eliminates excess general revenue medicare funding (as defined in section 801(c)) for each fiscal year in the 7-fiscal-year reporting period.

(e) CONSIDERATION.—After the date on which the Committee on Finance has reported medicare funding legislation described in subsection (c)(1), or has been discharged (under subsection (d)) from further consideration of, such legislation, it is in order (even though a previous motion to the same effect has been disagreed to) for any Member of the Senate to move to proceed to the consideration of such legislation.

(f) RULES OF THE SENATE.—This section is enacted by the Senate—

(1) as an exercise of the rulemaking power of the Senate and as such it is deemed a part of the rules of the Senate, but applicable only with respect to the procedure to be followed in the Senate in the case of a bill described in this paragraph, and it supersedes other rules only to the extent that it is inconsistent with such rules; and

(2) with full recognition of the constitutional right of the Senate to change the rules (so far as relating to the procedure of the Senate) at any time, in the same manner, and to the same extent as in the case of any other rule of the Senate.

Subtitle B—Income-Related Reduction in Part B Premium Subsidy

SEC. 811. INCOME-RELATED REDUCTION IN PART B PREMIUM SUBSIDY.

(a) IN GENERAL.—Section 1839 (42 U.S.C. 1395r), as amended by section 241(c), is amended by adding at the end the following:

''(i) REDUCTION IN PREMIUM SUBSIDY BASED ON INCOME.—

''(1) IN GENERAL.—In the case of an individual whose modified adjusted gross income exceeds the threshold amount under paragraph (2), the monthly amount of the premium subsidy applicable to the premium under this section for a month after December 2006 shall be reduced (and the monthly premium shall be increased) by the monthly adjustment amount specified in paragraph (3).

''(2) THRESHOLD AMOUNT.—For purposes of this subsection, the threshold amount is—

''(A) except as provided in subparagraph (B), $80,000, and

''(B) in the case of a joint return, twice the amount applicable under subparagraph (A) for the calendar year.

''(3) MONTHLY ADJUSTMENT AMOUNT.—

''(A) IN GENERAL.—Subject to subparagraph (B), the monthly adjustment amount specified in this paragraph for an individual for a month in a year is equal to the product of the following:

''(i) SLIDING SCALE PERCENTAGE.—The applicable percentage specified in the table in subparagraph (C) for the individual minus 25 percentage points.

''(ii) UNSUBSIDIZED PART B PREMIUM AMOUNT.—200 percent of the monthly actuarial rate for enrollees age 65 and over (as determined under subsection (a)(1) for the year).

''(B) 5-YEAR PHASE IN.—The monthly adjustment amount specified in this paragraph for an individual for a month in a year before 2011 is equal to the following percentage of the monthly adjustment amount specified in subparagraph (A):

''(i) For 2007, 20 percent.

''(ii) For 2008, 40 percent.

''(iii) For 2009, 60 percent.

''(iv) for 2010, 80 percent.

''(C) APPLICABLE PERCENTAGE.—

''(i) IN GENERAL.—

''If the modified adjusted gross income is:	***The applicable percentage is:***
More than $80,000 but not more than $100,000.	*35percent*
More than $100,000 but not more than $150,000.	*50 percent*
More than $150,000 but not more than $200,000.	*65 percent*
More than $200,000	*80 percent.*

''(ii) JOINT RETURNS.—In the case of a joint return, clause (i) shall be applied by substituting dollar amounts which are twice the dollar amounts otherwise applicable under clause (i) for the calendar year.

''(iii) MARRIED INDIVIDUALS FILING SEPARATE RETURNS.—In the case of an individual who—

''(I) is married as of the close of the taxable year (within the meaning of section 7703 of the

Internal Revenue Code of 1986) but does not file a joint return for such year, and

''(II) does not live apart from such individual's spouse at all times during the taxable year,

clause (i) shall be applied by reducing each of the dollar amounts otherwise applicable under such clause for the calendar year by the threshold amount for such year applicable to an unmarried individual.

''(4) MODIFIED ADJUSTED GROSS INCOME.—

''(A) IN GENERAL.—For purposes of this subsection, the term 'modified adjusted gross income' means adjusted gross income (as defined in section 62 of the Internal Revenue Code of 1986)—

''(i) determined without regard to sections 135, 911, 931, and 933 of such Code; and

''(ii) increased by the amount of interest received or accrued during the taxable year which is exempt from tax under such Code.

In the case of an individual filing a joint return, any reference in this subsection to the modified adjusted gross income of such individual shall be to such return's modified adjusted gross income.

''(B) TAXABLE YEAR TO BE USED IN DETERMINING MODIFIED ADJUSTED GROSS INCOME.—

''(i) IN GENERAL.—In applying this subsection for an individual's premiums in a month in a year, subject to clause (ii) and subparagraph (C), the individual's modified adjusted gross income shall be such income determined for the individual's last taxable year beginning in the second calendar year preceding the year involved.

''(ii) TEMPORARY USE OF OTHER DATA.—If, as of October 15 before a calendar year, the Secretary of the Treasury does not have adequate data for an individual in appropriate electronic form for the taxable year referred to in clause (i), the individual's modified adjusted gross income shall be determined using the data in such form from the previous taxable year. Except as provided in regulations prescribed by the Commissioner of Social Security in consultation with the Secretary, the preceding sentence shall cease to apply when adequate data in appropriate electronic form are available for the individual for the taxable year referred to in clause (i), and proper adjustments shall be made to the extent that the premium adjustments determined under the preceding sentence were inconsistent with those determined using such taxable year.

''(iii) NON-FILERS.—In the case of individuals with respect to whom the Secretary of the Treasury does not have adequate data in appropriate electronic form for either taxable year referred to in clause (i) or clause (ii), the Commissioner of Social Security, in consultation with the Secretary, shall prescribe regulations which provide for the treatment of the premium adjustment with respect to such individual under this subsection, including regulations which provide for—

''(I) the application of the highest applicable percentage under paragraph (3)(C) to such individual if the Commissioner has information which indicates that such individual's modified adjusted gross income might exceed the threshold amount for the taxable year referred to in clause (i), and

''(II) proper adjustments in the case of the application of an applicable percentage under subclause (I) to such individual which is inconsistent with such individual's modified adjusted gross income for such taxable year.

''(C) USE OF MORE RECENT TAXABLE YEAR.—

''(i) IN GENERAL.—The Commissioner of Social Security in consultation with the Secretary of the Treasury shall establish a procedures under which an individual's modified adjusted gross income shall, at the request of such individual, be determined under this subsection—

''(I) for a more recent taxable year than the taxable year otherwise used under subparagraph (B), or

''(II) by such methodology as the Commissioner, in consultation with such Secretary, determines to be appropriate, which may include a methodology for aggregating or disaggregating information from tax returns in the case of marriage or divorce.

''(ii) STANDARD FOR GRANTING REQUESTS.—A request under clause (i)(I) to use a more recent taxable year may be granted only if—

''(I) the individual furnishes to such Commissioner with respect to such year such documentation, such as a copy of a filed Federal income tax return or an equivalent document, as the Commissioner specifies for purposes of determining the premium adjustment (if any) under this subsection; and

''(II) the individual's modified adjusted gross income for such year is significantly less than such income for the taxable year determined under subparagraph (B) by reason of the death of such individual's spouse, the marriage or divorce of such individual, or other major life changing events specified in regulations prescribed by the Commissioner in consultation with the Secretary.

''(5) INFLATION ADJUSTMENT.—

''(A) IN GENERAL.—In the case of any calendar year beginning after 2007, each dollar amount in paragraph (2) or (3) shall be increased by an amount equal to—

''(i) such dollar amount, multiplied by

''(ii) the percentage (if any) by which the average of the Consumer Price Index for all urban consumers (United States city average) for the 12-month period ending with August of the preceding calendar year exceeds such average for the 12-month period ending with August 2006.

''(B) ROUNDING.—If any dollar amount after being increased under subparagraph (A) is not a multiple of $1,000, such dollar amount shall be rounded to the nearest multiple of $1,000.

''(6) JOINT RETURN DEFINED.—For purposes of this subsection, the term 'joint return' has the meaning given to such term by section 7701(a)(38) of the Internal Revenue Code of 1986.''.

(b) CONFORMING AMENDMENTS.—

(1) Section 1839 (42 U.S.C. 1395r) is amended—

(A) in subsection (a)(2), by striking ''and (f)'' and inserting ''(f), and (i)'';

(B) in subsection (b), inserting ''(without regard to any adjustment under subsection (i))'' after ''subsection (a)''; and

(C) in subsection (f)—

(i) by striking ''and if'' and inserting ''if''; and

(ii) by inserting ''and if the amount of the individual's premium is not adjusted for such January under subsection (i),'' after ''section 1840(b)(1),''.

(2) Section 1844 (42 U.S.C. 1395w) is amended—

(A) in subsection (a)(1)—

(i) in subparagraph (B), by striking ''plus'' at the end and inserting ''minus''; and

(ii) by adding at the end the following new subparagraph:

''(C) the aggregate amount of additional premium payments attributable to the application of section 1839(i); plus''; and

(B) in subsection (c), by inserting before the period at the end the following: ''and without regard to any premium adjustment under section 1839(i)''.

(c) REPORTING REQUIREMENTS FOR SECRETARY OF THE TREASURY.—

(1) IN GENERAL.—Subsection (l) of section 6103 of the Internal Revenue Code of 1986 (relating to disclosure of returns and return information for purposes other than tax administration), as amended by section 105(e), is amended by adding at the end the following new paragraph:

''(20) DISCLOSURE OF RETURN INFORMATION TO CARRY OUT MEDICARE PART B PREMIUM SUBSIDY ADJUSTMENT.—

''(A) IN GENERAL.—The Secretary shall, upon written request from the Commissioner of Social Security, disclose to officers, employees, and contractors of the Social Security Administration return information of a taxpayer whose premium (according to the records of the Secretary) may be subject to adjustment under section 1839(i) of the Social Security Act. Such return information shall be limited to—

''(i) taxpayer identity information with respect to such taxpayer,

''(ii) the filing status of such taxpayer,

''(iii) the adjusted gross income of such taxpayer,

''(iv) the amounts excluded from such taxpayer's gross income under sections 135 and 911 to the extent such information is available,

''(v) the interest received or accrued during the taxable year which is exempt from the tax imposed by chapter 1 to the extent such information is available,

''(vi) the amounts excluded from such taxpayer's gross income by sections 931 and 933 to the extent such information is available,

''(vii) such other information relating to the liability of the taxpayer as is prescribed by the Secretary by regulation as might indicate in the case of a taxpayer who is an individual described in subsection (i)(4)(B)(iii) of section 1839 of the Social Security Act that the amount of the premium of the taxpayer under such section may be subject to adjustment under subsection (i) of such section and the amount of such adjustment, and

''(viii) the taxable year with respect to which the preceding information relates.

''(B) RESTRICTION ON USE OF DISCLOSED INFORMATION.—Return information disclosed under subparagraph (A) may be used by officers, employees, and contractors of the Social Security Administration only for the purposes of, and to the extent necessary in, establishing the appropriate amount of any premium adjustment under such section 1839(i).''

(2) CONFORMING AMENDMENTS.—

(A) Paragraph (3) of section 6103(a) of such Code, as amended by section 105(e)(1), is amended by striking ''or (19)'' and inserting ''(19), or (20)''.

(B) Paragraph (4) of section 6103(p) of such Code, as amended by section 105(e)(3), is amended by striking ''(l)(16), (17), or (19)'' each place it appears and inserting ''(l)(16), (17), (19), or (20)''.

(C) Paragraph (2) of section 7213(a) of such Code, as amended by section 105(e)(4), is amended by striking ''or (19)'' and inserting ''(19), or (20)''.

TITLE IX—ADMINISTRATIVE IMPROVEMENTS, REGULATORY REDUCTION, AND CONTRACTING REFORM

SEC. 900. ADMINISTRATIVE IMPROVEMENTS WITHIN THE CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS).

(a) COORDINATED ADMINISTRATION OF MEDICARE PRESCRIPTION DRUG AND MEDICARE ADVANTAGE PROGRAMS.—Title XVIII (42 U.S.C. 1395 et seq.), as amended by section 721, is amended by inserting after 1807 the following new section:

''PROVISIONS RELATING TO ADMINISTRATION

''SEC. 1808. (a) COORDINATED ADMINISTRATION OF MEDICARE PRESCRIPTION DRUG AND MEDICARE ADVANTAGE PROGRAMS.—

''(1) IN GENERAL.—There is within the Centers for Medicare & Medicaid Services a center to carry out the duties described in paragraph (3).

''(2) DIRECTOR.—Such center shall be headed by a director who shall report directly to the Administrator of the Centers for Medicare & Medicaid Services.

''(3) DUTIES.—The duties described in this paragraph are the following:

''(A) The administration of parts C and D.

''(B) The provision of notice and information under section 1804.

''(C) Such other duties as the Secretary may specify.

''(4) DEADLINE.—The Secretary shall ensure that the center is carrying out the duties described in paragraph (3) by not later than January 1, 2008.''.

(b) MANAGEMENT STAFF FOR THE CENTERS FOR MEDICARE & MEDICAID SERVICES.—Such section is further amended by adding at the end the following new subsection:

''(b) EMPLOYMENT OF MANAGEMENT STAFF.—

''(1) IN GENERAL.—The Secretary may employ, within the Centers for Medicare & Medicaid Services, such individuals as management staff as the Secretary determines to be appropriate. With respect to the administration of parts C and D, such individuals shall include individuals with private sector expertise in negotiations with health benefits plans.

''(2) ELIGIBILITY.—To be eligible for employment under paragraph (1) an individual shall be required to have demonstrated, by their education and experience (either in the public or private sector), superior expertise in at least one of the following areas:

''(A) The review, negotiation, and administration of health care contracts.

''(B) The design of health care benefit plans.

''(C) Actuarial sciences.

''(D) Compliance with health plan contracts.

''(E) Consumer education and decision making.

''(F) Any other area specified by the Secretary that requires specialized management or other expertise.

''(3) RATES OF PAYMENT.—

''(A) PERFORMANCE-RELATED PAY.—Subject to subparagraph (B), the Secretary shall establish the rate of pay for an individual employed under paragraph (1). Such rate shall take into account expertise, experience, and performance.

''(B) LIMITATION.—In no case may the rate of compensation determined under subparagraph (A) exceed the highest rate of basic pay for the Senior Executive Service under section 5382(b) of title 5, United States Code.''.

(c) REQUIREMENT FOR DEDICATED ACTUARY FOR PRIVATE HEALTH PLANS.—Section 1117(b) (42 U.S.C. 1317(b)) is amended by adding at the end the following new paragraph:

''(3) In the office of the Chief Actuary there shall be an actuary whose duties relate exclusively to the programs under parts C and D of title XVIII and related provisions of such title.''.

(d) INCREASE IN GRADE TO EXECUTIVE LEVEL III FOR THE ADMINISTRATOR OF THE CENTERS FOR MEDICARE & MEDICAID SERVICES.—

(1) IN GENERAL.—Section 5314 of title 5, United States Code, is amended by adding at the end the following:

''Administrator of the Centers for Medicare & Medicaid Services.''.

(2) CONFORMING AMENDMENT.—Section 5315 of such title is amended by striking ''Administrator of the Health Care Financing Administration.''.

(3) EFFECTIVE DATE.—The amendments made by this subsection take effect on January 1, 2004.

(e) CONFORMING AMENDMENTS RELATING TO HEALTH CARE FINANCING ADMINISTRATION.—

(1) AMENDMENTS TO THE SOCIAL SECURITY ACT.—The Social Security Act is amended—

(A) in section 1117 (42 U.S.C. 1317)—

(i) in the heading to read as follows:

''APPOINTMENT OF THE ADMINISTRATOR AND CHIEF ACTUARY OF THE CENTERS FOR MEDICARE & MEDICAID SERVICES'';

(ii) in subsection (a), by striking ''Health Care Financing Administration'' and inserting ''Centers for Medicare & Medicaid Services''; and

(iii) in subsection (b)(1)—

(I) by striking ''Health Care Financing Administration'' and inserting ''Centers for Medicare & Medicaid Services''; and

(II) by striking ''Administration'' and inserting ''Centers'';

(B) in section 1140(a) (42 U.S.C. 1320b–10(a))—

(i) in paragraph (1), by striking ''Health Care Financing Administration'' both places it appears in the matter following subparagraph (B) and inserting ''Centers for Medicare & Medicaid Services'';

(ii) in paragraph (1)(A)—

(I) by striking ''Health Care Financing Administration'' and inserting ''Centers for Medicare & Medicaid Services''; and

(II) by striking ''HCFA'' and inserting ''CMS''; and

(iii) in paragraph (1)(B), by striking ''Health Care Financing Administration'' both places it appears and inserting ''Centers for Medicare & Medicaid Services'';

(C) in section 1142(b)(3) (42 U.S.C. 1320b–12(b)(3)), by striking ''Health Care Financing Administration'' and inserting ''Centers for Medicare & Medicaid Services'';

(D) in section 1817(b) (42 U.S.C. 1395i(b))—

(i) by striking ''Health Care Financing Administration'', both in the fifth sentence of the matter preceding paragraph (1) and in the second sentence of the matter following paragraph (4), and inserting ''Centers for Medicare & Medicaid Services''; and

(ii) by striking ''Chief Actuarial Officer'' in the second sentence of the matter following paragraph (4) and inserting ''Chief Actuary'';

(E) in section 1841(b) (42 U.S.C. 1395t(b))—

(i) by striking ''Health Care Financing Administration'', both in the fifth sentence of the matter preceding paragraph (1) and in the second sentence of the matter following paragraph (4), and inserting ''Centers for Medicare & Medicaid Services''; and

(ii) by striking ''Chief Actuarial Officer'' in the second sentence of the matter following paragraph (4) and inserting ''Chief Actuary'';

(F) in section 1852(a)(5) (42 U.S.C. 1395w–22(a)(5)), by striking ''Health Care Financing Administration'' in the matter following subparagraph (B) and inserting ''Centers for Medicare & Medicaid Services'';

(G) in section 1853 (42 U.S.C. 1395w–23)—

(i) in subsection (b)(4), by striking ''Health Care Financing Administration'' in the first sentence and inserting ''Centers for Medicare & Medicaid Services''; and

(ii) in subsection (c)(7), by striking ''Health Care Financing Administration'' in the last sentence and inserting ''Centers for Medicare & Medicaid Services'';

(H) in section 1854(a)(5)(A) (42 U.S.C. 1395w–24(a)(5)(A)), by striking ''Health Care Financing Administration''and inserting ''Centers for Medicare & Medicaid Services'';

(I) in section 1857(d)(4)(A)(ii) (42 U.S.C. 1395w–27(d)(4)(A)(ii)), by striking ''Health Care Financing Administration'' and inserting ''Secretary'';

(J) in section 1862(b)(5)(A)(ii) (42 U.S.C. 1395y(b)(5)(A)(ii)), by striking ''Health Care Financing Administration'' and inserting ''Centers for Medicare & Medicaid Services'';

(K) in section 1927(e)(4) (42 U.S.C. 1396r–8(e)(4)), by striking ''HCFA'' and inserting ''The Secretary'';

(L) in section 1927(f)(2) (42 U.S.C. 1396r–8(f)(2)), by striking ''HCFA'' and inserting ''The Secretary''; and

(M) in section 2104(g)(3) (42 U.S.C. 1397dd(g)(3)) by inserting ''or CMS Form 64 or CMS Form 21, as the case may be,'' after ''HCFA Form 64 or HCFA Form 21''.

(2) AMENDMENTS TO THE PUBLIC HEALTH SERVICE ACT.—The Public Health Service Act is amended—

(A) in section 501(d)(18) (42 U.S.C. 290aa(d)(18)), by striking ''Health Care Financing Administration'' and inserting ''Centers for Medicare & Medicaid Services'';

(B) in section 507(b)(6) (42 U.S.C. 290bb(b)(6)), by striking ''Health Care Financing Administration'' and inserting ''Centers for Medicare & Medicaid Services'';

(C) in section 916 (42 U.S.C. 299b–5)—

(i) in subsection (b)(2), by striking ''Health Care Financing Administration'' and inserting ''Centers for Medicare & Medicaid Services''; and

(ii) in subsection (c)(2), by striking ''Health Care Financing Administration'' and inserting ''Centers for Medicare & Medicaid Services'';

(D) in section 921(c)(3)(A) (42 U.S.C. 299c(c)(3)(A)), by striking ''Health Care Financing Administration'' and inserting ''Centers for Medicare & Medicaid Services'';

(E) in section 1318(a)(2) (42 U.S.C. 300e–17(a)(2)), by striking ''Health Care Financing Administration'' and inserting ''Centers for Medicare & Medicaid Services'';

(F) in section 2102(a)(7) (42 U.S.C. 300aa–2(a)(7)), by striking ''Health Care Financing Administration'' and inserting ''Centers for Medicare & Medicaid Services''; and

(G) in section 2675(a) (42 U.S.C. 300ff–75(a)), by striking ''Health Care Financing Administration'' in the first sentence and inserting ''Centers for Medicare & Medicaid Services''.

(3) AMENDMENTS TO THE INTERNAL REVENUE CODE OF 1986.—Section 6103(l)(12) of the Internal Revenue Code of 1986 is amended—

(A) in subparagraph (B), by striking ''Health Care Financing Administration'' in the matter preceding clause (i) and inserting ''Centers for Medicare & Medicaid Services''; and

(B) in subparagraph (C)—

(i) by striking ''HEALTH CARE FINANCING ADMINISTRATION'' in the heading and inserting ''CENTERS FOR MEDICARE & MEDICAID SERVICES''; and

(ii) by striking ''Health Care Financing Administration'' in the matter preceding clause (i) and inserting ''Centers for Medicare & Medicaid Services''.

(4) AMENDMENTS TO TITLE 10, UNITED STATES CODE.—Title 10, United States Code, is amended—

(A) in section 1086(d)(4), by striking ''administrator of the Health Care Financing Administration'' in the last sentence and inserting ''Administrator of the Centers for Medicare & Medicaid Services''; and

(B) in section 1095(k)(2), by striking ''Health Care Financing Administration'' in the second sentence and inserting ''Centers for Medicare & Medicaid Services''.

(5) AMENDMENTS TO THE ALZHEIMER'S DISEASE AND RELATED DEMENTIAS SERVICES RESEARCH ACT OF 1992.—The Alzheimer's Disease and Related Dementias Research Act of 1992 (42 U.S.C. 11271 et seq.) is amended—

(A) in the heading of subpart 3 of part D to read as follows:

''Subpart 3—Responsibilities of the Centers for Medicare & Medicaid Services'';

(B) in section 937 (42 U.S.C. 11271)—

(i) in subsection (a), by striking ''National Health Care Financing Administration'' and inserting ''Centers for Medicare & Medicaid Services'';

(ii) in subsection (b)(1), by striking ''Health Care Financing Administration'' and inserting ''Centers for Medicare & Medicaid Services'';

(iii) in subsection (b)(2), by striking ''Health Care Financing Administration'' and inserting ''Centers for Medicare & Medicaid Services''; and

(iv) in subsection (c), by striking ''Health Care Financing Administration'' and inserting ''Centers for Medicare & Medicaid Services''; and

(C) in section 938 (42 U.S.C. 11272), by striking ''Health Care Financing Administration'' and inserting ''Centers for Medicare & Medicaid Services''.

(6) MISCELLANEOUS AMENDMENTS.—

(A) REHABILITATION ACT OF 1973.—Section 202(b)(8) of the Rehabilitation Act of 1973 (29 U.S.C. 762(b)(8)) is amended by striking ''Health Care Financing Administration'' and inserting ''Centers for Medicare & Medicaid Services''.

(B) INDIAN HEALTH CARE IMPROVEMENT ACT.—Section 405(d)(1) of the Indian Health Care Improvement Act (25 U.S.C. 1645(d)(1)) is amended by striking ''Health Care Financing Administration'' in the matter preceding subparagraph (A) and inserting ''Centers for Medicare & Medicaid Services''.

(C) INDIVIDUALS WITH DISABILITIES EDUCATION ACT.—Section 644(b)(5) of the Individuals with

Disabilities Education Act (20 U.S.C. 1444(b)(5)) is amended by striking ''Health Care Financing Administration'' and inserting ''Centers for Medicare & Medicaid Services''.

(D) THE HOME HEALTH CARE AND ALZHEIMER'S DISEASE AMENDMENTS OF 1990.—Section 302(a)(9) of the Home Health Care and Alzheimer's Disease Amendments of 1990 (42 U.S.C. 242q–1(a)(9)) is amended by striking ''Health Care Financing Administration'' and inserting ''Centers for Medicare & Medicaid Services''.

(E) THE CHILDREN'S HEALTH ACT OF 2000.—Section 2503(a) of the Children's Health Act of 2000 (42 U.S.C. 247b–3a(a)) is amended by striking ''Health Care Financing Administration'' and inserting ''Centers for Medicare & Medicaid Services''.

(F) THE NATIONAL INSTITUTES OF HEALTH REVITALIZATION ACT OF 1993.—Section 1909 of the National Institutes of Health Revitalization Act of 1993 (42 U.S.C. 299a note) is amended by striking ''Health Care Financing Administration'' and inserting ''Centers for Medicare & Medicaid Services''.

(G) THE OMNIBUS BUDGET RECONCILIATION ACT OF 1990.—Section 4359(d) of the Omnibus Budget Reconciliation Act of 1990 (42 U.S.C. 1395b–3(d)) is amended by striking ''Health Care Financing Administration'' and inserting ''Centers for Medicare & Medicaid Services''.

(H) THE MEDICARE, MEDICAID, AND SCHIP BENEFITS IMPROVEMENT AND PROTECTION ACT OF 2000.—Section 104(d)(4) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (42 U.S.C. 1395m note) is amended by striking ''Health Care Financing Administration'' and inserting ''Health Care''.

(7) ADDITIONAL AMENDMENT.—Section 403 of the Act entitled, ''An Act to authorize certain appropriations for the territories of the United States, to amend certain Acts relating thereto, and for other purposes'', enacted October 15, 1977 (48 U.S.C. 1574–1; 48 U.S.C. 1421q–1), is amended by striking ''Health Care Financing Administration'' and inserting ''Centers for Medicare & Medicaid Services''.

Subtitle A—Regulatory Reform

SEC. 901. CONSTRUCTION; DEFINITION OF SUPPLIER.

(a) CONSTRUCTION.—Nothing in this title shall be construed—

(1) to compromise or affect existing legal remedies for addressing fraud or abuse, whether it be criminal prosecution, civil enforcement, or administrative remedies, including under sections 3729 through 3733 of title 31, United States Code (commonly known as the ''False Claims Act''); or

(2) to prevent or impede the Department of Health and Human Services in any way from its ongoing efforts to eliminate waste, fraud, and abuse in the medicare program.

Furthermore, the consolidation of medicare administrative contracting set forth in this division does not constitute consolidation of the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund or reflect any position on that issue.

(b) DEFINITION OF SUPPLIER.—Section 1861 (42 U.S.C. 1395x) is amended by inserting after subsection (c) the following new subsection:

''Supplier

''(d) The term 'supplier' means, unless the context otherwise requires, a physician or other practitioner, a facility, or other entity (other than a provider of services) that furnishes items or services under this title.''.

SEC. 902. ISSUANCE OF REGULATIONS.

(a) REGULAR TIMELINE FOR PUBLICATION OF FINAL RULES.—

(1) IN GENERAL.—Section 1871(a) (42 U.S.C. 1395hh(a)) is amended by adding at the end the following new paragraph:

''(3)(A) The Secretary, in consultation with the Director of the Office of Management and Budget, shall establish and publish a regular timeline for the publication of final regulations based on the previous publication of a proposed regulation or an interim final regulation.

''(B) Such timeline may vary among different regulations based on differences in the complexity of the regulation, the number and scope of comments received, and other relevant factors, but shall not be longer than 3 years except under exceptional circumstances. If the Secretary intends to vary such timeline with respect to the publication of a final regulation, the Secretary shall cause to have published in the Federal Register notice of the different timeline by not later than the timeline previously established with respect to such regulation. Such notice shall include a brief explanation of the justification for such variation.

''(C) In the case of interim final regulations, upon the expiration of the regular timeline established under this paragraph for the publication of a final regulation after opportunity for public comment, the interim final regulation shall not continue in effect unless the Secretary publishes (at the end of the regular timeline and, if applicable, at the end of each succeeding 1-year period) a notice of continuation of the regulation that includes an explanation of why the regular timeline (and any subsequent 1-year extension) was not complied with. If such a notice is published, the regular timeline (or such timeline as previously extended under this paragraph) for publication of the final regulation shall be treated as having been extended for 1 additional year.

''(D) The Secretary shall annually submit to Congress a report that describes the instances in which the Secretary failed to publish a final regulation within the applicable regular timeline under this paragraph and that provides an explanation for such failures.''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on the date of the enactment of this Act. The Secretary shall provide for an appropriate transition to take into account the backlog of previously published interim final regulations.

(b) LIMITATIONS ON NEW MATTER IN FINAL REGULATIONS.—

(1) IN GENERAL.—Section 1871(a) (42 U.S.C. 1395hh(a)), as amended by subsection (a), is amended by adding at the end the following new paragraph:

''(4) If the Secretary publishes a final regulation that includes a provision that is not a logical outgrowth of a previously published notice of proposed rulemaking or interim final rule, such provision shall be treated as a proposed regulation and shall not take effect until there is the further opportunity for public comment and a publication of the provision again as a final regulation.''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to final regulations published on or after the date of the enactment of this Act.

SEC. 903. COMPLIANCE WITH CHANGES IN REGULATIONS AND POLICIES.

(a) NO RETROACTIVE APPLICATION OF SUBSTANTIVE CHANGES.—

(1) IN GENERAL.—Section 1871 (42 U.S.C. 1395hh), as amended by section 902(a), is amended by adding at the end the following new subsection:

''(e)(1)(A) A substantive change in regulations, manual instructions, interpretative rules, statements of policy, or guidelines of general applicability under this title shall not be applied (by extrapolation or otherwise) retroactively to items and services furnished before the effective date of the change, unless the Secretary determines that—

''(i) such retroactive application is necessary to comply with statutory requirements; or

''(ii) failure to apply the change retroactively would be contrary to the public interest.''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to substantive changes issued on or after the date of the enactment of this Act.

(b) TIMELINE FOR COMPLIANCE WITH SUBSTANTIVE CHANGES AFTER NOTICE.—

(1) IN GENERAL.—Section 1871(e)(1), as added by subsection (a), is amended by adding at the end the following:

''(B)(i) Except as provided in clause (ii), a substantive change referred to in subparagraph (A) shall not become effective before the end of the 30-day period that begins on the date that the Secretary has issued or published, as the case may be, the substantive change.

''(ii) The Secretary may provide for such a substantive change to take effect on a date that precedes the end of the 30-day period under clause (i) if the Secretary finds that waiver of such 30-day period is necessary to comply with statutory requirements or that the application of such 30-day period is contrary to the public interest. If the Secretary provides for an earlier effective date pursuant to this clause, the Secretary shall include in the issuance or publication of the substantive change a finding described in the first sentence, and a brief statement of the reasons for such finding.

''(C) No action shall be taken against a provider of services or supplier with respect to noncompliance with such a substantive change for items and services furnished before the effective date of such a change.''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to compliance actions undertaken on or after the date of the enactment of this Act.

(c) RELIANCE ON GUIDANCE.—

(1) IN GENERAL.—Section 1871(e), as added by subsection (a), is further amended by adding at the end the following new paragraph:

''(2)(A) If—

''(i) a provider of services or supplier follows the written guidance (which may be transmitted electronically) provided by the Secretary or by a medicare contractor (as defined in section 1889(g)) acting within the scope of the contractor's contract authority, with respect to the furnishing of items or services and submission of a claim for benefits for such items or services with respect to such provider or supplier;

''(ii) the Secretary determines that the provider of services or supplier has accurately presented the circumstances relating to such items, services, and claim to the contractor in writing; and

''(iii) the guidance was in error;

the provider of services or supplier shall not be subject to any penalty or interest under this title or the provisions of title XI insofar as they relate to this title (including interest under a repayment plan under section 1893 or otherwise) relating to the provision of such items or service or such claim if the provider of services or supplier reasonably relied on such guidance.

''(B) Subparagraph (A) shall not be construed as preventing the recoupment or repayment (without any additional penalty) relating to an overpayment insofar as the overpayment was solely the result of a clerical or technical operational error.''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on the date of the enactment of this Act and shall only apply to a penalty or interest imposed with respect to guidance provided on or after July 24, 2003.

SEC. 904. REPORTS AND STUDIES RELATING TO REGULATORY REFORM.

(a) GAO STUDY ON ADVISORY OPINION AUTHORITY.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study to determine the feasibility and appropriateness of establishing in the Secretary authority to provide legally binding advisory opinions on appropriate interpretation and application of regulations to carry out the medicare program under title XVIII of the Social Security Act. Such study shall examine the appropriate timeframe for issuing such advisory opinions, as well as the need for additional staff and funding to provide such opinions.

(2) REPORT.—The Comptroller General shall submit to Congress a report on the study conducted under paragraph (1) by not later than 1 year after the date of the enactment of this Act.

(b) REPORT ON LEGAL AND REGULATORY INCONSISTENCIES.—Section 1871 (42 U.S.C. 1395hh), as amended by section 903(a)(1), is amended by adding at the end the following new subsection:

''(f)(1) Not later than 2 years after the date of the enactment of this subsection, and every 3 years thereafter, the Secretary shall submit to Congress a report with respect to the administration of this title and areas of inconsistency or conflict among the various provisions under law and regulation.

''(2) In preparing a report under paragraph (1), the Secretary shall collect—

''(A) information from individuals entitled to benefits under part A or enrolled under part B, or both, providers of services, and suppliers and from the Medicare Beneficiary Ombudsman with respect to such areas of inconsistency and conflict; and

''(B) information from medicare contractors that tracks the nature of written and telephone inquiries.

''(3) A report under paragraph (1) shall include a description of efforts by the Secretary to reduce such inconsistency or conflicts, and recommendations for legislation or administrative action that the Secretary determines appropriate to further reduce such inconsistency or conflicts.''.

Subtitle B—Contracting Reform

SEC. 911. INCREASED FLEXIBILITY IN MEDICARE ADMINISTRATION.

(a) CONSOLIDATION AND FLEXIBILITY IN MEDICARE ADMINISTRATION.—

(1) IN GENERAL.—Title XVIII is amended by inserting after section 1874 the following new section:

''CONTRACTS WITH MEDICARE ADMINISTRATIVE CONTRACTORS

''SEC. 1874A. (a) AUTHORITY.—

''(1) AUTHORITY TO ENTER INTO CONTRACTS.—The Secretary may enter into contracts with any eligible entity to serve as a medicare administrative contractor with respect to the performance of any or all of the functions described in paragraph (4) or parts of those functions (or, to the extent provided in a contract, to secure performance thereof by other entities).

''(2) ELIGIBILITY OF ENTITIES.—An entity is eligible to enter into a contract with respect to the performance of a particular function described in paragraph (4) only if—

''(A) the entity has demonstrated capability to carry out such function;

''(B) the entity complies with such conflict of interest standards as are generally applicable to Federal acquisition and procurement;

''(C) the entity has sufficient assets to financially support the performance of such function; and

''(D) the entity meets such other requirements as the Secretary may impose.

''(3) MEDICARE ADMINISTRATIVE CONTRACTOR DEFINED.—For purposes of this title and title XI—

''(A) IN GENERAL.—The term 'medicare administrative contractor' means an agency, organization, or other person with a contract under this section.

''(B) APPROPRIATE MEDICARE ADMINISTRATIVE CONTRACTOR.—With respect to the performance of a particular function in relation to an individual entitled to benefits under part A or enrolled under part B, or both, a specific provider of services or supplier (or class of such providers of services or suppliers), the 'appropriate' medicare administrative contractor is the medicare administrative contractor that has a contract under this section with respect to the performance of that function in relation to that individual, provider of services or supplier or class of provider of services or supplier.

''(4) FUNCTIONS DESCRIBED.—The functions referred to in paragraphs (1) and (2) are payment functions (including the function of developing local coverage determinations, as defined in section 1869(f)(2)(B)), provider services functions, and functions relating to services furnished to individuals entitled to benefits under part A or enrolled under part B, or both, as follows:

''(A) DETERMINATION OF PAYMENT AMOUNTS.—Determining (subject to the provisions of section 1878 and to such review by the Secretary as may be provided for by the contracts) the amount of the payments required pursuant to this title to be made to providers of services, suppliers and individuals.

''(B) MAKING PAYMENTS.—Making payments described in subparagraph (A) (including receipt, disbursement, and accounting for funds in making such payments).

''(C) BENEFICIARY EDUCATION AND ASSISTANCE.—Providing education and outreach to individuals entitled to benefits under part A or enrolled under part B, or both, and providing assistance to those individuals with specific issues, concerns, or problems.

''(D) PROVIDER CONSULTATIVE SERVICES.—Providing consultative services to institutions, agencies, and other persons to enable them to establish and maintain fiscal records necessary for purposes of this title and otherwise to qualify as providers of services or suppliers.

''(E) COMMUNICATION WITH PROVIDERS.—Communicating to providers of services and suppliers any information or instructions furnished to the medicare administrative contractor by the Secretary, and facilitating communication between such providers and suppliers and the Secretary.

''(F) PROVIDER EDUCATION AND TECHNICAL ASSISTANCE.—Performing the functions relating to provider education, training, and technical assistance.

''(G) ADDITIONAL FUNCTIONS.—Performing such other functions, including (subject to paragraph (5)) functions under the Medicare Integrity Program under section 1893, as are necessary to carry out the purposes of this title.

''(5) RELATIONSHIP TO MIP CONTRACTS.—

''(A) NONDUPLICATION OF DUTIES.—In entering into contracts under this section, the Secretary shall assure that functions of medicare administrative contractors in carrying out activities under parts A and B do not duplicate activities carried out under a contract entered into under the Medicare Integrity Program under section 1893. The previous sentence shall not apply with respect to the activity described in section 1893(b)(5) (relating to prior authorization of certain items of durable medical equipment under section 1834(a)(15)).

''(B) CONSTRUCTION.—An entity shall not be treated as a medicare administrative contractor merely by reason of having entered into a contract with the Secretary under section 1893.

''(6) APPLICATION OF FEDERAL ACQUISITION REGULATION.—Except to the extent inconsistent with a specific requirement of this section, the Federal Acquisition Regulation applies to contracts under this section.

''(b) CONTRACTING REQUIREMENTS.—

''(1) USE OF COMPETITIVE PROCEDURES.—

''(A) IN GENERAL.—Except as provided in laws with general applicability to Federal acquisition and procurement or in subparagraph (B), the Secretary shall use competitive procedures when entering into contracts with medicare administrative contractors under this section, taking into account performance quality as well as price and other factors.

''(B) RENEWAL OF CONTRACTS.—The Secretary may renew a contract with a medicare administrative contractor under this section from term to term without regard to section 5 of title 41, United States Code, or any other provision of law requiring competition, if the medicare administrative contractor has met or exceeded the performance requirements applicable with respect to the contract and contractor, except that the Secretary shall provide for the application of competitive procedures under such a contract not less frequently than once every 5 years.

''(C) TRANSFER OF FUNCTIONS.—The Secretary may transfer functions among medicare administrative contractors consistent with the provisions of this paragraph. The Secretary shall ensure that performance quality is considered in such transfers. The Secretary shall provide public notice (whether in the Federal Register or otherwise) of any such transfer (including a description of the functions so transferred, a description of the providers of services and suppliers affected by such transfer, and contact information for the contractors involved).

''(D) INCENTIVES FOR QUALITY.—The Secretary shall provide incentives for medicare administrative contractors to provide quality service and to promote efficiency.

''(2) COMPLIANCE WITH REQUIREMENTS.—No contract under this section shall be entered into with any medicare administrative contractor unless the Secretary finds that such medicare administrative contractor will perform its obligations under the contract efficiently and effectively and will meet such requirements as to financial responsibility, legal authority, quality of services provided, and other matters as the Secretary finds pertinent.

''(3) PERFORMANCE REQUIREMENTS.—

''(A) DEVELOPMENT OF SPECIFIC PERFORMANCE REQUIREMENTS.—

''(i) IN GENERAL.—The Secretary shall develop contract performance requirements to carry out the specific requirements applicable under this title to a function described in subsection (a)(4) and shall develop standards for measuring the extent to which a contractor has met such requirements.

''(ii) CONSULTATION.—In developing such performance requirements and standards for measurement, the Secretary shall consult with providers of services, organizations representative of beneficiaries under this title, and organizations and agencies performing functions necessary to carry out the purposes of this section with respect to such performance requirements.

''(iii) PUBLICATION OF STANDARDS.—The Secretary shall make such performance requirements and measurement standards available to the public.

''(B) CONSIDERATIONS.—The Secretary shall include, as one of the standards developed under subparagraph (A), provider and beneficiary satisfaction levels.

''(C) INCLUSION IN CONTRACTS.—All contractor performance requirements shall be set forth in the contract between the Secretary and the appropriate medicare administrative contractor. Such performance requirements—

''(i) shall reflect the performance requirements published under subparagraph (A), but may include additional performance requirements;

''(ii) shall be used for evaluating contractor performance under the contract; and

''(iii) shall be consistent with the written statement of work provided under the contract.

''(4) INFORMATION REQUIREMENTS.—The Secretary shall not enter into a contract with a medicare administrative contractor under this section unless the contractor agrees—

''(A) to furnish to the Secretary such timely information and reports as the Secretary may find necessary in performing his functions under this title; and

''(B) to maintain such records and afford such access thereto as the Secretary finds necessary to assure the correctness and verification of the information and reports under subparagraph (A) and otherwise to carry out the purposes of this title.

''(5) SURETY BOND.—A contract with a medicare administrative contractor under this section may require the medicare administrative contractor, and any of its officers or employees certifying payments or disbursing funds pursuant to the contract, or otherwise participating in carrying out the contract, to give surety bond to the United States in such amount as the Secretary may deem appropriate.

''(c) TERMS AND CONDITIONS.—

''(1) IN GENERAL.—A contract with any medicare administrative contractor under this section may contain such terms and conditions as the Secretary finds necessary or appropriate and may provide for advances of funds to the medicare administrative contractor for the making of payments by it under subsection (a)(4)(B).

''(2) PROHIBITION ON MANDATES FOR CERTAIN DATA COLLECTION.—The Secretary may not require, as a condition of entering into, or renewing, a contract under this section, that the medicare administrative contractor match data obtained other than in its activities under this title with data used in the administration of this title for purposes of identifying situations in which the provisions of section 1862(b) may apply.

''(d) LIMITATION ON LIABILITY OF MEDICARE ADMINISTRATIVE CONTRACTORS AND CERTAIN OFFICERS.—

''(1) CERTIFYING OFFICER.—No individual designated pursuant to a contract under this section as a certifying officer shall, in the absence of the reckless disregard of the individual's obligations or the intent by that individual to defraud the United States, be liable with respect to any payments certified by the individual under this section.

''(2) DISBURSING OFFICER.—No disbursing officer shall, in the absence of the reckless disregard of the officer's obligations or the intent by that officer to defraud the United States, be liable with respect to any payment by such officer under this section if it was based upon an authorization (which meets the applicable requirements for such internal controls established by the Comptroller General of the United States) of a certifying officer designated as provided in paragraph (1) of this subsection.

''(3) LIABILITY OF MEDICARE ADMINISTRATIVE CONTRACTOR.—

''(A) IN GENERAL.—No medicare administrative contractor shall be liable to the United States for a payment by a certifying or disbursing officer unless, in connection with such payment, the medicare administrative contractor acted with reckless disregard of its obligations under its medicare administrative contract or with intent to defraud the United States.

''(B) RELATIONSHIP TO FALSE CLAIMS ACT.—Nothing in this subsection shall be construed to limit liability for conduct that would constitute a violation of sections 3729 through 3731 of title 31, United States Code.

''(4) INDEMNIFICATION BY SECRETARY.—

''(A) IN GENERAL.—Subject to subparagraphs (B) and (D), in the case of a medicare administrative contractor (or a person who is a director, officer, or employee of such a contractor or who is engaged by the contractor to participate directly in the claims administration process) who is made a party to any judicial or administrative proceeding arising from or relating directly to the claims administration process under this title, the Secretary may, to the extent the Secretary determines to be appropriate and as specified in the contract with the contractor, indemnify the contractor and such persons.

''(B) CONDITIONS.—The Secretary may not provide indemnification under subparagraph (A) insofar as the liability for such costs arises directly from conduct that is determined by the judicial proceeding or by the Secretary to be criminal in nature, fraudulent, or grossly negligent. If indemnification is provided by the Secretary with respect to a contractor before a determination that such costs arose directly from such conduct, the contractor shall reimburse the Secretary for costs of indemnification.

''(C) SCOPE OF INDEMNIFICATION.—Indemnification by the Secretary under subparagraph (A) may include payment of judgments, settlements (subject to subparagraph (D)), awards, and costs (including reasonable legal expenses).

''(D) WRITTEN APPROVAL FOR SETTLEMENTS OR COMPROMISES.—A contractor or other person described in subparagraph (A) may not propose to negotiate a settlement or compromise of a proceeding described in such subparagraph without the prior written approval of the Secretary to negotiate such settlement or compromise. Any indemnification under subparagraph (A) with respect to amounts paid under a settlement or compromise of a proceeding described in such subparagraph are conditioned upon prior written approval by the Secretary of the final settlement or compromise.

''(E) CONSTRUCTION.—Nothing in this paragraph shall be construed—

''(i) to change any common law immunity that may be available to a medicare administrative contractor or person described in subparagraph (A); or

''(ii) to permit the payment of costs not otherwise allowable, reasonable, or allocable under the Federal Acquisition Regulation.''.

(2) CONSIDERATION OF INCORPORATION OF CURRENT LAW STANDARDS.—In developing contract performance requirements under section 1874A(b) of the Social Security Act, as inserted by paragraph (1), the Secretary shall consider inclusion of the performance standards described in sections 1816(f)(2) of such Act (relating to timely processing of reconsiderations and applications for exemptions) and section 1842(b)(2)(B) of such Act (relating to timely review of determinations and fair hearing requests), as such sections were in effect before the date of the enactment of this Act.

(b) CONFORMING AMENDMENTS TO SECTION 1816 (RELATING TO FISCAL INTERMEDIARIES).—Section 1816 (42 U.S.C. 1395h) is amended as follows:

(1) The heading is amended to read as follows:

''PROVISIONS RELATING TO THE ADMINISTRATION OF PART A''.

(2) Subsection (a) is amended to read as follows:

''(a) The administration of this part shall be conducted through contracts with medicare administrative contractors under section 1874A.''.

(3) Subsection (b) is repealed.

(4) Subsection (c) is amended—

(A) by striking paragraph (1); and

(B) in each of paragraphs (2)(A) and (3)(A), by striking ''agreement under this section'' and inserting ''contract under section 1874A that provides for making payments under this part''.

(5) Subsections (d) through (i) are repealed.

(6) Subsections (j) and (k) are each amended—

(A) by striking ''An agreement with an agency or organization under this section'' and inserting ''A contract with a medicare administrative contractor under section 1874A with respect to the administration of this part''; and

(B) by striking ''such agency or organization'' and inserting ''such medicare administrative contractor'' each place it appears.

(7) Subsection (l) is repealed.

(c) CONFORMING AMENDMENTS TO SECTION 1842 (RELATING TO CARRIERS).—Section 1842 (42 U.S.C. 1395u) is amended as follows:

(1) The heading is amended to read as follows:

''PROVISIONS RELATING TO THE ADMINISTRATION OF PART B''.

(2) Subsection (a) is amended to read as follows:

''(a) The administration of this part shall be conducted through contracts with medicare administrative contractors under section 1874A.''.

(3) Subsection (b) is amended—

(A) by striking paragraph (1);

(B) in paragraph (2)—

(i) by striking subparagraphs (A) and (B);

(ii) in subparagraph (C), by striking ''carriers'' and inserting ''medicare administrative contractors''; and

(iii) by striking subparagraphs (D) and (E);

(C) in paragraph (3)—

(i) in the matter before subparagraph (A), by striking ''Each such contract shall provide that the carrier'' and inserting ''The Secretary'';

(ii) by striking ''will'' the first place it appears in each of subparagraphs (A), (B), (F), (G), (H), and (L) and inserting ''shall'';

(iii) in subparagraph (B), in the matter before clause (i), by striking ''to the policyholders and subscribers of the carrier'' and inserting ''to the policyholders and subscribers of the medicare administrative contractor'';

(iv) by striking subparagraphs (C), (D), and (E);

(v) in subparagraph (H)—

(I) by striking ''if it makes determinations or payments with respect to physicians' services,'' in the matter preceding clause (i); and

(II) by striking ''carrier'' and inserting ''medicare administrative contractor'' in clause (i);

(vi) by striking subparagraph (I);

(vii) in subparagraph (L), by striking the semicolon and inserting a period;

(viii) in the first sentence, after subparagraph (L), by striking ''and shall contain'' and all that follows through the period; and

(ix) in the seventh sentence, by inserting ''medicare administrative contractor,'' after ''carrier,'';

(D) by striking paragraph (5);

(E) in paragraph (6)(D)(iv), by striking ''carrier'' and inserting ''medicare administrative contractor''; and

(F) in paragraph (7), by striking ''the carrier'' and inserting ''the Secretary'' each place it appears.

(4) Subsection (c) is amended—

(A) by striking paragraph (1);

(B) in paragraph (2)(A), by striking ''contract under this section which provides for the disbursement of funds, as described in subsection (a)(1)(B),'' and inserting ''contract under section 1874A that provides for making payments under this part'';

(C) in paragraph (3)(A), by striking ''subsection (a)(1)(B)'' and inserting ''section 1874A(a)(3)(B)'';

(D) in paragraph (4), in the matter preceding subparagraph (A), by striking ''carrier'' and inserting ''medicare administrative contractor''; and

(E) by striking paragraphs (5) and (6).

(5) Subsections (d), (e), and (f) are repealed.

(6) Subsection (g) is amended by striking ''carrier or carriers'' and inserting ''medicare administrative contractor or contractors''.

(7) Subsection (h) is amended—

(A) in paragraph (2)—

(i) by striking ''Each carrier having an agreement with the Secretary under subsection (a)'' and inserting ''The Secretary''; and

(ii) by striking ''Each such carrier'' and inserting ''The Secretary'';

(B) in paragraph (3)(A)—

(i) by striking ''a carrier having an agreement with the Secretary under subsection (a)'' and inserting ''medicare administrative contractor having a contract under section 1874A that provides for making payments under this part''; and

(ii) by striking ''such carrier'' and inserting ''such contractor'';

(C) in paragraph (3)(B)—

(i) by striking ''a carrier'' and inserting ''a medicare administrative contractor'' each place it appears; and

(ii) by striking ''the carrier'' and inserting ''the contractor'' each place it appears; and

(D) in paragraphs (5)(A) and (5)(B)(iii), by striking ''carriers'' and inserting ''medicare administrative contractors'' each place it appears.

(8) Subsection (l) is amended—

(A) in paragraph (1)(A)(iii), by striking ''carrier'' and inserting ''medicare administrative contractor''; and

(B) in paragraph (2), by striking ''carrier'' and inserting ''medicare administrative contractor''.

(9) Subsection (p)(3)(A) is amended by striking ''carrier'' and inserting ''medicare administrative contractor''.

(10) Subsection (q)(1)(A) is amended by striking ''carrier''.

(d) EFFECTIVE DATE; TRANSITION RULE.—

(1) EFFECTIVE DATE.—

(A) IN GENERAL.—Except as otherwise provided in this subsection, the amendments made by this section shall take effect on October 1, 2005, and the Secretary is authorized to take such steps before such date as may be necessary to implement such amendments on a timely basis.

(B) CONSTRUCTION FOR CURRENT CONTRACTS.—Such amendments shall not apply to contracts in effect before the date specified under subparagraph (A) that continue to retain the terms and conditions in effect on such date (except as otherwise provided under this Act, other than under this section) until such date as the contract is let out for competitive bidding under such amendments.

(C) DEADLINE FOR COMPETITIVE BIDDING.—The Secretary shall provide for the letting by competitive bidding of all contracts for functions of medicare administrative contractors for annual contract periods that begin on or after October 1, 2011.

(2) GENERAL TRANSITION RULES.—

(A) AUTHORITY TO CONTINUE TO ENTER INTO NEW AGREEMENTS AND CONTRACTS AND WAIVER OF PROVIDER NOMINATION PROVISIONS DURING TRANSITION.—Prior to October 1, 2005, the Secretary may, consistent with subparagraph (B), continue to enter into agreements under section 1816 and contracts under section 1842 of the Social Security Act (42 U.S.C. 1395h, 1395u). The Secretary may enter into new agreements under section 1816 prior to October 1, 2005, without regard to any of the provider nomination provisions of such section.

(B) APPROPRIATE TRANSITION.—The Secretary shall take such steps as are necessary to provide for an appropriate transition from agreements under section 1816 and contracts under section 1842 of the Social Security Act (42 U.S.C. 1395h, 1395u) to contracts under section 1874A, as added by subsection (a)(1).

(3) AUTHORIZING CONTINUATION OF MIP FUNCTIONS UNDER CURRENT CONTRACTS AND AGREEMENTS AND UNDER TRANSITION CONTRACTS.—Notwithstanding the amendments made by this section, the provisions contained in the exception in section 1893(d)(2) of the Social Security Act (42 U.S.C. 1395ddd(d)(2)) shall continue to apply during the period that begins on the date of the enactment of this Act and ends on October 1, 2011, and any reference in such provisions to an agreement or contract shall be deemed to include a contract under section 1874A of such Act, as inserted by subsection (a)(1), that continues the activities referred to in such provisions.

(e) REFERENCES.—On and after the effective date provided under subsection (d)(1), any reference to a fiscal intermediary or carrier under title XI or XVIII of the Social Security Act (or any regulation, manual instruction, interpretative rule, statement of policy, or guideline issued to carry out such titles) shall be deemed a reference to a medicare administrative contractor (as provided under section 1874A of the Social Security Act).

(f) SECRETARIAL SUBMISSION OF LEGISLATIVE PROPOSAL.—Not later than 6 months after the date of the enactment of this Act, the Secretary shall submit to the appropriate committees of Congress a legislative proposal providing for such technical and conforming amendments in the law as are required by the provisions of this section.

(g) REPORTS ON IMPLEMENTATION.—

(1) PLAN FOR IMPLEMENTATION.—By not later than October 1, 2004, the Secretary shall submit a report to Congress and the Comptroller General of the United States that describes the plan for implementation of the amendments made by this section. The Comptroller General shall conduct an evaluation of such plan and shall submit to Congress, not later than 6 months after the date the report is received, a report on such evaluation and shall include in such report such recommendations as the Comptroller General deems appropriate.

(2) STATUS OF IMPLEMENTATION.—The Secretary shall submit a report to Congress not later than October 1, 2008, that describes the status of implementation of such amendments and that includes a description of the following:

(A) The number of contracts that have been competitively bid as of such date.

(B) The distribution of functions among contracts and contractors.

(C) A timeline for complete transition to full competition.

(D) A detailed description of how the Secretary has modified oversight and management of medicare contractors to adapt to full competition.

SEC. 912. REQUIREMENTS FOR INFORMATION SECURITY FOR MEDICARE ADMINISTRATIVE CONTRACTORS.

(a) IN GENERAL.—Section 1874A, as added by section 911(a)(1), is amended by adding at the end the following new subsection:

''(e) REQUIREMENTS FOR INFORMATION SECURITY.—

''(1) DEVELOPMENT OF INFORMATION SECURITY PROGRAM.—A medicare administrative contractor that performs the functions referred to in subparagraphs (A) and (B) of subsection (a)(4) (relating to determining and making payments) shall implement a contractor-wide information security program to provide information security for the operation and assets of the contractor with respect to such functions under this title. An information security program under this paragraph shall meet the requirements for information security programs imposed on Federal agencies under paragraphs (1) through (8) of section 3544(b) of title 44, United States Code (other than the requirements under paragraphs (2)(D)(i), (5)(A), and (5)(B) of such section).

''(2) INDEPENDENT AUDITS.—

''(A) PERFORMANCE OF ANNUAL EVALUATIONS.—Each year a medicare administrative contractor that performs the functions referred to in subparagraphs (A) and (B) of subsection (a)(4) (relating to determining and making payments) shall undergo an evaluation of the information security of the contractor with respect to such functions under this title. The evaluation shall—

''(i) be performed by an entity that meets such requirements for independence as the Inspector General of the Department of Health and Human Services may establish; and

''(ii) test the effectiveness of information security control techniques of an appropriate subset of the contractor's information systems (as defined in section 3502(8) of title 44, United States Code) relating to such functions under this title and an assessment of compliance with the requirements of this subsection and related information security policies, procedures, standards and guidelines, including policies and procedures as may be prescribed by the Director of the Office of Management and Budget and applicable information security standards promulgated under section 11331 of title 40, United States Code.

''(B) DEADLINE FOR INITIAL EVALUATION.—

''(i) NEW CONTRACTORS.—In the case of a medicare administrative contractor covered by this subsection that has not previously performed the functions referred to in subparagraphs (A) and (B) of subsection (a)(4) (relating to determining and making payments) as a fiscal intermediary or carrier under section 1816 or 1842, the first independent evaluation conducted pursuant to subparagraph (A) shall be completed prior to commencing such functions.

''(ii) OTHER CONTRACTORS.—In the case of a medicare administrative contractor covered by this subsection that is not described in clause (i), the first independent evaluation conducted pursuant to subparagraph (A) shall be completed within 1 year after the date the contractor commences functions referred to in clause (i) under this section.

''(C) REPORTS ON EVALUATIONS.—

''(i) TO THE DEPARTMENT OF HEALTH AND HUMAN SERVICES.—The results of independent evaluations under subparagraph (A) shall be submitted promptly to the Inspector General of the Department of Health and Human Services and to the Secretary.

''(ii) TO CONGRESS.—The Inspector General of the Department of Health and Human Services shall submit to Congress annual reports on the results of such evaluations, including assessments of the scope and sufficiency of such evaluations.

''(iii) AGENCY REPORTING.—The Secretary shall address the results of such evaluations in reports required under section 3544(c) of title 44, United States Code.''.

(b) APPLICATION OF REQUIREMENTS TO FISCAL INTERMEDIARIES AND CARRIERS.—

(1) IN GENERAL.—The provisions of section 1874A(e)(2) of the Social Security Act (other than subparagraph (B)), as added by subsection (a), shall apply to each fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and each carrier under section 1842 of such Act (42 U.S.C. 1395u) in the same manner as they apply to medicare administrative contractors under such provisions.

(2) DEADLINE FOR INITIAL EVALUATION.—In the case of such a fiscal intermediary or carrier with an agreement or contract under such respective section in effect as of the date of the enactment of this Act, the first evaluation under section 1874A(e)(2)(A) of the Social Security Act (as added by subsection (a)), pursuant to paragraph (1), shall be completed (and a report on the evaluation submitted to the Secretary) by not later than 1 year after such date.

Subtitle C—Education and Outreach

SEC. 921. PROVIDER EDUCATION AND TECHNICAL ASSISTANCE.

(a) COORDINATION OF EDUCATION FUNDING.—

(1) IN GENERAL.—Title XVIII is amended by inserting after section 1888 the following new section:

''PROVIDER EDUCATION AND TECHNICAL ASSISTANCE

''SEC. 1889. (a) COORDINATION OF EDUCATION FUNDING.—The Secretary shall coordinate the educational activities provided through medicare contractors (as defined in subsection (g), including under section 1893) in order to maximize the effectiveness of Federal education efforts for providers of services and suppliers.''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on the date of the enactment of this Act.

(3) REPORT.—Not later than October 1, 2004, the Secretary shall submit to Congress a report that includes a description and evaluation of the steps taken to coordinate the funding of provider education under section 1889(a) of the Social Security Act, as added by paragraph (1).

(b) INCENTIVES TO IMPROVE CONTRACTOR PERFORMANCE.—

(1) IN GENERAL.—Section 1874A, as added by section 911(a)(1) and as amended by section 912(a), is amended by adding at the end the following new subsection:

''(f) INCENTIVES TO IMPROVE CONTRACTOR PERFORMANCE IN PROVIDER EDUCATION AND OUTREACH.—The Secretary shall use specific claims payment error rates or similar methodology of medicare administrative contractors in the processing or reviewing of medicare claims in order to give such contractors an incentive to implement effective education and outreach programs for providers of services and suppliers.''.

(2) APPLICATION TO FISCAL INTERMEDIARIES AND CARRIERS.—The provisions of section 1874A(f) of the Social Security Act, as added by paragraph (1), shall apply to each fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and each carrier under section 1842 of such Act (42 U.S.C. 1395u) in the same manner as they apply to medicare administrative contractors under such provisions.

(3) GAO REPORT ON ADEQUACY OF METHODOLOGY.—Not later than October 1, 2004, the

Comptroller General of the United States shall submit to Congress and to the Secretary a report on the adequacy of the methodology under section 1874A(f) of the Social Security Act, as added by paragraph (1), and shall include in the report such recommendations as the Comptroller General determines appropriate with respect to the methodology.

(4) REPORT ON USE OF METHODOLOGY IN ASSESSING CONTRACTOR PERFORMANCE.—Not later than October 1, 2004, the Secretary shall submit to Congress a report that describes how the Secretary intends to use such methodology in assessing medicare contractor performance in implementing effective education and outreach programs, including whether to use such methodology as a basis for performance bonuses. The report shall include an analysis of the sources of identified errors and potential changes in systems of contractors and rules of the Secretary that could reduce claims error rates.

(c) PROVISION OF ACCESS TO AND PROMPT RESPONSES FROM MEDICARE ADMINISTRATIVE CONTRACTORS.—

(1) IN GENERAL.—Section 1874A, as added by section 911(a)(1) and as amended by section 912(a) and subsection (b), is further amended by adding at the end the following new subsection:

''(g) COMMUNICATIONS WITH BENEFICIARIES, PROVIDERS OF SERVICES AND SUPPLIERS.—

''(1) COMMUNICATION STRATEGY.—The Secretary shall develop a strategy for communications with individuals entitled to benefits under part A or enrolled under part B, or both, and with providers of services and suppliers under this title.

''(2) RESPONSE TO WRITTEN INQUIRIES.—Each medicare administrative contractor shall, for those providers of services and suppliers which submit claims to the contractor for claims processing and for those individuals entitled to benefits under part A or enrolled under part B, or both, with respect to whom claims are submitted for claims processing, provide general written responses (which may be through electronic transmission) in a clear, concise, and accurate manner to inquiries of providers of services, suppliers, and individuals entitled to benefits under part A or enrolled under part B, or both, concerning the programs under this title within 45 business days of the date of receipt of such inquiries.

''(3) RESPONSE TO TOLL-FREE LINES.—The Secretary shall ensure that each medicare administrative contractor shall provide, for those providers of services and suppliers which submit claims to the contractor for claims processing and for those individuals entitled to benefits under part A or enrolled under part B, or both, with respect to whom claims are submitted for claims processing, a toll-free telephone number at which such individuals, providers of services, and suppliers may obtain information regarding billing, coding, claims, coverage, and other appropriate information under this title.

''(4) MONITORING OF CONTRACTOR RESPONSES.—

''(A) IN GENERAL.—Each medicare administrative contractor shall, consistent with standards developed by the Secretary under subparagraph (B)—

''(i) maintain a system for identifying who provides the information referred to in paragraphs (2) and (3); and

''(ii) monitor the accuracy, consistency, and timeliness of the information so provided.

''(B) DEVELOPMENT OF STANDARDS.—

''(i) IN GENERAL.—The Secretary shall establish and make public standards to monitor the accuracy, consistency, and timeliness of the information provided in response to written and telephone inquiries under this subsection. Such standards shall be consistent with the performance requirements established under subsection (b)(3).

''(ii) EVALUATION.—In conducting evaluations of individual medicare administrative contractors, the Secretary shall take into account the results of the monitoring conducted under subparagraph (A) taking into account as performance requirements the standards established under clause (i). The Secretary shall, in consultation with organizations representing providers of services, suppliers, and individuals entitled to benefits under part A or enrolled under part B, or both, establish standards relating to the accuracy, consistency, and timeliness of the information so provided.

''(C) DIRECT MONITORING.—Nothing in this paragraph shall be construed as preventing the Secretary from directly monitoring the accuracy, consistency, and timeliness of the information so provided.

''(5) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as are necessary to carry out this subsection.''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect October 1, 2004.

(3) APPLICATION TO FISCAL INTERMEDIARIES AND CARRIERS.—The provisions of section 1874A(g) of the Social Security Act, as added by paragraph (1), shall apply to each fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and each carrier under section 1842 of such Act (42 U.S.C. 1395u) in the same manner as they apply to medicare administrative contractors under such provisions.

(d) IMPROVED PROVIDER EDUCATION AND TRAINING.—

(1) IN GENERAL.—Section 1889, as added by subsection (a), is amended by adding at the end the following new subsections:

''(b) ENHANCED EDUCATION AND TRAINING.—

''(1) ADDITIONAL RESOURCES.—There are authorized to be appropriated to the Secretary (in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund) such sums as may be necessary for fiscal years beginning with fiscal year 2005.

''(2) USE.—The funds made available under paragraph (1) shall be used to increase the conduct by medicare contractors of education and training of providers of services and suppliers regarding billing, coding, and other appropriate items and may also be used to improve the accuracy, consistency, and timeliness of contractor responses.

''(c) TAILORING EDUCATION AND TRAINING ACTIVITIES FOR SMALL PROVIDERS OR SUPPLIERS.—

''(1) IN GENERAL.—Insofar as a medicare contractor conducts education and training activities, it shall tailor such activities to meet the special needs of small providers of services or suppliers (as defined in paragraph (2)). Such education and training activities for small providers of services and suppliers may include the provision of technical assistance (such as review of billing systems and internal controls to determine program compliance and to suggest more efficient and effective means of achieving such compliance).

''(2) SMALL PROVIDER OF SERVICES OR SUPPLIER.—In this subsection, the term 'small provider of services or supplier' means—

''(A) a provider of services with fewer than 25 full-time-equivalent employees; or

''(B) a supplier with fewer than 10 full-time-equivalent employees.''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on October 1, 2004.

(e) REQUIREMENT TO MAINTAIN INTERNET WEBSITES.—

(1) IN GENERAL.—Section 1889, as added by subsection (a) and as amended by subsection (d), is further amended by adding at the end the following new subsection:

''(d) INTERNET WEBSITES; FAQS.—The Secretary, and each medicare contractor insofar as it provides services (including claims processing) for providers of services or suppliers, shall maintain an Internet website which—

''(1) provides answers in an easily accessible format to frequently asked questions, and

''(2) includes other published materials of the contractor,

that relate to providers of services and suppliers under the programs under this title (and title XI insofar as it relates to such programs).''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on October 1, 2004.

(f) ADDITIONAL PROVIDER EDUCATION PROVISIONS.—

(1) IN GENERAL.—Section 1889, as added by subsection (a) and as amended by subsections (d) and (e), is further amended by adding at the end the following new subsections:

''(e) ENCOURAGEMENT OF PARTICIPATION IN EDUCATION PROGRAM ACTIVITIES.—A medicare contractor may not use a record of attendance at (or failure to attend) educational activities or other information gathered during an educational program conducted under this section or otherwise by the Secretary to select or track providers of services or suppliers for the purpose of conducting any type of audit or prepayment review.

''(f) CONSTRUCTION.—Nothing in this section or section 1893(g) shall be construed as providing for disclosure by a medicare contractor—

''(1) of the screens used for identifying claims that will be subject to medical review; or

''(2) of information that would compromise pending law enforcement activities or reveal findings of law enforcement-related audits.

''(g) DEFINITIONS.—For purposes of this section, the term 'medicare contractor' includes the following:

''(1) A medicare administrative contractor with a contract under section 1874A, including a fiscal intermediary with a contract under section 1816 and a carrier with a contract under section 1842.

''(2) An eligible entity with a contract under section 1893.

Such term does not include, with respect to activities of a specific provider of services or supplier an entity that has no authority under this title or title IX with respect to such activities and such provider of services or supplier.''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on the date of the enactment of this Act.

SEC. 922. SMALL PROVIDER TECHNICAL ASSISTANCE DEMONSTRATION PROGRAM.

(a) ESTABLISHMENT.—

(1) IN GENERAL.—The Secretary shall establish a demonstration program (in this section referred to as the ''demonstration program'') under which technical assistance described in paragraph (2) is made available, upon request and on a voluntary basis, to small providers of services or suppliers in order to improve compliance with the applicable requirements of the programs under medicare program under title XVIII of the Social Security Act (including provisions of title XI of such Act insofar as they relate to such title and are not administered by the Office of the Inspector General of the Department of Health and Human Services).

(2) FORMS OF TECHNICAL ASSISTANCE.—The technical assistance described in this paragraph is—

(A) evaluation and recommendations regarding billing and related systems; and

(B) information and assistance regarding policies and procedures under the medicare program, including coding and reimbursement.

(3) SMALL PROVIDERS OF SERVICES OR SUPPLIERS.—In this section, the term ''small providers of services or suppliers'' means—

(A) a provider of services with fewer than 25 full-time-equivalent employees; or

(B) a supplier with fewer than 10 full-time-equivalent employees.

(b) QUALIFICATION OF CONTRACTORS.—In conducting the demonstration program, the Secretary shall enter into contracts with qualified

organizations (such as peer review organizations or entities described in section 1889(g)(2) of the Social Security Act, as inserted by section 921(f)(1)) with appropriate expertise with billing systems of the full range of providers of services and suppliers to provide the technical assistance. In awarding such contracts, the Secretary shall consider any prior investigations of the entity's work by the Inspector General of Department of Health and Human Services or the Comptroller General of the United States.

(c) DESCRIPTION OF TECHNICAL ASSISTANCE.—The technical assistance provided under the demonstration program shall include a direct and in-person examination of billing systems and internal controls of small providers of services or suppliers to determine program compliance and to suggest more efficient or effective means of achieving such compliance.

(d) GAO EVALUATION.—Not later than 2 years after the date the demonstration program is first implemented, the Comptroller General, in consultation with the Inspector General of the Department of Health and Human Services, shall conduct an evaluation of the demonstration program. The evaluation shall include a determination of whether claims error rates are reduced for small providers of services or suppliers who participated in the program and the extent of improper payments made as a result of the demonstration program. The Comptroller General shall submit a report to the Secretary and the Congress on such evaluation and shall include in such report recommendations regarding the continuation or extension of the demonstration program.

(e) FINANCIAL PARTICIPATION BY PROVIDERS.—The provision of technical assistance to a small provider of services or supplier under the demonstration program is conditioned upon the small provider of services or supplier paying an amount estimated (and disclosed in advance of a provider's or supplier's participation in the program) to be equal to 25 percent of the cost of the technical assistance.

(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated, from amounts not otherwise appropriated in the Treasury, such sums as may be necessary to carry out this section.

SEC. 923. MEDICARE BENEFICIARY OMBUDSMAN.

(a) IN GENERAL.—Section 1808, as added and amended by section 900, is amended by adding at the end the following new subsection:

''(c) MEDICARE BENEFICIARY OMBUDSMAN.—

''(1) IN GENERAL.—The Secretary shall appoint within the Department of Health and Human Services a Medicare Beneficiary Ombudsman who shall have expertise and experience in the fields of health care and education of (and assistance to) individuals entitled to benefits under this title.

''(2) DUTIES.—The Medicare Beneficiary Ombudsman shall—

''(A) receive complaints, grievances, and requests for information submitted by individuals entitled to benefits under part A or enrolled under part B, or both, with respect to any aspect of the medicare program;

''(B) provide assistance with respect to complaints, grievances, and requests referred to in subparagraph (A), including—

''(i) assistance in collecting relevant information for such individuals, to seek an appeal of a decision or determination made by a fiscal intermediary, carrier, MA organization, or the Secretary;

''(ii) assistance to such individuals with any problems arising from disenrollment from an MA plan under part C; and

''(iii) assistance to such individuals in presenting information under section 1839(i)(4)(C) (relating to income-related premium adjustment; and

''(C) submit annual reports to Congress and the Secretary that describe the activities of the Office and that include such recommendations for improvement in the administration of this title as the Ombudsman determines appropriate.

The Ombudsman shall not serve as an advocate for any increases in payments or new coverage of services, but may identify issues and problems in payment or coverage policies.

''(3) WORKING WITH HEALTH INSURANCE COUNSELING PROGRAMS.—To the extent possible, the Ombudsman shall work with health insurance counseling programs (receiving funding under section 4360 of Omnibus Budget Reconciliation Act of 1990) to facilitate the provision of information to individuals entitled to benefits under part A or enrolled under part B, or both regarding MA plans and changes to those plans. Nothing in this paragraph shall preclude further collaboration between the Ombudsman and such programs.''.

(b) DEADLINE FOR APPOINTMENT.—By not later than 1 year after the date of the enactment of this Act, the Secretary shall appoint the Medicare Beneficiary Ombudsman under section 1808(c) of the Social Security Act, as added by subsection (a).

(c) FUNDING.—There are authorized to be appropriated to the Secretary (in appropriate part from the Federal Hospital Insurance Trust Fund, established under section 1817 of the Social Security Act (42 U.S.C. 1395i), and the Federal Supplementary Medical Insurance Trust Fund, established under section 1841 of such Act (42 U.S.C. 1395t)) to carry out section 1808(c) of such Act (relating to the Medicare Beneficiary Ombudsman), as added by subsection (a), such sums as are necessary for fiscal year 2004 and each succeeding fiscal year.

(d) USE OF CENTRAL, TOLL-FREE NUMBER (1–800–MEDICARE).—

(1) PHONE TRIAGE SYSTEM; LISTING IN MEDICARE HANDBOOK INSTEAD OF OTHER TOLL-FREE NUMBERS.—Section 1804(b) (42 U.S.C. 1395b–2(b)) is amended by adding at the end the following: ''The Secretary shall provide, through the toll-free telephone number 1–800–MEDICARE, for a means by which individuals seeking information about, or assistance with, such programs who phone such toll-free number are transferred (without charge) to appropriate entities for the provision of such information or assistance. Such toll-free number shall be the toll-free number listed for general information and assistance in the annual notice under subsection (a) instead of the listing of numbers of individual contractors.''.

(2) MONITORING ACCURACY.—

(A) STUDY.—The Comptroller General of the United States shall conduct a study to monitor the accuracy and consistency of information provided to individuals entitled to benefits under part A or enrolled under part B, or both, through the toll-free telephone number 1–800–MEDICARE, including an assessment of whether the information provided is sufficient to answer questions of such individuals. In conducting the study, the Comptroller General shall examine the education and training of the individuals providing information through such number.

(B) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General shall submit to Congress a report on the study conducted under subparagraph (A).

SEC. 924. BENEFICIARY OUTREACH DEMONSTRATION PROGRAM.

(a) IN GENERAL.—The Secretary shall establish a demonstration program (in this section referred to as the ''demonstration program'') under which medicare specialists employed by the Department of Health and Human Services provide advice and assistance to individuals entitled to benefits under part A of title XVIII of the Social Security Act, or enrolled under part B of such title, or both, regarding the medicare program at the location of existing local offices of the Social Security Administration.

(b) LOCATIONS.—

(1) IN GENERAL.—The demonstration program shall be conducted in at least 6 offices or areas. Subject to paragraph (2), in selecting such offices and areas, the Secretary shall provide preference for offices with a high volume of visits by individuals referred to in subsection (a).

(2) ASSISTANCE FOR RURAL BENEFICIARIES.—The Secretary shall provide for the selection of at least 2 rural areas to participate in the demonstration program. In conducting the demonstration program in such rural areas, the Secretary shall provide for medicare specialists to travel among local offices in a rural area on a scheduled basis.

(c) DURATION.—The demonstration program shall be conducted over a 3-year period.

(d) EVALUATION AND REPORT.—

(1) EVALUATION.—The Secretary shall provide for an evaluation of the demonstration program. Such evaluation shall include an analysis of—

(A) utilization of, and satisfaction of those individuals referred to in subsection (a) with, the assistance provided under the program; and

(B) the cost-effectiveness of providing beneficiary assistance through out-stationing medicare specialists at local offices of the Social Security Administration.

(2) REPORT.—The Secretary shall submit to Congress a report on such evaluation and shall include in such report recommendations regarding the feasibility of permanently out-stationing medicare specialists at local offices of the Social Security Administration.

SEC. 925. INCLUSION OF ADDITIONAL INFORMATION IN NOTICES TO BENEFICIARIES ABOUT SKILLED NURSING FACILITY BENEFITS.

(a) IN GENERAL.—The Secretary shall provide that in medicare beneficiary notices provided (under section 1806(a) of the Social Security Act, 42 U.S.C. 1395b–7(a)) with respect to the provision of post-hospital extended care services under part A of title XVIII of the Social Security Act, there shall be included information on the number of days of coverage of such services remaining under such part for the medicare beneficiary and spell of illness involved.

(b) EFFECTIVE DATE.—Subsection (a) shall apply to notices provided during calendar quarters beginning more than 6 months after the date of the enactment of this Act.

SEC. 926. INFORMATION ON MEDICARE-CERTIFIED SKILLED NURSING FACILITIES IN HOSPITAL DISCHARGE PLANS.

(a) AVAILABILITY OF DATA.—The Secretary shall publicly provide information that enables hospital discharge planners, medicare beneficiaries, and the public to identify skilled nursing facilities that are participating in the medicare program.

(b) INCLUSION OF INFORMATION IN CERTAIN HOSPITAL DISCHARGE PLANS.—

(1) IN GENERAL.—Section 1861(ee)(2)(D) (42 U.S.C. 1395x(ee)(2)(D)) is amended—

(A) by striking ''hospice services'' and inserting ''hospice care and post-hospital extended care services''; and

(B) by inserting before the period at the end the following: ''and, in the case of individuals who are likely to need post-hospital extended care services, the availability of such services through facilities that participate in the program under this title and that serve the area in which the patient resides''.

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to discharge plans made on or after such date as the Secretary shall specify, but not later than 6 months after the date the Secretary provides for availability of information under subsection (a).

Subtitle D—Appeals and Recovery

SEC. 931. TRANSFER OF RESPONSIBILITY FOR MEDICARE APPEALS.

(a) TRANSITION PLAN.—

(1) IN GENERAL.—Not later than April 1, 2004, the Commissioner of Social Security and the

Secretary shall develop and transmit to Congress and the Comptroller General of the United States a plan under which the functions of administrative law judges responsible for hearing cases under title XVIII of the Social Security Act (and related provisions in title XI of such Act) are transferred from the responsibility of the Commissioner and the Social Security Administration to the Secretary and the Department of Health and Human Services.

(2) CONTENTS.—The plan shall include information on the following:

(A) WORKLOAD.—The number of such administrative law judges and support staff required now and in the future to hear and decide such cases in a timely manner, taking into account the current and anticipated claims volume, appeals, number of beneficiaries, and statutory changes.

(B) COST PROJECTIONS AND FINANCING.—Funding levels required for fiscal year 2005 and subsequent fiscal years to carry out the functions transferred under the plan.

(C) TRANSITION TIMETABLE.—A timetable for the transition.

(D) REGULATIONS.—The establishment of specific regulations to govern the appeals process.

(E) CASE TRACKING.—The development of a unified case tracking system that will facilitate the maintenance and transfer of case specific data across both the fee-for-service and managed care components of the medicare program.

(F) FEASIBILITY OF PRECEDENTIAL AUTHORITY.—The feasibility of developing a process to give decisions of the Departmental Appeals Board in the Department of Health and Human Services addressing broad legal issues binding, precedential authority.

(G) ACCESS TO ADMINISTRATIVE LAW JUDGES.—The feasibility of—

(i) filing appeals with administrative law judges electronically; and

(ii) conducting hearings using tele- or videoconference technologies.

(H) INDEPENDENCE OF ADMINISTRATIVE LAW JUDGES.—The steps that should be taken to ensure the independence of administrative law judges consistent with the requirements of subsection (b)(2).

(I) GEOGRAPHIC DISTRIBUTION.—The steps that should be taken to provide for an appropriate geographic distribution of administrative law judges throughout the United States to carry out subsection (b)(3).

(J) HIRING.—The steps that should be taken to hire administrative law judges (and support staff) to carry out subsection (b)(4).

(K) PERFORMANCE STANDARDS.—The appropriateness of establishing performance standards for administrative law judges with respect to timelines for decisions in cases under title XVIII of the Social Security Act taking into account requirements under subsection (b)(2) for the independence of such judges and consistent with the applicable provisions of title 5, United States Code relating to impartiality.

(L) SHARED RESOURCES.—The steps that should be taken to carry out subsection (b)(6) (relating to the arrangements with the Commissioner of Social Security to share office space, support staff, and other resources, with appropriate reimbursement).

(M) TRAINING.—The training that should be provided to administrative law judges with respect to laws and regulations under title XVIII of the Social Security Act.

(3) ADDITIONAL INFORMATION.—The plan may also include recommendations for further congressional action, including modifications to the requirements and deadlines established under section 1869 of the Social Security Act (42 U.S.C. 1395ff) (as amended by this Act).

(4) GAO EVALUATION.—The Comptroller General of the United States shall evaluate the plan and, not later than the date that is 6 months after the date on which the plan is received by the Comptroller General, shall submit to Congress a report on such evaluation.

(b) TRANSFER OF ADJUDICATION AUTHORITY.—

(1) IN GENERAL.—Not earlier than July 1, 2005, and not later than October 1, 2005, the Commissioner of Social Security and the Secretary shall implement the transition plan under subsection (a) and transfer the administrative law judge functions described in such subsection from the Social Security Administration to the Secretary.

(2) ASSURING INDEPENDENCE OF JUDGES.—The Secretary shall assure the independence of administrative law judges performing the administrative law judge functions transferred under paragraph (1) from the Centers for Medicare & Medicaid Services and its contractors. In order to assure such independence, the Secretary shall place such judges in an administrative office that is organizationally and functionally separate from such Centers. Such judges shall report to, and be under the general supervision of, the Secretary, but shall not report to, or be subject to supervision by, another officer of the Department of Health and Human Services.

(3) GEOGRAPHIC DISTRIBUTION.—The Secretary shall provide for an appropriate geographic distribution of administrative law judges performing the administrative law judge functions transferred under paragraph (1) throughout the United States to ensure timely access to such judges.

(4) HIRING AUTHORITY.—Subject to the amounts provided in advance in appropriations Acts, the Secretary shall have authority to hire administrative law judges to hear such cases, taking into consideration those judges with expertise in handling medicare appeals and in a manner consistent with paragraph (3), and to hire support staff for such judges.

(5) FINANCING.—Amounts payable under law to the Commissioner for administrative law judges performing the administrative law judge functions transferred under paragraph (1) from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund shall become payable to the Secretary for the functions so transferred.

(6) SHARED RESOURCES.—The Secretary shall enter into such arrangements with the Commissioner as may be appropriate with respect to transferred functions of administrative law judges to share office space, support staff, and other resources, with appropriate reimbursement from the Trust Funds described in paragraph (5).

(c) INCREASED FINANCIAL SUPPORT.—In addition to any amounts otherwise appropriated, to ensure timely action on appeals before administrative law judges and the Departmental Appeals Board consistent with section 1869 of the Social Security Act (42 U.S.C. 1395ff) (as amended by this Act), there are authorized to be appropriated (in appropriate part from the Federal Hospital Insurance Trust Fund, established under section 1817 of the Social Security Act (42 U.S.C. 1395i), and the Federal Supplementary Medical Insurance Trust Fund, established under section 1841 of such Act (42 U.S.C. 1395t)) to the Secretary such sums as are necessary for fiscal year 2005 and each subsequent fiscal year to—

(1) increase the number of administrative law judges (and their staffs) under subsection (b)(4);

(2) improve education and training opportunities for administrative law judges (and their staffs); and

(3) increase the staff of the Departmental Appeals Board.

(d) CONFORMING AMENDMENT.—Section 1869(f)(2)(A)(i) (42 U.S.C. 1395ff(f)(2)(A)(i)) is amended by striking ''of the Social Security Administration''.

SEC. 932. PROCESS FOR EXPEDITED ACCESS TO REVIEW.

(a) EXPEDITED ACCESS TO JUDICIAL REVIEW.—

(1) IN GENERAL.—Section 1869(b) (42 U.S.C. 1395ff(b)) is amended—

(A) in paragraph (1)(A), by inserting '', subject to paragraph (2),'' before ''to judicial review of the Secretary's final decision''; and

(B) by adding at the end the following new paragraph:

''(2) EXPEDITED ACCESS TO JUDICIAL REVIEW.—

''(A) IN GENERAL.—The Secretary shall establish a process under which a provider of services or supplier that furnishes an item or service or an individual entitled to benefits under part A or enrolled under part B, or both, who has filed an appeal under paragraph (1) (other than an appeal filed under paragraph (1)(F)(i)) may obtain access to judicial review when a review entity (described in subparagraph (D)), on its own motion or at the request of the appellant, determines that the Departmental Appeals Board does not have the authority to decide the question of law or regulation relevant to the matters in controversy and that there is no material issue of fact in dispute. The appellant may make such request only once with respect to a question of law or regulation for a specific matter in dispute in a case of an appeal.

''(B) PROMPT DETERMINATIONS.—If, after or coincident with appropriately filing a request for an administrative hearing, the appellant requests a determination by the appropriate review entity that the Departmental Appeals Board does not have the authority to decide the question of law or regulations relevant to the matters in controversy and that there is no material issue of fact in dispute, and if such request is accompanied by the documents and materials as the appropriate review entity shall require for purposes of making such determination, such review entity shall make a determination on the request in writing within 60 days after the date such review entity receives the request and such accompanying documents and materials. Such a determination by such review entity shall be considered a final decision and not subject to review by the Secretary.

''(C) ACCESS TO JUDICIAL REVIEW.—

''(i) IN GENERAL.—If the appropriate review entity—

''(I) determines that there are no material issues of fact in dispute and that the only issues to be adjudicated are ones of law or regulation that the Departmental Appeals Board does not have authority to decide; or

''(II) fails to make such determination within the period provided under subparagraph (B),

then the appellant may bring a civil action as described in this subparagraph.

''(ii) DEADLINE FOR FILING.—Such action shall be filed, in the case described in—

''(I) clause (i)(I), within 60 days of the date of the determination described in such clause; or

''(II) clause (i)(II), within 60 days of the end of the period provided under subparagraph (B) for the determination.

''(iii) VENUE.—Such action shall be brought in the district court of the United States for the judicial district in which the appellant is located (or, in the case of an action brought jointly by more than one applicant, the judicial district in which the greatest number of applicants are located) or in the District Court for the District of Columbia.

''(iv) INTEREST ON ANY AMOUNTS IN CONTROVERSY.—Where a provider of services or supplier is granted judicial review pursuant to this paragraph, the amount in controversy (if any) shall be subject to annual interest beginning on the first day of the first month beginning after the 60-day period as determined pursuant to clause (ii) and equal to the rate of interest on obligations issued for purchase by the Federal Supplementary Medical Insurance Trust Fund for the month in which the civil action authorized under this paragraph is commenced, to be awarded by the reviewing court in favor of the prevailing party. No interest awarded pursuant to the preceding sentence shall be deemed income or cost for the purposes of determining reimbursement due providers of services or suppliers under this title.

''(D) REVIEW ENTITY DEFINED.—For purposes of this subsection, the term 'review entity' means an entity of up to three reviewers who

are administrative law judges or members of the Departmental Appeals Board selected for purposes of making determinations under this paragraph.''.

(2) CONFORMING AMENDMENT.—Section 1869(b)(1)(F)(ii) (42 U.S.C. 1395ff(b)(1)(F)(ii)) is amended to read as follows:

''(ii) REFERENCE TO EXPEDITED ACCESS TO JUDICIAL REVIEW.—For the provision relating to expedited access to judicial review, see paragraph (2).''.

(b) APPLICATION TO PROVIDER AGREEMENT DETERMINATIONS.—Section 1866(h)(1) (42 U.S.C. 1395cc(h)(1)) is amended—

(1) by inserting ''(A)'' after ''(h)(1)''; and

(2) by adding at the end the following new subparagraph:

''(B) An institution or agency described in subparagraph (A) that has filed for a hearing under subparagraph (A) shall have expedited access to judicial review under this subparagraph in the same manner as providers of services, suppliers, and individuals entitled to benefits under part A or enrolled under part B, or both, may obtain expedited access to judicial review under the process established under section 1869(b)(2). Nothing in this subparagraph shall be construed to affect the application of any remedy imposed under section 1819 during the pendency of an appeal under this subparagraph.''.

(c) EXPEDITED REVIEW OF CERTAIN PROVIDER AGREEMENT DETERMINATIONS.—

(1) TERMINATION AND CERTAIN OTHER IMMEDIATE REMEDIES.—Section 1866(h)(1) (42 U.S.C. 1395cc(h)(1)), as amended by subsection (b), is amended by adding at the end the following new subparagraph:

''(C)(i) The Secretary shall develop and implement a process to expedite proceedings under this subsection in which—

''(I) the remedy of termination of participation has been imposed;

''(II) a remedy described in clause (i) or (iii) of section 1819(h)(2)(B) has been imposed, but only if such remedy has been imposed on an immediate basis; or

''(III) a determination has been made as to a finding of substandard quality of care that results in the loss of approval of a skilled nursing facility's nurse aide training program.

''(ii) Under such process under clause (i), priority shall be provided in cases of termination described in clause (i)(I).

''(iii) Nothing in this subparagraph shall be construed to affect the application of any remedy imposed under section 1819 during the pendency of an appeal under this subparagraph.''.

(2) WAIVER OF DISAPPROVAL OF NURSE-AIDE TRAINING PROGRAMS.—Sections 1819(f)(2) and section 1919(f)(2) (42 U.S.C. 1395i–3(f)(2) and 1396r(f)(2)) are each amended—

(A) in subparagraph (B)(iii), by striking ''subparagraph (C)'' and inserting ''subparagraphs (C) and (D)''; and

(B) by adding at the end the following new subparagraph:

''(D) WAIVER OF DISAPPROVAL OF NURSE-AIDE TRAINING PROGRAMS.—Upon application of a nursing facility, the Secretary may waive the application of subparagraph (B)(iii)(I)(c) if the imposition of the civil monetary penalty was not related to the quality of care provided to residents of the facility. Nothing in this subparagraph shall be construed as eliminating any requirement upon a facility to pay a civil monetary penalty described in the preceding sentence.''.

(3) INCREASED FINANCIAL SUPPORT.—In addition to any amounts otherwise appropriated, to reduce by 50 percent the average time for administrative determinations on appeals under section 1866(h) of the Social Security Act (42 U.S.C. 1395cc(h)), there are authorized to be appropriated (in appropriate part from the Federal Hospital Insurance Trust Fund, established under section 1817 of the Social Security Act (42 U.S.C. 1395i), and the Federal Supplementary Medical Insurance Trust Fund, established under section 1841 of such Act (42 U.S.C. 1395t)) to the Secretary such additional sums for fiscal year 2004 and each subsequent fiscal year as may be necessary. The purposes for which such amounts are available include increasing the number of administrative law judges (and their staffs) and the appellate level staff at the Departmental Appeals Board of the Department of Health and Human Services and educating such judges and staffs on long-term care issues.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to appeals filed on or after October 1, 2004.

SEC. 933. REVISIONS TO MEDICARE APPEALS PROCESS.

(a) REQUIRING FULL AND EARLY PRESENTATION OF EVIDENCE.—

(1) IN GENERAL.—Section 1869(b) (42 U.S.C. 1395ff(b)), as amended by section 932(a), is further amended by adding at the end the following new paragraph:

''(3) REQUIRING FULL AND EARLY PRESENTATION OF EVIDENCE BY PROVIDERS.—A provider of services or supplier may not introduce evidence in any appeal under this section that was not presented at the reconsideration conducted by the qualified independent contractor under subsection (c), unless there is good cause which precluded the introduction of such evidence at or before that reconsideration.''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on October 1, 2004.

(b) USE OF PATIENTS' MEDICAL RECORDS.—Section 1869(c)(3)(B)(i) (42 U.S.C. 1395ff(c)(3)(B)(i)) is amended by inserting ''(including the medical records of the individual involved)'' after ''clinical experience''.

(c) NOTICE REQUIREMENTS FOR MEDICARE APPEALS.—

(1) INITIAL DETERMINATIONS AND REDETERMINATIONS.—Section 1869(a) (42 U.S.C. 1395ff(a)) is amended by adding at the end the following new paragraphs:

''(4) REQUIREMENTS OF NOTICE OF DETERMINATIONS.—With respect to an initial determination insofar as it results in a denial of a claim for benefits—

''(A) the written notice on the determination shall include—

''(i) the reasons for the determination, including whether a local medical review policy or a local coverage determination was used;

''(ii) the procedures for obtaining additional information concerning the determination, including the information described in subparagraph (B); and

''(iii) notification of the right to seek a redetermination or otherwise appeal the determination and instructions on how to initiate such a redetermination under this section;

''(B) such written notice shall be provided in printed form and written in a manner calculated to be understood by the individual entitled to benefits under part A or enrolled under part B, or both; and

''(C) the individual provided such written notice may obtain, upon request, information on the specific provision of the policy, manual, or regulation used in making the redetermination.

''(5) REQUIREMENTS OF NOTICE OF REDETERMINATIONS.—With respect to a redetermination insofar as it results in a denial of a claim for benefits—

''(A) the written notice on the redetermination shall include—

''(i) the specific reasons for the redetermination;

''(ii) as appropriate, a summary of the clinical or scientific evidence used in making the redetermination;

''(iii) a description of the procedures for obtaining additional information concerning the redetermination; and

''(iv) notification of the right to appeal the redetermination and instructions on how to initiate such an appeal under this section;

''(B) such written notice shall be provided in printed form and written in a manner calculated to be understood by the individual entitled to benefits under part A or enrolled under part B, or both; and

''(C) the individual provided such written notice may obtain, upon request, information on the specific provision of the policy, manual, or regulation used in making the redetermination.''.

(2) RECONSIDERATIONS.—Section 1869(c)(3)(E) (42 U.S.C. 1395ff(c)(3)(E)) is amended—

(A) by inserting ''be written in a manner calculated to be understood by the individual entitled to benefits under part A or enrolled under part B, or both, and shall include (to the extent appropriate)'' after ''in writing,''; and

(B) by inserting ''and a notification of the right to appeal such determination and instructions on how to initiate such appeal under this section'' after ''such decision,''.

(3) APPEALS.—Section 1869(d) (42 U.S.C. 1395ff(d)) is amended—

(A) in the heading, by inserting ''; NOTICE'' after ''SECRETARY''; and

(B) by adding at the end the following new paragraph:

''(4) NOTICE.—Notice of the decision of an administrative law judge shall be in writing in a manner calculated to be understood by the individual entitled to benefits under part A or enrolled under part B, or both, and shall include—

''(A) the specific reasons for the determination (including, to the extent appropriate, a summary of the clinical or scientific evidence used in making the determination);

''(B) the procedures for obtaining additional information concerning the decision; and

''(C) notification of the right to appeal the decision and instructions on how to initiate such an appeal under this section.''.

(4) SUBMISSION OF RECORD FOR APPEAL.—Section 1869(c)(3)(J)(i) (42 U.S.C. 1395ff(c)(3)(J)(i)) is amended by striking ''prepare'' and inserting ''submit'' and by striking ''with respect to'' and all that follows through ''and relevant policies''.

(d) QUALIFIED INDEPENDENT CONTRACTORS.—

(1) ELIGIBILITY REQUIREMENTS OF QUALIFIED INDEPENDENT CONTRACTORS.—Section 1869(c)(3) (42 U.S.C. 1395ff(c)(3)) is amended—

(A) in subparagraph (A), by striking ''sufficient training and expertise in medical science and legal matters'' and inserting ''sufficient medical, legal, and other expertise (including knowledge of the program under this title) and sufficient staffing''; and

(B) by adding at the end the following new subparagraph:

''(K) INDEPENDENCE REQUIREMENTS.—

''(i) IN GENERAL.—Subject to clause (ii), a qualified independent contractor shall not conduct any activities in a case unless the entity—

''(I) is not a related party (as defined in subsection (g)(5));

''(II) does not have a material familial, financial, or professional relationship with such a party in relation to such case; and

''(III) does not otherwise have a conflict of interest with such a party.

''(ii) EXCEPTION FOR REASONABLE COMPENSATION.—Nothing in clause (i) shall be construed to prohibit receipt by a qualified independent contractor of compensation from the Secretary for the conduct of activities under this section if the compensation is provided consistent with clause (iii).

''(iii) LIMITATIONS ON ENTITY COMPENSATION.—Compensation provided by the Secretary to a qualified independent contractor in connection with reviews under this section shall not be contingent on any decision rendered by the contractor or by any reviewing professional.''.

(2) ELIGIBILITY REQUIREMENTS FOR REVIEWERS.—Section 1869 (42 U.S.C. 1395ff) is amended—

(A) by amending subsection (c)(3)(D) to read as follows:

''(D) QUALIFICATIONS FOR REVIEWERS.—The requirements of subsection (g) shall be met (relating to qualifications of reviewing professionals).''; and

(B) by adding at the end the following new subsection:

''(g) QUALIFICATIONS OF REVIEWERS.—

''(1) IN GENERAL.—In reviewing determinations under this section, a qualified independent contractor shall assure that—

''(A) each individual conducting a review shall meet the qualifications of paragraph (2);

''(B) compensation provided by the contractor to each such reviewer is consistent with paragraph (3); and

''(C) in the case of a review by a panel described in subsection (c)(3)(B) composed of physicians or other health care professionals (each in this subsection referred to as a 'reviewing professional'), a reviewing professional meets the qualifications described in paragraph (4) and, where a claim is regarding the furnishing of treatment by a physician (allopathic or osteopathic) or the provision of items or services by a physician (allopathic or osteopathic), a reviewing professional shall be a physician (allopathic or osteopathic).

''(2) INDEPENDENCE.—

''(A) IN GENERAL.—Subject to subparagraph (B), each individual conducting a review in a case shall—

''(i) not be a related party (as defined in paragraph (5));

''(ii) not have a material familial, financial, or professional relationship with such a party in the case under review; and

''(iii) not otherwise have a conflict of interest with such a party.

''(B) EXCEPTION.—Nothing in subparagraph (A) shall be construed to—

''(i) prohibit an individual, solely on the basis of a participation agreement with a fiscal intermediary, carrier, or other contractor, from serving as a reviewing professional if—

''(I) the individual is not involved in the provision of items or services in the case under review;

''(II) the fact of such an agreement is disclosed to the Secretary and the individual entitled to benefits under part A or enrolled under part B, or both, or such individual's authorized representative, and neither party objects; and

''(III) the individual is not an employee of the intermediary, carrier, or contractor and does not provide services exclusively or primarily to or on behalf of such intermediary, carrier, or contractor;

''(ii) prohibit an individual who has staff privileges at the institution where the treatment involved takes place from serving as a reviewer merely on the basis of having such staff privileges if the existence of such privileges is disclosed to the Secretary and such individual (or authorized representative), and neither party objects; or

''(iii) prohibit receipt of compensation by a reviewing professional from a contractor if the compensation is provided consistent with paragraph (3).

For purposes of this paragraph, the term 'participation agreement' means an agreement relating to the provision of health care services by the individual and does not include the provision of services as a reviewer under this subsection.

''(3) LIMITATIONS ON REVIEWER COMPENSATION.—Compensation provided by a qualified independent contractor to a reviewer in connection with a review under this section shall not be contingent on the decision rendered by the reviewer.

''(4) LICENSURE AND EXPERTISE.—Each reviewing professional shall be—

''(A) a physician (allopathic or osteopathic) who is appropriately credentialed or licensed in one or more States to deliver health care services and has medical expertise in the field of practice that is appropriate for the items or services at issue; or

''(B) a health care professional who is legally authorized in one or more States (in accordance with State law or the State regulatory mechanism provided by State law) to furnish the health care items or services at issue and has medical expertise in the field of practice that is appropriate for such items or services.

''(5) RELATED PARTY DEFINED.—For purposes of this section, the term 'related party' means, with respect to a case under this title involving a specific individual entitled to benefits under part A or enrolled under part B, or both, any of the following:

''(A) The Secretary, the medicare administrative contractor involved, or any fiduciary, officer, director, or employee of the Department of Health and Human Services, or of such contractor.

''(B) The individual (or authorized representative).

''(C) The health care professional that provides the items or services involved in the case.

''(D) The institution at which the items or services (or treatment) involved in the case are provided.

''(E) The manufacturer of any drug or other item that is included in the items or services involved in the case.

''(F) Any other party determined under any regulations to have a substantial interest in the case involved.''.

(3) REDUCING MINIMUM NUMBER OF QUALIFIED INDEPENDENT CONTRACTORS.—Section 1869(c)(4) (42 U.S.C. 1395ff(c)(4)) is amended by striking ''not fewer than 12 qualified independent contractors under this subsection'' and inserting ''a sufficient number of qualified independent contractors (but not fewer than 4 such contractors) to conduct reconsiderations consistent with the timeframes applicable under this subsection''.

(4) EFFECTIVE DATE.—The amendments made by paragraphs (1) and (2) shall be effective as if included in the enactment of the respective provisions of subtitle C of title V of BIPA (114 Stat. 2763A–534).

(5) TRANSITION.—In applying section 1869(g) of the Social Security Act (as added by paragraph (2)), any reference to a medicare administrative contractor shall be deemed to include a reference to a fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and a carrier under section 1842 of such Act (42 U.S.C. 1395u).

SEC. 934. PREPAYMENT REVIEW.

(a) IN GENERAL.—Section 1874A, as added by section 911(a)(1) and as amended by sections 912(b), 921(b)(1), and 921(c)(1), is further amended by adding at the end the following new subsection:

''(h) CONDUCT OF PREPAYMENT REVIEW.—

''(1) CONDUCT OF RANDOM PREPAYMENT REVIEW.—

''(A) IN GENERAL.—A medicare administrative contractor may conduct random prepayment review only to develop a contractor-wide or program-wide claims payment error rates or under such additional circumstances as may be provided under regulations, developed in consultation with providers of services and suppliers.

''(B) USE OF STANDARD PROTOCOLS WHEN CONDUCTING PREPAYMENT REVIEWS.—When a medicare administrative contractor conducts a random prepayment review, the contractor may conduct such review only in accordance with a standard protocol for random prepayment audits developed by the Secretary.

''(C) CONSTRUCTION.—Nothing in this paragraph shall be construed as preventing the denial of payments for claims actually reviewed under a random prepayment review.

''(D) RANDOM PREPAYMENT REVIEW.—For purposes of this subsection, the term 'random prepayment review' means a demand for the production of records or documentation absent cause with respect to a claim.

''(2) LIMITATIONS ON NON-RANDOM PREPAYMENT REVIEW.—

''(A) LIMITATIONS ON INITIATION OF NON-RANDOM PREPAYMENT REVIEW.—A medicare administrative contractor may not initiate non-random prepayment review of a provider of services or supplier based on the initial identification by that provider of services or supplier of an improper billing practice unless there is a likelihood of sustained or high level of payment error under section 1893(f)(3)(A).

''(B) TERMINATION OF NON-RANDOM PREPAYMENT REVIEW.—The Secretary shall issue regulations relating to the termination, including termination dates, of non-random prepayment review. Such regulations may vary such a termination date based upon the differences in the circumstances triggering prepayment review.''.

(b) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as provided in this subsection, the amendment made by subsection (a) shall take effect 1 year after the date of the enactment of this Act.

(2) DEADLINE FOR PROMULGATION OF CERTAIN REGULATIONS.—The Secretary shall first issue regulations under section 1874A(h) of the Social Security Act, as added by subsection (a), by not later than 1 year after the date of the enactment of this Act.

(3) APPLICATION OF STANDARD PROTOCOLS FOR RANDOM PREPAYMENT REVIEW.—Section 1874A(h)(1)(B) of the Social Security Act, as added by subsection (a), shall apply to random prepayment reviews conducted on or after such date (not later than 1 year after the date of the enactment of this Act) as the Secretary shall specify.

(c) APPLICATION TO FISCAL INTERMEDIARIES AND CARRIERS.—The provisions of section 1874A(h) of the Social Security Act, as added by subsection (a), shall apply to each fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and each carrier under section 1842 of such Act (42 U.S.C. 1395u) in the same manner as they apply to medicare administrative contractors under such provisions.

SEC. 935. RECOVERY OF OVERPAYMENTS.

(a) IN GENERAL.—Section 1893 (42 U.S.C. 1395ddd) is amended by adding at the end the following new subsection:

''(f) RECOVERY OF OVERPAYMENTS.—

''(1) USE OF REPAYMENT PLANS.—

''(A) IN GENERAL.—If the repayment, within 30 days by a provider of services or supplier, of an overpayment under this title would constitute a hardship (as described in subparagraph (B)), subject to subparagraph (C), upon request of the provider of services or supplier the Secretary shall enter into a plan with the provider of services or supplier for the repayment (through offset or otherwise) of such overpayment over a period of at least 6 months but not longer than 3 years (or not longer than 5 years in the case of extreme hardship, as determined by the Secretary). Interest shall accrue on the balance through the period of repayment. Such plan shall meet terms and conditions determined to be appropriate by the Secretary.

''(B) HARDSHIP.—

''(i) IN GENERAL.—For purposes of subparagraph (A), the repayment of an overpayment (or overpayments) within 30 days is deemed to constitute a hardship if—

''(I) in the case of a provider of services that files cost reports, the aggregate amount of the overpayments exceeds 10 percent of the amount paid under this title to the provider of services for the cost reporting period covered by the most recently submitted cost report; or

''(II) in the case of another provider of services or supplier, the aggregate amount of the overpayments exceeds 10 percent of the amount paid under this title to the provider of services or supplier for the previous calendar year.

''(ii) RULE OF APPLICATION.—The Secretary shall establish rules for the application of this

subparagraph in the case of a provider of services or supplier that was not paid under this title during the previous year or was paid under this title only during a portion of that year.

''(iii) TREATMENT OF PREVIOUS OVERPAYMENTS.—If a provider of services or supplier has entered into a repayment plan under subparagraph (A) with respect to a specific overpayment amount, such payment amount under the repayment plan shall not be taken into account under clause (i) with respect to subsequent overpayment amounts.

''(C) EXCEPTIONS.—Subparagraph (A) shall not apply if—

''(i) the Secretary has reason to suspect that the provider of services or supplier may file for bankruptcy or otherwise cease to do business or discontinue participation in the program under this title; or

''(ii) there is an indication of fraud or abuse committed against the program.

''(D) IMMEDIATE COLLECTION IF VIOLATION OF REPAYMENT PLAN.—If a provider of services or supplier fails to make a payment in accordance with a repayment plan under this paragraph, the Secretary may immediately seek to offset or otherwise recover the total balance outstanding (including applicable interest) under the repayment plan.

''(E) RELATION TO NO FAULT PROVISION.—Nothing in this paragraph shall be construed as affecting the application of section 1870(c) (relating to no adjustment in the cases of certain overpayments).

''(2) LIMITATION ON RECOUPMENT.—

''(A) IN GENERAL.—In the case of a provider of services or supplier that is determined to have received an overpayment under this title and that seeks a reconsideration by a qualified independent contractor on such determination under section 1869(b)(1), the Secretary may not take any action (or authorize any other person, including any medicare contractor, as defined in subparagraph (C)) to recoup the overpayment until the date the decision on the reconsideration has been rendered. If the provisions of section 1869(b)(1) (providing for such a reconsideration by a qualified independent contractor) are not in effect, in applying the previous sentence any reference to such a reconsideration shall be treated as a reference to a redetermination by the fiscal intermediary or carrier involved.

''(B) COLLECTION WITH INTEREST.—Insofar as the determination on such appeal is against the provider of services or supplier, interest on the overpayment shall accrue on and after the date of the original notice of overpayment. Insofar as such determination against the provider of services or supplier is later reversed, the Secretary shall provide for repayment of the amount recouped plus interest at the same rate as would apply under the previous sentence for the period in which the amount was recouped.

''(C) MEDICARE CONTRACTOR DEFINED.—For purposes of this subsection, the term 'medicare contractor' has the meaning given such term in section 1889(g).

''(3) LIMITATION ON USE OF EXTRAPOLATION.—A medicare contractor may not use extrapolation to determine overpayment amounts to be recovered by recoupment, offset, or otherwise unless the Secretary determines that—

''(A) there is a sustained or high level of payment error; or

''(B) documented educational intervention has failed to correct the payment error.

There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of determinations by the Secretary of sustained or high levels of payment errors under this paragraph.

''(4) PROVISION OF SUPPORTING DOCUMENTATION.—In the case of a provider of services or supplier with respect to which amounts were previously overpaid, a medicare contractor may request the periodic production of records or supporting documentation for a limited sample of submitted claims to ensure that the previous practice is not continuing.

''(5) CONSENT SETTLEMENT REFORMS.—

''(A) IN GENERAL.—The Secretary may use a consent settlement (as defined in subparagraph (D)) to settle a projected overpayment.

''(B) OPPORTUNITY TO SUBMIT ADDITIONAL INFORMATION BEFORE CONSENT SETTLEMENT OFFER.—Before offering a provider of services or supplier a consent settlement, the Secretary shall—

''(i) communicate to the provider of services or supplier—

''(I) that, based on a review of the medical records requested by the Secretary, a preliminary evaluation of those records indicates that there would be an overpayment;

''(II) the nature of the problems identified in such evaluation; and

''(III) the steps that the provider of services or supplier should take to address the problems; and

''(ii) provide for a 45-day period during which the provider of services or supplier may furnish additional information concerning the medical records for the claims that had been reviewed.

''(C) CONSENT SETTLEMENT OFFER.—The Secretary shall review any additional information furnished by the provider of services or supplier under subparagraph (B)(ii). Taking into consideration such information, the Secretary shall determine if there still appears to be an overpayment. If so, the Secretary—

''(i) shall provide notice of such determination to the provider of services or supplier, including an explanation of the reason for such determination; and

''(ii) in order to resolve the overpayment, may offer the provider of services or supplier—

''(I) the opportunity for a statistically valid random sample; or

''(II) a consent settlement.

The opportunity provided under clause (ii)(I) does not waive any appeal rights with respect to the alleged overpayment involved.

''(D) CONSENT SETTLEMENT DEFINED.—For purposes of this paragraph, the term 'consent settlement' means an agreement between the Secretary and a provider of services or supplier whereby both parties agree to settle a projected overpayment based on less than a statistically valid sample of claims and the provider of services or supplier agrees not to appeal the claims involved.

''(6) NOTICE OF OVER-UTILIZATION OF CODES.—The Secretary shall establish, in consultation with organizations representing the classes of providers of services and suppliers, a process under which the Secretary provides for notice to classes of providers of services and suppliers served by the contractor in cases in which the contractor has identified that particular billing codes may be overutilized by that class of providers of services or suppliers under the programs under this title (or provisions of title XI insofar as they relate to such programs).

''(7) PAYMENT AUDITS.—

''(A) WRITTEN NOTICE FOR POST-PAYMENT AUDITS.—Subject to subparagraph (C), if a medicare contractor decides to conduct a post-payment audit of a provider of services or supplier under this title, the contractor shall provide the provider of services or supplier with written notice (which may be in electronic form) of the intent to conduct such an audit.

''(B) EXPLANATION OF FINDINGS FOR ALL AUDITS.—Subject to subparagraph (C), if a medicare contractor audits a provider of services or supplier under this title, the contractor shall—

''(i) give the provider of services or supplier a full review and explanation of the findings of the audit in a manner that is understandable to the provider of services or supplier and permits the development of an appropriate corrective action plan;

''(ii) inform the provider of services or supplier of the appeal rights under this title as well as consent settlement options (which are at the discretion of the Secretary);

''(iii) give the provider of services or supplier an opportunity to provide additional information to the contractor; and

''(iv) take into account information provided, on a timely basis, by the provider of services or supplier under clause (iii).

''(C) EXCEPTION.—Subparagraphs (A) and (B) shall not apply if the provision of notice or findings would compromise pending law enforcement activities, whether civil or criminal, or reveal findings of law enforcement-related audits.

''(8) STANDARD METHODOLOGY FOR PROBE SAMPLING.—The Secretary shall establish a standard methodology for medicare contractors to use in selecting a sample of claims for review in the case of an abnormal billing pattern.''.

(b) EFFECTIVE DATES AND DEADLINES.—

(1) USE OF REPAYMENT PLANS.—Section 1893(f)(1) of the Social Security Act, as added by subsection (a), shall apply to requests for repayment plans made after the date of the enactment of this Act.

(2) LIMITATION ON RECOUPMENT.—Section 1893(f)(2) of the Social Security Act, as added by subsection (a), shall apply to actions taken after the date of the enactment of this Act.

(3) USE OF EXTRAPOLATION.—Section 1893(f)(3) of the Social Security Act, as added by subsection (a), shall apply to statistically valid random samples initiated after the date that is 1 year after the date of the enactment of this Act.

(4) PROVISION OF SUPPORTING DOCUMENTATION.—Section 1893(f)(4) of the Social Security Act, as added by subsection (a), shall take effect on the date of the enactment of this Act.

(5) CONSENT SETTLEMENT.—Section 1893(f)(5) of the Social Security Act, as added by subsection (a), shall apply to consent settlements entered into after the date of the enactment of this Act.

(6) NOTICE OF OVERUTILIZATION.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall first establish the process for notice of overutilization of billing codes under section 1893A(f)(6) of the Social Security Act, as added by subsection (a).

(7) PAYMENT AUDITS.—Section 1893A(f)(7) of the Social Security Act, as added by subsection (a), shall apply to audits initiated after the date of the enactment of this Act.

(8) STANDARD FOR ABNORMAL BILLING PATTERNS.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall first establish a standard methodology for selection of sample claims for abnormal billing patterns under section 1893(f)(8) of the Social Security Act, as added by subsection (a).

SEC. 936. PROVIDER ENROLLMENT PROCESS; RIGHT OF APPEAL.

(a) IN GENERAL.—Section 1866 (42 U.S.C. 1395cc) is amended—

(1) by adding at the end of the heading the following: ''; ENROLLMENT PROCESSES''; and

(2) by adding at the end the following new subsection:

''(j) ENROLLMENT PROCESS FOR PROVIDERS OF SERVICES AND SUPPLIERS.—

''(1) ENROLLMENT PROCESS.—

''(A) IN GENERAL.—The Secretary shall establish by regulation a process for the enrollment of providers of services and suppliers under this title.

''(B) DEADLINES.—The Secretary shall establish by regulation procedures under which there are deadlines for actions on applications for enrollment (and, if applicable, renewal of enrollment). The Secretary shall monitor the performance of medicare administrative contractors in meeting the deadlines established under this subparagraph.

''(C) CONSULTATION BEFORE CHANGING PROVIDER ENROLLMENT FORMS.—The Secretary shall consult with providers of services and suppliers before making changes in the provider enrollment forms required of such providers and suppliers to be eligible to submit claims for which payment may be made under this title.

''(2) HEARING RIGHTS IN CASES OF DENIAL OR NON-RENEWAL.—A provider of services or supplier whose application to enroll (or, if applicable, to renew enrollment) under this title is denied may have a hearing and judicial review of such denial under the procedures that apply under subsection (h)(1)(A) to a provider of services that is dissatisfied with a determination by the Secretary.''.

(b) EFFECTIVE DATES.—

(1) ENROLLMENT PROCESS.—The Secretary shall provide for the establishment of the enrollment process under section 1866(j)(1) of the Social Security Act, as added by subsection (a)(2), within 6 months after the date of the enactment of this Act.

(2) CONSULTATION.—Section 1866(j)(1)(C) of the Social Security Act, as added by subsection (a)(2), shall apply with respect to changes in provider enrollment forms made on or after January 1, 2004.

(3) HEARING RIGHTS.—Section 1866(j)(2) of the Social Security Act, as added by subsection (a)(2), shall apply to denials occurring on or after such date (not later than 1 year after the date of the enactment of this Act) as the Secretary specifies.

SEC. 937. PROCESS FOR CORRECTION OF MINOR ERRORS AND OMISSIONS WITHOUT PURSUING APPEALS PROCESS.

(a) CLAIMS.—The Secretary shall develop, in consultation with appropriate medicare contractors (as defined in section 1889(g) of the Social Security Act, as inserted by section 301(a)(1)) and representatives of providers of services and suppliers, a process whereby, in the case of minor errors or omissions (as defined by the Secretary) that are detected in the submission of claims under the programs under title XVIII of such Act, a provider of services or supplier is given an opportunity to correct such an error or omission without the need to initiate an appeal. Such process shall include the ability to resubmit corrected claims.

(b) DEADLINE.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall first develop the process under subsection (a).

SEC. 938. PRIOR DETERMINATION PROCESS FOR CERTAIN ITEMS AND SERVICES; ADVANCE BENEFICIARY NOTICES.

(a) IN GENERAL.—Section 1869 (42 U.S.C. 1395ff(b)), as amended by section 933(d)(2)(B), is further amended by adding at the end the following new subsection:

''(h) PRIOR DETERMINATION PROCESS FOR CERTAIN ITEMS AND SERVICES.—

''(1) ESTABLISHMENT OF PROCESS.—

''(A) IN GENERAL.—With respect to a medicare administrative contractor that has a contract under section 1874A that provides for making payments under this title with respect to physicians' services (as defined in section 1848(j)(3)), the Secretary shall establish a prior determination process that meets the requirements of this subsection and that shall be applied by such contractor in the case of eligible requesters.

''(B) ELIGIBLE REQUESTER.—For purposes of this subsection, each of the following shall be an eligible requester:

''(i) A participating physician, but only with respect to physicians' services to be furnished to an individual who is entitled to benefits under this title and who has consented to the physician making the request under this subsection for those physicians' services.

''(ii) An individual entitled to benefits under this title, but only with respect to a physicians' service for which the individual receives, from a physician, an advance beneficiary notice under section 1879(a).

''(2) SECRETARIAL FLEXIBILITY.—The Secretary shall establish by regulation reasonable limits on the physicians' services for which a prior determination of coverage may be requested under this subsection. In establishing such limits, the Secretary may consider the dollar amount involved with respect to the physicians' service, administrative costs and burdens, and other relevant factors.

''(3) REQUEST FOR PRIOR DETERMINATION.—

''(A) IN GENERAL.—Subject to paragraph (2), under the process established under this subsection an eligible requester may submit to the contractor a request for a determination, before the furnishing of a physicians' service, as to whether the physicians' service is covered under this title consistent with the applicable requirements of section 1862(a)(1)(A) (relating to medical necessity).

''(B) ACCOMPANYING DOCUMENTATION.—The Secretary may require that the request be accompanied by a description of the physicians' service, supporting documentation relating to the medical necessity for the physicians' service, and any other appropriate documentation. In the case of a request submitted by an eligible requester who is described in paragraph (1)(B)(ii), the Secretary may require that the request also be accompanied by a copy of the advance beneficiary notice involved.

''(4) RESPONSE TO REQUEST.—

''(A) IN GENERAL.—Under such process, the contractor shall provide the eligible requester with written notice of a determination as to whether—

''(i) the physicians' service is so covered;

''(ii) the physicians' service is not so covered; or

''(iii) the contractor lacks sufficient information to make a coverage determination with respect to the physicians' service.

''(B) CONTENTS OF NOTICE FOR CERTAIN DETERMINATIONS.—

''(i) NONCOVERAGE.—If the contractor makes the determination described in subparagraph (A)(ii), the contractor shall include in the notice a brief explanation of the basis for the determination, including on what national or local coverage or noncoverage determination (if any) the determination is based, and a description of any applicable rights under subsection (a).

''(ii) INSUFFICIENT INFORMATION.—If the contractor makes the determination described in subparagraph (A)(iii), the contractor shall include in the notice a description of the additional information required to make the coverage determination.

''(C) DEADLINE TO RESPOND.—Such notice shall be provided within the same time period as the time period applicable to the contractor providing notice of initial determinations on a claim for benefits under subsection (a)(2)(A).

''(D) INFORMING BENEFICIARY IN CASE OF PHYSICIAN REQUEST.—In the case of a request by a participating physician under paragraph (1)(B)(i), the process shall provide that the individual to whom the physicians' service is proposed to be furnished shall be informed of any determination described in subparagraph (A)(ii) (relating to a determination of non-coverage) and the right (referred to in paragraph (6)(B)) to obtain the physicians' service and have a claim submitted for the physicians' service.

''(5) BINDING NATURE OF POSITIVE DETERMINATION.—If the contractor makes the determination described in paragraph (4)(A)(i), such determination shall be binding on the contractor in the absence of fraud or evidence of misrepresentation of facts presented to the contractor.

''(6) LIMITATION ON FURTHER REVIEW.—

''(A) IN GENERAL.—Contractor determinations described in paragraph (4)(A)(ii) or (4)(A)(iii) (relating to pre-service claims) are not subject to further administrative appeal or judicial review under this section or otherwise.

''(B) DECISION NOT TO SEEK PRIOR DETERMINATION OR NEGATIVE DETERMINATION DOES NOT IMPACT RIGHT TO OBTAIN SERVICES, SEEK REIMBURSEMENT, OR APPEAL RIGHTS.—Nothing in this subsection shall be construed as affecting the right of an individual who—

''(i) decides not to seek a prior determination under this subsection with respect to physicians' services; or

''(ii) seeks such a determination and has received a determination described in paragraph (4)(A)(ii), from receiving (and submitting a claim for) such physicians' services and from obtaining administrative or judicial review respecting such claim under the other applicable provisions of this section. Failure to seek a prior determination under this subsection with respect to physicians' service shall not be taken into account in such administrative or judicial review.

''(C) NO PRIOR DETERMINATION AFTER RECEIPT OF SERVICES.—Once an individual is provided physicians' services, there shall be no prior determination under this subsection with respect to such physicians' services.''.

(b) EFFECTIVE DATE; SUNSET; TRANSITION.—

(1) EFFECTIVE DATE.—The Secretary shall establish the prior determination process under the amendment made by subsection (a) in such a manner as to provide for the acceptance of requests for determinations under such process filed not later than 18 months after the date of the enactment of this Act.

(2) SUNSET.—Such prior determination process shall not apply to requests filed after the end of the 5-year period beginning on the first date on which requests for determinations under such process are accepted.

(3) TRANSITION.—During the period in which the amendment made by subsection (a) has become effective but contracts are not provided under section 1874A of the Social Security Act with medicare administrative contractors, any reference in section 1869(g) of such Act (as added by such amendment) to such a contractor is deemed a reference to a fiscal intermediary or carrier with an agreement under section 1816, or contract under section 1842, respectively, of such Act.

(4) LIMITATION ON APPLICATION TO SGR.—For purposes of applying section 1848(f)(2)(D) of the Social Security Act (42 U.S.C. 1395w–4(f)(2)(D)), the amendment made by subsection (a) shall not be considered to be a change in law or regulation.

(c) PROVISIONS RELATING TO ADVANCE BENEFICIARY NOTICES; REPORT ON PRIOR DETERMINATION PROCESS.—

(1) DATA COLLECTION.—The Secretary shall establish a process for the collection of information on the instances in which an advance beneficiary notice (as defined in paragraph (5)) has been provided and on instances in which a beneficiary indicates on such a notice that the beneficiary does not intend to seek to have the item or service that is the subject of the notice furnished.

(2) OUTREACH AND EDUCATION.—The Secretary shall establish a program of outreach and education for beneficiaries and providers of services and other persons on the appropriate use of advance beneficiary notices and coverage policies under the medicare program.

(3) GAO REPORT ON USE OF ADVANCE BENEFICIARY NOTICES.—Not later than 18 months after the date on which section 1869(h) of the Social Security Act (as added by subsection (a)) takes effect, the Comptroller General of the United States shall submit to Congress a report on the use of advance beneficiary notices under title XVIII of such Act. Such report shall include information concerning the providers of services and other persons that have provided such notices and the response of beneficiaries to such notices.

(4) GAO REPORT ON USE OF PRIOR DETERMINATION PROCESS.—Not later than 36 months after the date on which section 1869(h) of the Social Security Act (as added by subsection (a)) takes effect, the Comptroller General of the United States shall submit to Congress a report on the use of the prior determination process under such section. Such report shall include—

(A) information concerning—

(i) the number and types of procedures for which a prior determination has been sought;

(ii) determinations made under the process;

(iii) the percentage of beneficiaries prevailing;

(iv) in those cases in which the beneficiaries do not prevail, the reasons why such beneficiaries did not prevail; and

(v) changes in receipt of services resulting from the application of such process;

(B) an evaluation of whether the process was useful for physicians (and other suppliers) and beneficiaries, whether it was timely, and whether the amount of information required was burdensome to physicians and beneficiaries; and

(C) recommendations for improvements or continuation of such process.

(5) ADVANCE BENEFICIARY NOTICE DEFINED.—In this subsection, the term ''advance beneficiary notice'' means a written notice provided under section 1879(a) of the Social Security Act (42 U.S.C. 1395pp(a)) to an individual entitled to benefits under part A or enrolled under part B of title XVIII of such Act before items or services are furnished under such part in cases where a provider of services or other person that would furnish the item or service believes that payment will not be made for some or all of such items or services under such title.

SEC. 939. APPEALS BY PROVIDERS WHEN THERE IS NO OTHER PARTY AVAILABLE.

(a) IN GENERAL.—Section 1870 (42 U.S.C. 1395gg) is amended by adding at the end the following new subsection:

''(h) Notwithstanding subsection (f) or any other provision of law, the Secretary shall permit a provider of services or supplier to appeal any determination of the Secretary under this title relating to services rendered under this title to an individual who subsequently dies if there is no other party available to appeal such determination.''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect on the date of the enactment of this Act and shall apply to items and services furnished on or after such date.

SEC. 940. REVISIONS TO APPEALS TIMEFRAMES AND AMOUNTS.

(a) TIMEFRAMES.—Section 1869 (42 U.S.C. 1395ff) is amended—

(1) in subsection (a)(3)(C)(ii), by striking ''30-day period'' each place it appears and inserting ''60-day period''; and

(2) in subsection (c)(3)(C)(i), by striking ''30-day period'' and inserting ''60-day period''.

(b) AMOUNTS.—

(1) IN GENERAL.—Section 1869(b)(1)(E) (42 U.S.C. 1395ff(b)(1)(E)) is amended by adding at the end the following new clause:

''(iii) ADJUSTMENT OF DOLLAR AMOUNTS.—For requests for hearings or judicial review made in a year after 2004, the dollar amounts specified in clause (i) shall be equal to such dollar amounts increased by the percentage increase in the medical care component of the consumer price index for all urban consumers (U.S. city average) for July 2003 to the July preceding the year involved. Any amount determined under the previous sentence that is not a multiple of $10 shall be rounded to the nearest multiple of $10.''.

(2) CONFORMING AMENDMENTS.—(A) Section 1852(g)(5) (42 U.S.C. 1395w–22(g)(5)) is amended by adding at the end the following: ''The provisions of section 1869(b)(1)(E)(iii) shall apply with respect to dollar amounts specified in the first 2 sentences of this paragraph in the same manner as they apply to the dollar amounts specified in section 1869(b)(1)(E)(i).''.

(B) Section 1876(b)(5)(B) (42 U.S.C. 1395mm(b)(5)(B)) is amended by adding at the end the following: ''The provisions of section 1869(b)(1)(E)(iii) shall apply with respect to dollar amounts specified in the first 2 sentences of this subparagraph in the same manner as they apply to the dollar amounts specified in section 1869(b)(1)(E)(i).''.

SEC. 940A. MEDIATION PROCESS FOR LOCAL COVERAGE DETERMINATIONS.

(a) IN GENERAL.—Section 1869 (42 U.S.C. 1395ff), as amended by section 938(a), is amended by adding at the end the following new subsection:

''(i) MEDIATION PROCESS FOR LOCAL COVERAGE DETERMINATIONS.—

''(1) ESTABLISHMENT OF PROCESS.—The Secretary shall establish a mediation process under this subsection through the use of a physician trained in mediation and employed by the Centers for Medicare & Medicaid Services.

''(2) RESPONSIBILITY OF MEDIATOR.—Under the process established in paragraph (1), such a mediator shall mediate in disputes between groups representing providers of services, suppliers (as defined in section 1861(d)), and the medical director for a medicare administrative contractor whenever the regional administrator (as defined by the Secretary) involved determines that there was a systematic pattern and a large volume of complaints from such groups regarding decisions of such director or there is a complaint from the co-chair of the advisory committee for that contractor to such regional administrator regarding such dispute.''.

(b) INCLUSION IN MAC CONTRACTS.—Section 1874A(b)(3)(A)(i), as added by section 911(a)(1), is amended by adding at the end the following: ''Such requirements shall include specific performance duties expected of a medical director of a medicare administrative contractor, including requirements relating to professional relations and the availability of such director to conduct medical determination activities within the jurisdiction of such a contractor.''.

Subtitle E—Miscellaneous Provisions

SEC. 941. POLICY DEVELOPMENT REGARDING EVALUATION AND MANAGEMENT (E & M) DOCUMENTATION GUIDELINES.

(a) IN GENERAL.—The Secretary may not implement any new or modified documentation guidelines (which for purposes of this section includes clinical examples) for evaluation and management physician services under the title XVIII of the Social Security Act on or after the date of the enactment of this Act unless the Secretary—

(1) has developed the guidelines in collaboration with practicing physicians (including both generalists and specialists) and provided for an assessment of the proposed guidelines by the physician community;

(2) has established a plan that contains specific goals, including a schedule, for improving the use of such guidelines;

(3) has conducted appropriate and representative pilot projects under subsection (b) to test such guidelines;

(4) finds, based on reports submitted under subsection (b)(5) with respect to pilot projects conducted for such or related guidelines, that the objectives described in subsection (c) will be met in the implementation of such guidelines; and

(5) has established, and is implementing, a program to educate physicians on the use of such guidelines and that includes appropriate outreach.

The Secretary shall make changes to the manner in which existing evaluation and management documentation guidelines are implemented to reduce paperwork burdens on physicians.

(b) PILOT PROJECTS TO TEST MODIFIED OR NEW EVALUATION AND MANAGEMENT DOCUMENTATION GUIDELINES.—

(1) IN GENERAL.—With respect to proposed new or modified documentation guidelines referred to in subsection (a), the Secretary shall conduct under this subsection appropriate and representative pilot projects to test the proposed guidelines.

(2) LENGTH AND CONSULTATION.—Each pilot project under this subsection shall—

(A) be voluntary;

(B) be of sufficient length as determined by the Secretary (but in no case to exceed 1 year) to allow for preparatory physician and medicare contractor education, analysis, and use and assessment of potential evaluation and management guidelines; and

(C) be conducted, in development and throughout the planning and operational stages of the project, in consultation with practicing physicians (including both generalists and specialists).

(3) RANGE OF PILOT PROJECTS.—Of the pilot projects conducted under this subsection with respect to proposed new or modified documentation guidelines—

(A) at least one shall focus on a peer review method by physicians (not employed by a medicare contractor) which evaluates medical record information for claims submitted by physicians identified as statistical outliers relative to codes used for billing purposes for such services;

(B) at least one shall focus on an alternative method to detailed guidelines based on physician documentation of face to face encounter time with a patient;

(C) at least one shall be conducted for services furnished in a rural area and at least one for services furnished outside such an area; and

(D) at least one shall be conducted in a setting where physicians bill under physicians' services in teaching settings and at least one shall be conducted in a setting other than a teaching setting.

(4) STUDY OF IMPACT.—Each pilot project shall examine the effect of the proposed guidelines on—

(A) different types of physician practices, including those with fewer than 10 full-time-equivalent employees (including physicians); and

(B) the costs of physician compliance, including education, implementation, auditing, and monitoring.

(5) REPORT ON PILOT PROJECTS.—Not later than 6 months after the date of completion of pilot projects carried out under this subsection with respect to a proposed guideline described in paragraph (1), the Secretary shall submit to Congress a report on the pilot projects. Each such report shall include a finding by the Secretary of whether the objectives described in subsection (c) will be met in the implementation of such proposed guideline.

(c) OBJECTIVES FOR EVALUATION AND MANAGEMENT GUIDELINES.—The objectives for modified evaluation and management documentation guidelines developed by the Secretary shall be to—

(1) identify clinically relevant documentation needed to code accurately and assess coding levels accurately;

(2) decrease the level of non-clinically pertinent and burdensome documentation time and content in the physician's medical record;

(3) increase accuracy by reviewers; and

(4) educate both physicians and reviewers.

(d) STUDY OF SIMPLER, ALTERNATIVE SYSTEMS OF DOCUMENTATION FOR PHYSICIAN CLAIMS.—

(1) STUDY.—The Secretary shall carry out a study of the matters described in paragraph (2).

(2) MATTERS DESCRIBED.—The matters referred to in paragraph (1) are—

(A) the development of a simpler, alternative system of requirements for documentation accompanying claims for evaluation and management physician services for which payment is made under title XVIII of the Social Security Act; and

(B) consideration of systems other than current coding and documentation requirements for payment for such physician services.

(3) CONSULTATION WITH PRACTICING PHYSICIANS.—In designing and carrying out the study under paragraph (1), the Secretary shall consult with practicing physicians, including physicians who are part of group practices and including both generalists and specialists.

(4) APPLICATION OF HIPAA UNIFORM CODING REQUIREMENTS.—In developing an alternative system under paragraph (2), the Secretary shall consider requirements of administrative simplification under part C of title XI of the Social Security Act.

(5) REPORT TO CONGRESS.—(A) Not later than October 1, 2005, the Secretary shall submit to Congress a report on the results of the study conducted under paragraph (1).

(B) The Medicare Payment Advisory Commission shall conduct an analysis of the results of the study included in the report under subparagraph (A) and shall submit a report on such analysis to Congress.

(e) STUDY ON APPROPRIATE CODING OF CERTAIN EXTENDED OFFICE VISITS.—The Secretary shall conduct a study of the appropriateness of coding in cases of extended office visits in which there is no diagnosis made. Not later than October 1, 2005, the Secretary shall submit a report to Congress on such study and shall include recommendations on how to code appropriately for such visits in a manner that takes into account the amount of time the physician spent with the patient.

(f) DEFINITIONS.—In this section—

(1) the term ''rural area'' has the meaning given that term in section 1886(d)(2)(D) of the Social Security Act (42 U.S.C. 1395ww(d)(2)(D)); and

(2) the term ''teaching settings'' are those settings described in section 415.150 of title 42, Code of Federal Regulations.

SEC. 942. IMPROVEMENT IN OVERSIGHT OF TECHNOLOGY AND COVERAGE.

(a) COUNCIL FOR TECHNOLOGY AND INNOVATION.—Section 1868 (42 U.S.C. 1395ee) is amended—

(1) by adding at the end of the heading the following: ''; COUNCIL FOR TECHNOLOGY AND INNOVATION'';

(2) by inserting ''PRACTICING PHYSICIANS ADVISORY COUNCIL.—(1)'' after ''(a)'';

(3) in paragraph (1), as so redesignated under paragraph (2), by striking ''in this section'' and inserting ''in this subsection'';

(4) by redesignating subsections (b) and (c) as paragraphs (2) and (3), respectively; and

(5) by adding at the end the following new subsection:

''(b) COUNCIL FOR TECHNOLOGY AND INNOVATION.—

''(1) ESTABLISHMENT.—The Secretary shall establish a Council for Technology and Innovation within the Centers for Medicare & Medicaid Services (in this section referred to as 'CMS').

''(2) COMPOSITION.—The Council shall be composed of senior CMS staff and clinicians and shall be chaired by the Executive Coordinator for Technology and Innovation (appointed or designated under paragraph (4)).

''(3) DUTIES.—The Council shall coordinate the activities of coverage, coding, and payment processes under this title with respect to new technologies and procedures, including new drug therapies, and shall coordinate the exchange of information on new technologies between CMS and other entities that make similar decisions.

''(4) EXECUTIVE COORDINATOR FOR TECHNOLOGY AND INNOVATION.—The Secretary shall appoint (or designate) a noncareer appointee (as defined in section 3132(a)(7) of title 5, United States Code) who shall serve as the Executive Coordinator for Technology and Innovation. Such executive coordinator shall report to the Administrator of CMS, shall chair the Council, shall oversee the execution of its duties, and shall serve as a single point of contact for outside groups and entities regarding the coverage, coding, and payment processes under this title.''.

(b) METHODS FOR DETERMINING PAYMENT BASIS FOR NEW LAB TESTS.—Section 1833(h) (42 U.S.C. 1395l(h)) is amended by adding at the end the following:

''(8)(A) The Secretary shall establish by regulation procedures for determining the basis for, and amount of, payment under this subsection for any clinical diagnostic laboratory test with respect to which a new or substantially revised HCPCS code is assigned on or after January 1, 2005 (in this paragraph referred to as 'new tests').

''(B) Determinations under subparagraph (A) shall be made only after the Secretary—

''(i) makes available to the public (through an Internet website and other appropriate mechanisms) a list that includes any such test for which establishment of a payment amount under this subsection is being considered for a year;

''(ii) on the same day such list is made available, causes to have published in the Federal Register notice of a meeting to receive comments and recommendations (and data on which recommendations are based) from the public on the appropriate basis under this subsection for establishing payment amounts for the tests on such list;

''(iii) not less than 30 days after publication of such notice convenes a meeting, that includes representatives of officials of the Centers for Medicare & Medicaid Services involved in determining payment amounts, to receive such comments and recommendations (and data on which the recommendations are based);

''(iv) taking into account the comments and recommendations (and accompanying data) received at such meeting, develops and makes available to the public (through an Internet website and other appropriate mechanisms) a list of proposed determinations with respect to the appropriate basis for establishing a payment amount under this subsection for each such code, together with an explanation of the reasons for each such determination, the data on which the determinations are based, and a request for public written comments on the proposed determination; and

''(v) taking into account the comments received during the public comment period, develops and makes available to the public (through an Internet website and other appropriate mechanisms) a list of final determinations of the payment amounts for such tests under this subsection, together with the rationale for each such determination, the data on which the determinations are based, and responses to comments and suggestions received from the public.

''(C) Under the procedures established pursuant to subparagraph (A), the Secretary shall—

''(i) set forth the criteria for making determinations under subparagraph (A); and

''(ii) make available to the public the data (other than proprietary data) considered in making such determinations.

''(D) The Secretary may convene such further public meetings to receive public comments on payment amounts for new tests under this subsection as the Secretary deems appropriate.

''(E) For purposes of this paragraph:

''(i) The term 'HCPCS' refers to the Health Care Procedure Coding System.

''(ii) A code shall be considered to be 'substantially revised' if there is a substantive change to the definition of the test or procedure to which the code applies (such as a new analyte or a new methodology for measuring an existing analyte-specific test).''.

(c) GAO STUDY ON IMPROVEMENTS IN EXTERNAL DATA COLLECTION FOR USE IN THE MEDICARE INPATIENT PAYMENT SYSTEM.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study that analyzes which external data can be collected in a shorter timeframe by the Centers for Medicare & Medicaid Services for use in computing payments for inpatient hospital services. The study may include an evaluation of the feasibility and appropriateness of using quarterly samples or special surveys or any other methods. The study shall include an analysis of whether other executive agencies, such as the Bureau of Labor Statistics in the Department of Commerce, are best suited to collect this information.

(2) REPORT.—By not later than October 1, 2004, the Comptroller General shall submit a report to Congress on the study under paragraph (1).

SEC. 943. TREATMENT OF HOSPITALS FOR CERTAIN SERVICES UNDER MEDICARE SECONDARY PAYOR (MSP) PROVISIONS.

(a) IN GENERAL.—The Secretary shall not require a hospital (including a critical access hospital) to ask questions (or obtain information) relating to the application of section 1862(b) of the Social Security Act (relating to medicare secondary payor provisions) in the case of reference laboratory services described in subsection (b), if the Secretary does not impose such requirement in the case of such services furnished by an independent laboratory.

(b) REFERENCE LABORATORY SERVICES DESCRIBED.—Reference laboratory services described in this subsection are clinical laboratory diagnostic tests (or the interpretation of such tests, or both) furnished without a face-to-face encounter between the individual entitled to benefits under part A or enrolled under part B, or both, and the hospital involved and in which the hospital submits a claim only for such test or interpretation.

SEC. 944. EMTALA IMPROVEMENTS.

(a) PAYMENT FOR EMTALA-MANDATED SCREENING AND STABILIZATION SERVICES.—

(1) IN GENERAL.—Section 1862 (42 U.S.C. 1395y) is amended by inserting after subsection (c) the following new subsection:

''(d) For purposes of subsection (a)(1)(A), in the case of any item or service that is required to be provided pursuant to section 1867 to an individual who is entitled to benefits under this title, determinations as to whether the item or service is reasonable and necessary shall be made on the basis of the information available to the treating physician or practitioner (including the patient's presenting symptoms or complaint) at the time the item or service was ordered or furnished by the physician or practitioner (and not on the patient's principal diagnosis). When making such determinations with respect to such an item or service, the Secretary shall not consider the frequency with which the item or service was provided to the patient before or after the time of the admission or visit.''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to items and services furnished on or after January 1, 2004.

(b) NOTIFICATION OF PROVIDERS WHEN EMTALA INVESTIGATION CLOSED.—Section 1867(d) (42 U.S.C. 42 U.S.C. 1395dd(d)) is amended by adding at the end the following new paragraph:

''(4) NOTICE UPON CLOSING AN INVESTIGATION.—The Secretary shall establish a procedure to notify hospitals and physicians when an investigation under this section is closed.''.

(c) PRIOR REVIEW BY PEER REVIEW ORGANIZATIONS IN EMTALA CASES INVOLVING TERMINATION OF PARTICIPATION.—

(1) IN GENERAL.—Section 1867(d)(3) (42 U.S.C. 1395dd(d)(3)) is amended—

(A) in the first sentence, by inserting ''or in terminating a hospital's participation under this title'' after ''in imposing sanctions under paragraph (1)''; and

(B) by adding at the end the following new sentences: ''Except in the case in which a delay would jeopardize the health or safety of individuals, the Secretary shall also request such a review before making a compliance determination as part of the process of terminating a hospital's participation under this title for violations related to the appropriateness of a medical screening examination, stabilizing treatment, or an appropriate transfer as required by this section, and shall provide a period of 5 days for such review. The Secretary shall provide a copy of the organization's report to the hospital or physician consistent with confidentiality requirements imposed on the organization under such part B.''.

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to terminations of participation initiated on or after the date of the enactment of this Act.

SEC. 945. EMERGENCY MEDICAL TREATMENT AND LABOR ACT (EMTALA) TECHNICAL ADVISORY GROUP.

(a) ESTABLISHMENT.—The Secretary shall establish a Technical Advisory Group (in this section referred to as the ''Advisory Group'') to review issues related to the Emergency Medical Treatment and Labor Act (EMTALA) and its implementation. In this section, the term ''EMTALA'' refers to the provisions of section 1867 of the Social Security Act (42 U.S.C. 1395dd).

(b) MEMBERSHIP.—The Advisory Group shall be composed of 19 members, including the Administrator of the Centers for Medicare & Medicaid Services and the Inspector General of the Department of Health and Human Services and of which—

(1) 4 shall be representatives of hospitals, including at least one public hospital, that have experience with the application of EMTALA and at least 2 of which have not been cited for EMTALA violations;

(2) 7 shall be practicing physicians drawn from the fields of emergency medicine, cardiology or cardiothoracic surgery, orthopedic surgery, neurosurgery, pediatrics or a pediatric subspecialty, obstetrics-gynecology, and psychiatry, with not more than one physician from any particular field;

(3) 2 shall represent patients;

(4) 2 shall be staff involved in EMTALA investigations from different regional offices of the Centers for Medicare & Medicaid Services; and

(5) 1 shall be from a State survey office involved in EMTALA investigations and 1 shall be from a peer review organization, both of whom shall be from areas other than the regions represented under paragraph (4).

In selecting members described in paragraphs (1) through (3), the Secretary shall consider qualified individuals nominated by organizations representing providers and patients.

(c) GENERAL RESPONSIBILITIES.—The Advisory Group—

(1) shall review EMTALA regulations;

(2) may provide advice and recommendations to the Secretary with respect to those regulations and their application to hospitals and physicians;

(3) shall solicit comments and recommendations from hospitals, physicians, and the public regarding the implementation of such regulations; and

(4) may disseminate information on the application of such regulations to hospitals, physicians, and the public.

(d) ADMINISTRATIVE MATTERS.—

(1) CHAIRPERSON.—The members of the Advisory Group shall elect a member to serve as chairperson of the Advisory Group for the life of the Advisory Group.

(2) MEETINGS.—The Advisory Group shall first meet at the direction of the Secretary. The Advisory Group shall then meet twice per year and at such other times as the Advisory Group may provide.

(e) TERMINATION.—The Advisory Group shall terminate 30 months after the date of its first meeting.

(f) WAIVER OF ADMINISTRATIVE LIMITATION.—The Secretary shall establish the Advisory Group notwithstanding any limitation that may apply to the number of advisory committees that may be established (within the Department of Health and Human Services or otherwise).

SEC. 946. AUTHORIZING USE OF ARRANGEMENTS TO PROVIDE CORE HOSPICE SERVICES IN CERTAIN CIRCUMSTANCES.

(a) IN GENERAL.—Section 1861(dd)(5) (42 U.S.C. 1395x(dd)(5)) is amended by adding at the end the following:

''(D) In extraordinary, exigent, or other nonroutine circumstances, such as unanticipated periods of high patient loads, staffing shortages due to illness or other events, or temporary travel of a patient outside a hospice program's service area, a hospice program may enter into arrangements with another hospice program for the provision by that other program of services described in paragraph (2)(A)(ii)(I). The provisions of paragraph (2)(A)(ii)(II) shall apply with respect to the services provided under such arrangements.

''(E) A hospice program may provide services described in paragraph (1)(A) other than directly by the program if the services are highly specialized services of a registered professional nurse and are provided non-routinely and so infrequently so that the provision of such services directly would be impracticable and prohibitively expensive.''.

(b) CONFORMING PAYMENT PROVISION.—Section 1814(i) (42 U.S.C. 1395f(i)), as amended by section 512(b), is amended by adding at the end the following new paragraph:

''(5) In the case of hospice care provided by a hospice program under arrangements under section 1861(dd)(5)(D) made by another hospice program, the hospice program that made the arrangements shall bill and be paid for the hospice care.''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to hospice care provided on or after the date of the enactment of this Act.

SEC. 947. APPLICATION OF OSHA BLOODBORNE PATHOGENS STANDARD TO CERTAIN HOSPITALS.

(a) IN GENERAL.—Section 1866 (42 U.S.C. 1395cc), as amended by section 506, is amended—

(1) in subsection (a)(1)—

(A) in subparagraph (T), by striking ''and'' at the end;

(B) in subparagraph (U), by striking the period at the end and inserting '', and''; and

(C) by inserting after subparagraph (U) the following new subparagraph:

''(V) in the case of hospitals that are not otherwise subject to the Occupational Safety and Health Act of 1970 (or a State occupational safety and health plan that is approved under 18(b) of such Act), to comply with the Bloodborne Pathogens standard under section 1910.1030 of title 29 of the Code of Federal Regulations (or as subsequently redesignated).''; and

(2) by adding at the end of subsection (b) the following new paragraph:

''(4)(A) A hospital that fails to comply with the requirement of subsection (a)(1)(V) (relating to the Bloodborne Pathogens standard) is subject to a civil money penalty in an amount described in subparagraph (B), but is not subject to termination of an agreement under this section.

''(B) The amount referred to in subparagraph (A) is an amount that is similar to the amount of civil penalties that may be imposed under section 17 of the Occupational Safety and Health Act of 1970 for a violation of the Bloodborne Pathogens standard referred to in subsection (a)(1)(U) by a hospital that is subject to the provisions of such Act.

''(C) A civil money penalty under this paragraph shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A are imposed and collected under that section.''.

(b) EFFECTIVE DATE.—The amendments made by this subsection (a) shall apply to hospitals as of July 1, 2004.

SEC. 948. BIPA-RELATED TECHNICAL AMENDMENTS AND CORRECTIONS.

(a) TECHNICAL AMENDMENTS RELATING TO ADVISORY COMMITTEE UNDER BIPA SECTION 522.—(1) Subsection (i) of section 1114 (42 U.S.C. 1314)—

(A) is transferred to section 1862 and added at the end of such section; and

(B) is redesignated as subsection (j).

(2) Section 1862 (42 U.S.C. 1395y) is amended—

(A) in the last sentence of subsection (a), by striking ''established under section 1114(f)''; and

(B) in subsection (j), as so transferred and redesignated—

(i) by striking ''under subsection (f)''; and

(ii) by striking ''section 1862(a)(1)'' and inserting ''subsection (a)(1)''.

(b) TERMINOLOGY CORRECTIONS.—(1) Section 1869(c)(3)(I)(ii) (42 U.S.C. 1395ff(c)(3)(I)(ii)) is amended—

(A) in subclause (III), by striking ''policy'' and inserting ''determination''; and

(B) in subclause (IV), by striking ''medical review policies'' and inserting ''coverage determinations''.

(2) Section 1852(a)(2)(C) (42 U.S.C. 1395w–22(a)(2)(C)) is amended by striking ''policy'' and ''POLICY'' and inserting ''determination'' each place it appears and ''DETERMINATION'', respectively.

(c) REFERENCE CORRECTIONS.—Section 1869(f)(4) (42 U.S.C. 1395ff(f)(4)) is amended—

(1) in subparagraph (A)(iv), by striking ''subclause (I), (II), or (III)'' and inserting ''clause (i), (ii), or (iii)'';

(2) in subparagraph (B), by striking ''clause (i)(IV)'' and ''clause (i)(III)'' and inserting ''subparagraph (A)(iv)'' and ''subparagraph (A)(iii)'', respectively; and

(3) in subparagraph (C), by striking ''clause (i)'', ''subclause (IV)'' and ''subparagraph (A)'' and inserting ''subparagraph (A)'', ''clause (iv)'' and ''paragraph (1)(A)'', respectively each place it appears.

(d) OTHER CORRECTIONS.—Effective as if included in the enactment of section 521(c) of BIPA, section 1154(e) (42 U.S.C. 1320c–3(e)) is amended by striking paragraph (5).

(e) EFFECTIVE DATE.—Except as otherwise provided, the amendments made by this section shall be effective as if included in the enactment of BIPA.

SEC. 949. CONFORMING AUTHORITY TO WAIVE A PROGRAM EXCLUSION.

The first sentence of section 1128(c)(3)(B) (42 U.S.C. 1320a–7(c)(3)(B)) is amended to read as follows: ''Subject to subparagraph (G), in the case of an exclusion under subsection (a), the minimum period of exclusion shall be not less than five years, except that, upon the request of the administrator of a Federal health care program (as defined in section 1128B(f)) who determines that the exclusion would impose a hardship on individuals entitled to benefits under part A of title XVIII or enrolled under part B of such title, or both, the Secretary may, after consulting with the Inspector General of the Department of Health and Human Services, waive the exclusion under subsection (a)(1), (a)(3), or (a)(4) with respect to that program in the case of an individual or entity that is the sole community physician or sole source of essential specialized services in a community.''.

SEC. 950. TREATMENT OF CERTAIN DENTAL CLAIMS.

(a) IN GENERAL.—Section 1862 (42 U.S.C. 1395y) is amended by adding at the end, after the subsection transferred and redesignated by section 948(a), the following new subsection:

''(k)(1) Subject to paragraph (2), a group health plan (as defined in subsection (a)(1)(A)(v)) providing supplemental or secondary coverage to individuals also entitled to services under this title shall not require a medicare claims determination under this title for dental benefits specifically excluded under subsection (a)(12) as a condition of making a claims determination for such benefits under the group health plan.

''(2) A group health plan may require a claims determination under this title in cases involving or appearing to involve inpatient dental hospital services or dental services expressly covered under this title pursuant to actions taken by the Secretary.''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect on the date that is 60 days after the date of the enactment of this Act.

SEC. 951. FURNISHING HOSPITALS WITH INFORMATION TO COMPUTE DSH FORMULA.

Beginning not later than 1 year after the date of the enactment of this Act, the Secretary shall

arrange to furnish to subsection (d) hospitals (as defined in section 1886(d)(1)(B) of the Social Security Act, 42 U.S.C. 1395ww(d)(1)(B)) the data necessary for such hospitals to compute the number of patient days used in computing the disproportionate patient percentage under such section for that hospital for the current cost reporting year. Such data shall also be furnished to other hospitals which would qualify for additional payments under part A of title XVIII of the Social Security Act on the basis of such data.

SEC. 952. REVISIONS TO REASSIGNMENT PROVISIONS.

(a) IN GENERAL.—Section 1842(b)(6)(A) (42 U.S.C. 1395u(b)(6)(A)) is amended by striking ''or (ii) (where the service was provided in a hospital, critical access hospital, clinic, or other facility) to the facility in which the service was provided if there is a contractual arrangement between such physician or other person and such facility under which such facility submits the bill for such service,'' and inserting ''or (ii) where the service was provided under a contractual arrangement between such physician or other person and an entity, to the entity if, under the contractual arrangement, the entity submits the bill for the service and the contractual arrangement meets such program integrity and other safeguards as the Secretary may determine to be appropriate,''.

(b) CONFORMING AMENDMENT.—The second sentence of section 1842(b)(6) (42 U.S.C. 1395u(b)(6)) is amended by striking ''except to an employer or facility as described in clause (A)'' and inserting ''except to an employer or entity as described in subparagraph (A)''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to payments made on or after the date of the enactment of this Act.

SEC. 953. OTHER PROVISIONS.

(a) GAO REPORTS ON THE PHYSICIAN COMPENSATION.—

(1) SUSTAINABLE GROWTH RATE AND UPDATES.—Not later than 6 months after the date of the enactment of this Act, the Comptroller General of the United States shall submit to Congress a report on the appropriateness of the updates in the conversion factor under subsection (d)(3) of section 1848 of the Social Security Act (42 U.S.C. 1395w–4), including the appropriateness of the sustainable growth rate formula under subsection (f) of such section for 2002 and succeeding years. Such report shall examine the stability and predictability of such updates and rate and alternatives for the use of such rate in the updates.

(2) PHYSICIAN COMPENSATION GENERALLY.—Not later than 12 months after the date of the enactment of this Act, the Comptroller General shall submit to Congress a report on all aspects of physician compensation for services furnished under title XVIII of the Social Security Act, and how those aspects interact and the effect on appropriate compensation for physician services. Such report shall review alternatives for the physician fee schedule under section 1848 of such title (42 U.S.C. 1395w–4).

(b) ANNUAL PUBLICATION OF LIST OF NATIONAL COVERAGE DETERMINATIONS.—The Secretary shall provide, in an appropriate annual publication available to the public, a list of national coverage determinations made under title XVIII of the Social Security Act in the previous year and information on how to get more information with respect to such determinations.

(c) GAO REPORT ON FLEXIBILITY IN APPLYING HOME HEALTH CONDITIONS OF PARTICIPATION TO PATIENTS WHO ARE NOT MEDICARE BENEFICIARIES.—Not later than 6 months after the date of the enactment of this Act, the Comptroller General of the United States shall submit to Congress a report on the implications if there were flexibility in the application of the medicare conditions of participation for home health agencies with respect to groups or types of patients who are not medicare beneficiaries. The report shall include an analysis of the potential impact of such flexible application on clinical operations and the recipients of such services and an analysis of methods for monitoring the quality of care provided to such recipients.

(d) OIG REPORT ON NOTICES RELATING TO USE OF HOSPITAL LIFETIME RESERVE DAYS.—Not later than 1 year after the date of the enactment of this Act, the Inspector General of the Department of Health and Human Services shall submit a report to Congress on—

(1) the extent to which hospitals provide notice to medicare beneficiaries in accordance with applicable requirements before they use the 60 lifetime reserve days described in section 1812(a)(1) of the Social Security Act (42 U.S.C. 1395d(a)(1)); and

(2) the appropriateness and feasibility of hospitals providing a notice to such beneficiaries before they completely exhaust such lifetime reserve days.

TITLE X—MEDICAID AND MISCELLANEOUS PROVISIONS

Subtitle A—Medicaid Provisions

SEC. 1001. MEDICAID DISPROPORTIONATE SHARE HOSPITAL (DSH) PAYMENTS.

(a) TEMPORARY INCREASE.—Section 1923(f)(3) (42 U.S.C. 1396r–4(f)(3)) is amended—

(1) in subparagraph (A), by striking ''subparagraph (B)'' and inserting ''subparagraphs (B) and (C)''; and

(2) by adding at the end the following new subparagraphs:

''(C) SPECIAL, TEMPORARY INCREASE IN ALLOTMENTS ON A ONE-TIME, NON-CUMULATIVE BASIS.—The DSH allotment for any State (other than a State with a DSH allotment determined under paragraph (5))—

''(i) for fiscal year 2004 is equal to 116 percent of the DSH allotment for the State for fiscal year 2003 under this paragraph, notwithstanding subparagraph (B); and

''(ii) for each succeeding fiscal year is equal to the DSH allotment for the State for fiscal year 2004 or, in the case of fiscal years beginning with the fiscal year specified in subparagraph (D) for that State, the DSH allotment for the State for the previous fiscal year increased by the percentage change in the consumer price index for all urban consumers (all items; U.S. city average), for the previous fiscal year.

''(D) FISCAL YEAR SPECIFIED.—For purposes of subparagraph (C)(ii), the fiscal year specified in this subparagraph for a State is the first fiscal year for which the Secretary estimates that the DSH allotment for that State will equal (or no longer exceed) the DSH allotment for that State under the law as in effect before the date of the enactment of this subparagraph.''.

(b) INCREASE IN FLOOR FOR TREATMENT AS A LOW DSH STATE.—Section 1923(f)(5) (42 U.S.C. 1396r–4(f)(5)) is amended—

(1) in the paragraph heading, by striking ''EXTREMELY'';

(2) by striking ''In the case of'' and inserting the following:

''(A) FOR FISCAL YEARS 2001 THROUGH 2003 FOR EXTREMELY LOW DSH STATES.—In the case of'';

(3) by inserting ''before fiscal year 2004'' after ''In subsequent years''; and

(4) by adding at the end the following:

''(B) FOR FISCAL YEAR 2004 AND SUBSEQUENT FISCAL YEARS.—In the case of a State in which the total expenditures under the State plan (including Federal and State shares) for disproportionate share hospital adjustments under this section for fiscal year 2000, as reported to the Administrator of the Centers for Medicare & Medicaid Services as of August 31, 2003, is greater than 0 but less than 3 percent of the State's total amount of expenditures under the State plan for medical assistance during the fiscal year, the DSH allotment for the State with respect to—

''(i) fiscal year 2004 shall be the DSH allotment for the State for fiscal year 2003 increased by 16 percent;

''(ii) each succeeding fiscal year before fiscal year 2009 shall be the DSH allotment for the State for the previous fiscal year increased by 16 percent; and

''(iii) fiscal year 2009 and any subsequent fiscal year, shall be the DSH allotment for the State for the previous year subject to an increase for inflation as provided in paragraph (3)(A).''.

(c) ALLOTMENT ADJUSTMENT.—Section 1923(f) (42 U.S.C. 1396r–4(f)) is amended—

(1) in paragraph (3)(A), by striking ''The DSH'' and inserting ''Except as provided in paragraph (6), the DSH'';

(2) by redesignating paragraph (6) as paragraph (7); and

(3) by inserting after paragraph (5) the following:

''(6) ALLOTMENT ADJUSTMENT.—Only with respect to fiscal year 2004 or 2005, if a statewide waiver under section 1115 is revoked or terminated before the end of either such fiscal year and there is no DSH allotment for the State, the Secretary shall—

''(A) permit the State whose waiver was revoked or terminated to submit an amendment to its State plan that would describe the methodology to be used by the State (after the effective date of such revocation or termination) to identify and make payments to disproportionate share hospitals, including children's hospitals and institutions for mental diseases or other mental health facilities (other than State-owned institutions or facilities), on the basis of the proportion of patients served by such hospitals that are low-income patients with special needs; and

''(B) provide for purposes of this subsection for computation of an appropriate DSH allotment for the State for fiscal year 2004 or 2005 (or both) that would not exceed the amount allowed under paragraph (3)(B)(ii) and that does not result in greater expenditures under this title than would have been made if such waiver had not been revoked or terminated.

In determining the amount of an appropriate DSH allotment under subparagraph (B) for a State, the Secretary shall take into account the level of DSH expenditures for the State for the fiscal year preceding the fiscal year in which the waiver commenced.''.

(d) INCREASED REPORTING AND OTHER REQUIREMENTS TO ENSURE THE APPROPRIATE USE OF MEDICAID DSH PAYMENT ADJUSTMENTS.—Section 1923 (42 U.S.C. 1396r–4) is amended by adding at the end the following new subsection:

''(j) ANNUAL REPORTS AND OTHER REQUIREMENTS REGARDING PAYMENT ADJUSTMENTS.—With respect to fiscal year 2004 and each fiscal year thereafter, the Secretary shall require a State, as a condition of receiving a payment under section 1903(a)(1) with respect to a payment adjustment made under this section, to do the following:

''(1) REPORT.—The State shall submit an annual report that includes the following:

''(A) An identification of each disproportionate share hospital that received a payment adjustment under this section for the preceding fiscal year and the amount of the payment adjustment made to such hospital for the preceding fiscal year.

''(B) Such other information as the Secretary determines necessary to ensure the appropriateness of the payment adjustments made under this section for the preceding fiscal year.

''(2) INDEPENDENT CERTIFIED AUDIT.—The State shall annually submit to the Secretary an independent certified audit that verifies each of the following:

''(A) The extent to which hospitals in the State have reduced their uncompensated care costs to reflect the total amount of claimed expenditures made under this section.

''(B) Payments under this section to hospitals that comply with the requirements of subsection (g).

''(C) Only the uncompensated care costs of providing inpatient hospital and outpatient hospital services to individuals described in paragraph (1)(A) of such subsection are included in the calculation of the hospital-specific limits under such subsection.

''(D) The State included all payments under this title, including supplemental payments, in the calculation of such hospital-specific limits.

''(E) The State has separately documented and retained a record of all of its costs under this title, claimed expenditures under this title, uninsured costs in determining payment adjustments under this section, and any payments made on behalf of the uninsured from payment adjustments under this section.''.

(e) CLARIFICATION REGARDING NON-REGULATION OF TRANSFERS.—

(1) IN GENERAL.—Nothing in section 1903(w) of the Social Security Act (42 U.S.C. 1396b(w)) shall be construed by the Secretary as prohibiting a State's use of funds as the non-Federal share of expenditures under title XIX of such Act where such funds are transferred from or certified by a publicly-owned regional medical center located in another State and described in paragraph (2), so long as the Secretary determines that such use of funds is proper and in the interest of the program under title XIX.

(2) CENTER DESCRIBED.—A center described in this paragraph is a publicly-owned regional medical center that—

(A) provides level 1 trauma and burn care service;

(B) provides level 3 neonatal care services;

(C) is obligated to serve all patients, regardless of State of origin;

(D) is located within a Standard Metropolitan Statistical Area (SMSA) that includes at least 3 States, including the States described in paragraph (1);

(E) serves as a tertiary care provider for patients residing within a 125 mile radius; and

(F) meets the criteria for a disproportionate share hospital under section 1923 of such Act in at least one State other than the one in which the center is located.

(3) EFFECTIVE PERIOD.—This subsection shall apply through December 31, 2005.

SEC. 1002. CLARIFICATION OF INCLUSION OF INPATIENT DRUG PRICES CHARGED TO CERTAIN PUBLIC HOSPITALS IN THE BEST PRICE EXEMPTIONS FOR THE MEDICAID DRUG REBATE PROGRAM.

(a) IN GENERAL.—Section 1927(c)(1)(C)(i)(I) (42 U.S.C. 1396r–8(c)(1)(C)(i)(I)) is amended by inserting before the semicolon the following: ''(including inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the Public Health Service Act)''.

(b) ANTI-DIVERSION PROTECTION.—Section 1927(c)(1)(C) (42 U.S.C. 1396r–8(c)(1)(C)) is amended by adding at the end the following:

''(iii) APPLICATION OF AUDITING AND RECORDKEEPING REQUIREMENTS.—With respect to a covered entity described in section 340B(a)(4)(L) of the Public Health Service Act, any drug purchased for inpatient use shall be subject to the auditing and recordkeeping requirements described in section 340B(a)(5)(C) of the Public Health Service Act.''.

SEC. 1003. EXTENSION OF MORATORIUM.

(a) IN GENERAL.—Section 6408(a)(3) of the Omnibus Budget Reconciliation Act of 1989, as amended by section 13642 of the Omnibus Budget Reconciliation Act of 1993 and section 4758 of the Balanced Budget Act of 1997, is amended—

(1) by striking ''until December 31, 2002'', and

(2) by striking ''Kent Community Hospital Complex in Michigan or.''

(b) EFFECTIVE DATES.—

(1) PERMANENT EXTENSION.—The amendment made by subsection (a)(1) shall take effect as if included in the amendment made by section 4758 of the Balanced Budget Act of 1997.

(2) MODIFICATION.—The amendment made by subsection (a)(2) shall take effect on the date of enactment of this Act.

Subtitle B—Miscellaneous Provisions

SEC. 1011. FEDERAL REIMBURSEMENT OF EMERGENCY HEALTH SERVICES FURNISHED TO UNDOCUMENTED ALIENS.

(a) TOTAL AMOUNT AVAILABLE FOR ALLOTMENT.—

(1) IN GENERAL.—Out of any funds in the Treasury not otherwise appropriated, there are appropriated to the Secretary $250,000,000 for each of fiscal years 2005 through 2008 for the purpose of making allotments under this section for payments to eligible providers in States described in paragraph (1) or (2) of subsection (b).

(2) AVAILABILITY.—Funds appropriated under paragraph (1) shall remain available until expended.

(b) STATE ALLOTMENTS.—

(1) BASED ON PERCENTAGE OF UNDOCUMENTED ALIENS.—

(A) IN GENERAL.—Out of the amount appropriated under subsection (a) for a fiscal year, the Secretary shall use $167,000,000 of such amount to make allotments for such fiscal year in accordance with subparagraph (B).

(B) FORMULA.—The amount of the allotment for payments to eligible providers in each State for a fiscal year shall be equal to the product of—

(i) the total amount available for allotments under this paragraph for the fiscal year; and

(ii) the percentage of undocumented aliens residing in the State as compared to the total number of such aliens residing in all States, as determined by the Statistics Division of the Immigration and Naturalization Service, as of January 2003, based on the 2000 decennial census.

(2) BASED ON NUMBER OF UNDOCUMENTED ALIEN APPREHENSION STATES.—

(A) IN GENERAL.—Out of the amount appropriated under subsection (a) for a fiscal year, the Secretary shall use $83,000,000 of such amount to make allotments, in addition to amounts allotted under paragraph (1), for such fiscal year for each of the 6 States with the highest number of undocumented alien apprehensions for such fiscal year.

(B) DETERMINATION OF ALLOTMENTS.—The amount of the allotment for each State described in subparagraph (A) for a fiscal year shall be equal to the product of—

(i) the total amount available for allotments under this paragraph for the fiscal year; and

(ii) the percentage of undocumented alien apprehensions in the State in that fiscal year as compared to the total of such apprehensions for all such States for the preceding fiscal year.

(C) DATA.—For purposes of this paragraph, the highest number of undocumented alien apprehensions for a fiscal year shall be based on the apprehension rates for the 4-consecutive-quarter period ending before the beginning of the fiscal year for which information is available for undocumented aliens in such States, as reported by the Department of Homeland Security.

(c) USE OF FUNDS.—

(1) AUTHORITY TO MAKE PAYMENTS.—From the allotments made for a State under subsection (b) for a fiscal year, the Secretary shall pay the amount (subject to the total amount available from such allotments) determined under paragraph (2) directly to eligible providers located in the State for the provision of eligible services to aliens described in paragraph (5) to the extent that the eligible provider was not otherwise reimbursed (through insurance or otherwise) for such services during that fiscal year.

(2) DETERMINATION OF PAYMENT AMOUNTS.—

(A) IN GENERAL.—Subject to subparagraph (B), the payment amount determined under this paragraph shall be an amount determined by the Secretary that is equal to the lesser of—

(i) the amount that the provider demonstrates was incurred for the provision of such services; or

(ii) amounts determined under a methodology established by the Secretary for purposes of this subsection.

(B) PRO-RATA REDUCTION.—If the amount of funds allotted to a State under subsection (b) for a fiscal year is insufficient to ensure that each eligible provider in that State receives the amount of payment calculated under subparagraph (A), the Secretary shall reduce that amount of payment with respect to each eligible provider to ensure that the entire amount allotted to the State for that fiscal year is paid to such eligible providers.

(3) METHODOLOGY.—In establishing a methodology under paragraph (2)(A)(ii), the Secretary—

(A) may establish different methodologies for types of eligible providers;

(B) may base payments for hospital services on estimated hospital charges, adjusted to estimated cost, through the application of hospital-specific cost-to-charge ratios;

(C) shall provide for the election by a hospital to receive either payments to the hospital for—

(i) hospital and physician services; or

(ii) hospital services and for a portion of the on-call payments made by the hospital to physicians; and

(D) shall make quarterly payments under this section to eligible providers.

If a hospital makes the election under subparagraph (C)(i), the hospital shall pass on payments for services of a physician to the physician and may not charge any administrative or other fee with respect to such payments.

(4) LIMITATION ON USE OF FUNDS.—Payments made to eligible providers in a State from allotments made under subsection (b) for a fiscal year may only be used for costs incurred in providing eligible services to aliens described in paragraph (5).

(5) ALIENS DESCRIBED.—For purposes of paragraphs (1) and (2), aliens described in this paragraph are any of the following:

(A) Undocumented aliens.

(B) Aliens who have been paroled into the United States at a United States port of entry for the purpose of receiving eligible services.

(C) Mexican citizens permitted to enter the United States for not more than 72 hours under the authority of a biometric machine readable border crossing identification card (also referred to as a ''laser visa'') issued in accordance with the requirements of regulations prescribed under section 101(a)(6) of the Immigration and Nationality Act (8 U.S.C. 1101(a)(6)).

(d) APPLICATIONS; ADVANCE PAYMENTS.—

(1) DEADLINE FOR ESTABLISHMENT OF APPLICATION PROCESS.—

(A) IN GENERAL.—Not later than September 1, 2004, the Secretary shall establish a process under which eligible providers located in a State may request payments under subsection (c).

(B) INCLUSION OF MEASURES TO COMBAT FRAUD AND ABUSE.—The Secretary shall include in the process established under subparagraph (A) measures to ensure that inappropriate, excessive, or fraudulent payments are not made from the allotments determined under subsection (b), including certification by the eligible provider of the veracity of the payment request.

(2) ADVANCE PAYMENT; RETROSPECTIVE ADJUSTMENT.—The process established under paragraph (1) may provide for making payments under this section for each quarter of a fiscal year on the basis of advance estimates of expenditures submitted by applicants for such payments and such other investigation as the Secretary may find necessary, and for making reductions or increases in the payments as necessary to adjust for any overpayment or underpayment for prior quarters of such fiscal year.

(e) DEFINITIONS.—In this section:

(1) ELIGIBLE PROVIDER.—The term ''eligible provider'' means a hospital, physician, or provider of ambulance services (including an Indian Health Service facility whether operated by the Indian Health Service or by an Indian tribe or tribal organization).

(2) ELIGIBLE SERVICES.—The term ''eligible services'' means health care services required by

the application of section 1867 of the Social Security Act (42 U.S.C. 1395dd), and related hospital inpatient and outpatient services and ambulance services (as defined by the Secretary).

(3) HOSPITAL.—The term ''hospital'' has the meaning given such term in section 1861(e) of the Social Security Act (42 U.S.C. 1395x(e)), except that such term shall include a critical access hospital (as defined in section 1861(mm)(1) of such Act (42 U.S.C. 1395x(mm)(1)).

(4) PHYSICIAN.—The term ''physician'' has the meaning given that term in section 1861(r) of the Social Security Act (42 U.S.C. 1395x(r)).

(5) INDIAN TRIBE; TRIBAL ORGANIZATION.—The terms ''Indian tribe'' and ''tribal organization'' have the meanings given such terms in section 4 of the Indian Health Care Improvement Act (25 U.S.C. 1603).

(6) STATE.—The term ''State'' means the 50 States and the District of Columbia.

SEC. 1012. COMMISSION ON SYSTEMIC INTEROPERABILITY.

(a) ESTABLISHMENT.—The Secretary shall establish a commission to be known as the ''Commission on Systemic Interoperability'' (in this section referred to as the ''Commission'').

(b) DUTIES.—

(1) IN GENERAL.—The Commission shall develop a comprehensive strategy for the adoption and implementation of health care information technology standards, that includes a timeline and prioritization for such adoption and implementation.

(2) CONSIDERATIONS.—In developing the comprehensive health care information technology strategy under paragraph (1), the Commission shall consider—

(A) the costs and benefits of the standards, both financial impact and quality improvement;

(B) the current demand on industry resources to implement this Act and other electronic standards, including HIPAA standards; and

(C) the most cost-effective and efficient means for industry to implement the standards.

(3) NONINTERFERENCE.—In carrying out this section, the Commission shall not interfere with any standards development of adoption processes underway in the private or public sector and shall not replicate activities related to such standards or the national health information infrastructure underway within the Department of Health and Human Services.

(4) REPORT.—Not later than October 31, 2005, the Commission shall submit to the Secretary and to Congress a report describing the strategy developed under paragraph (1), including an analysis of the matters considered under paragraph (2).

(c) MEMBERSHIP.—

(1) NUMBER AND APPOINTMENT.—The Commission shall be composed of 11 members appointed as follows:

(A) The President shall appoint 3 members, one of whom the President shall designate as Chairperson.

(B) The Majority Leader of the Senate shall appoint 2 members.

(C) The Minority Leader of the Senate shall appoint 2 members.

(D) The Speaker of the House of Representatives shall appoint 2 members.

(E) The Minority Leader of the House of Representatives shall appoint 2 members.

(2) QUALIFICATIONS.—The membership of the Commission shall include individuals with national recognition for their expertise in health finance and economics, health plans and integrated delivery systems, reimbursement of health facilities, practicing physicians, practicing pharmacists, and other providers of health services, health care technology and information systems, and other related fields, who provide a mix of different professionals, broad geographic representation, and a balance between urban and rural representatives.

(d) TERMS.—Each member shall be appointed for the life of the Commission.

(e) COMPENSATION.—

(1) RATES OF PAY.—Members shall each be paid at a rate not to exceed the daily equivalent of the rate of basic pay for level IV of the Executive Schedule for each day (including travel time) during which they are engaged in the actual performance of duties vested in the Commission.

(2) PROHIBITION OF COMPENSATION OF FEDERAL EMPLOYEES.—Members of the Commission who are full-time officers or employees of the United States or Members of Congress may not receive additional pay, allowances, or benefits by reason of their service on the Commission.

(3) TRAVEL EXPENSES.—Each member shall receive travel expenses, including per diem in lieu of subsistence, in accordance with applicable provisions under subchapter I of chapter 57 of title 5, United States Code.

(f) QUORUM.—A majority of the members of the Commission shall constitute a quorum but a lesser number may hold hearings.

(g) DIRECTOR AND STAFF OF COMMISSION; EXPERTS AND CONSULTANTS.—

(1) DIRECTOR.—The Commission shall have a Director who shall be appointed by the Chairperson. The Director shall be paid at a rate not to exceed the rate of basic pay for level IV of the Executive Schedule.

(2) STAFF.—With the approval of the Commission, the Director may appoint and fix the pay of such additional personnel as the Director considers appropriate.

(3) APPLICABILITY OF CERTAIN CIVIL SERVICE LAWS.—The Director and staff of the Commission may be appointed without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and may be paid without regard to the provisions of chapter 51 and subchapter III of chapter 53 of that title relating to classification and General Schedule pay rates, except that an individual so appointed may not receive pay in excess of level IV of the Executive Schedule.

(4) EXPERTS AND CONSULTANTS.—With the approval of the Commission, the Director may procure temporary and intermittent services under section 3109(b) of title 5, United States Code.

(5) STAFF OF FEDERAL AGENCIES.—Upon request of the Chairperson, the head of any Federal department or agency may detail, on a reimbursable basis, any of the personnel of that department or agency to the Commission to assist it in carrying out its duties under this Act.

(h) POWERS OF COMMISSION.—

(1) HEARINGS AND SESSIONS.—The Commission may, for the purpose of carrying out this Act, hold hearings, sit and act at times and places, take testimony, and receive evidence as the Commission considers appropriate.

(2) POWERS OF MEMBERS AND AGENTS.—Any member or agent of the Commission may, if authorized by the Commission, take any action which the Commission is authorized to take by this section.

(3) OBTAINING OFFICIAL DATA.—The Commission may secure directly from any department or agency of the United States information necessary to enable it to carry out this Act. Upon request of the Chairperson of the Commission, the head of that department or agency shall furnish that information to the Commission.

(4) GIFTS, BEQUESTS, AND DEVISES.—The Commission may accept, use, and dispose of gifts, bequests, or devises of services or property, both real and personal, for the purpose of aiding or facilitating the work of the Commission. Gifts, bequests, or devises of money and proceeds from sales of other property received as gifts, bequests, or devises shall be deposited in the Treasury and shall be available for disbursement upon order of the Commission. For purposes of Federal income, estate, and gift taxes, property accepted under this subsection shall be considered as a gift, bequest, or devise to the United States.

(5) MAILS.—The Commission may use the United States mails in the same manner and under the same conditions as other departments and agencies of the United States.

(6) ADMINISTRATIVE SUPPORT SERVICES.—Upon the request of the Commission, the Administrator of General Services shall provide to the Commission, on a reimbursable basis, the administrative support services necessary for the Commission to carry out its responsibilities under this Act.

(7) CONTRACT AUTHORITY.—The Commission may enter into contracts or make other arrangements, as may be necessary for the conduct of the work of the Commission (without regard to section 3709 of the Revised Statutes (41 U.S.C. 5)).

(i) TERMINATION.—The Commission shall terminate on 30 days after submitting its report pursuant to subsection (b)(3).

(j) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated such sums as may be necessary to carry out this section.

SEC. 1013. RESEARCH ON OUTCOMES OF HEALTH CARE ITEMS AND SERVICES.

(a) RESEARCH, DEMONSTRATIONS, AND EVALUATIONS.—

(1) IMPROVEMENT OF EFFECTIVENESS AND EFFICIENCY.—

(A) IN GENERAL.—To improve the quality, effectiveness, and efficiency of health care delivered pursuant to the programs established under titles XVIII, XIX, and XXI of the Social Security Act, the Secretary acting through the Director of the Agency for Healthcare Research and Quality (in this section referred to as the ''Director''), shall conduct and support research to meet the priorities and requests for scientific evidence and information identified by such programs with respect to—

(i) the outcomes, comparative clinical effectiveness, and appropriateness of health care items and services (including prescription drugs); and

(ii) strategies for improving the efficiency and effectiveness of such programs, including the ways in which such items and services are organized, managed, and delivered under such programs.

(B) SPECIFICATION.—To respond to priorities and information requests in subparagraph (A), the Secretary may conduct or support, by grant, contract, or interagency agreement, research, demonstrations, evaluations, technology assessments, or other activities, including the provision of technical assistance, scientific expertise, or methodological assistance.

(2) PRIORITIES.—

(A) IN GENERAL.—The Secretary shall establish a process to develop priorities that will guide the research, demonstrations, and evaluation activities undertaken pursuant to this section.

(B) INITIAL LIST.—Not later than 6 months after the date of the enactment of this Act, the Secretary shall establish an initial list of priorities for research related to health care items and services (including prescription drugs).

(C) PROCESS.—In carrying out subparagraph (A), the Secretary—

(i) shall ensure that there is broad and ongoing consultation with relevant stakeholders in identifying the highest priorities for research, demonstrations, and evaluations to support and improve the programs established under titles XVIII, XIX, and XXI of the Social Security Act;

(ii) may include health care items and services which impose a high cost on such programs, as well as those which may be underutilized or overutilized and which may significantly improve the prevention, treatment, or cure of diseases and conditions (including chronic conditions) which impose high direct or indirect costs on patients or society; and

(iii) shall ensure that the research and activities undertaken pursuant to this section are responsive to the specified priorities and are conducted in a timely manner.

(3) EVALUATION AND SYNTHESIS OF SCIENTIFIC EVIDENCE.—

(A) IN GENERAL.—The Secretary shall—

(i) evaluate and synthesize available scientific evidence related to health care items and services (including prescription drugs) identified as priorities in accordance with paragraph (2) with respect to the comparative clinical effectiveness, outcomes, appropriateness, and provision of such items and services (including prescription drugs);

(ii) identify issues for which existing scientific evidence is insufficient with respect to such health care items and services (including prescription drugs);

(iii) disseminate to prescription drug plans and MA–PD plans under part D of title XVIII of the Social Security Act, other health plans, and the public the findings made under clauses (i) and (ii); and

(iv) work in voluntary collaboration with public and private sector entities to facilitate the development of new scientific knowledge regarding health care items and services (including prescription drugs).

(B) INITIAL RESEARCH.—The Secretary shall complete the evaluation and synthesis of the initial research required by the priority list developed under paragraph (2)(B) not later than 18 months after the development of such list.

(C) DISSEMINATION.—

(i) IN GENERAL.—To enhance patient safety and the quality of health care, the Secretary shall make available and disseminate in appropriate formats to prescription drugs plans under part D, and MA–PD plans under part C, of title XVIII of the Social Security Act, other health plans, and the public the evaluations and syntheses prepared pursuant to subparagraph (A) and the findings of research conducted pursuant to paragraph (1). In carrying out this clause the Secretary, in order to facilitate the availability of such evaluations and syntheses or findings at every decision point in the health care system, shall—

(I) present such evaluations and syntheses or findings in a form that is easily understood by the individuals receiving health care items and services (including prescription drugs) under such plans and periodically assess that the requirements of this subclause have been met; and

(II) provide such evaluations and syntheses or findings and other relevant information through easily accessible and searchable electronic mechanisms, and in hard copy formats as appropriate.

(ii) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as—

(I) affecting the authority of the Secretary or the Commissioner of Food and Drugs under the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act; or

(II) conferring any authority referred to in subclause (I) to the Director.

(D) ACCOUNTABILITY.—In carrying out this paragraph, the Secretary shall implement activities in a manner that—

(i) makes publicly available all scientific evidence relied upon and the methodologies employed, provided such evidence and method are not protected from public disclosure by section 1905 of title 18, United States Code, or other applicable law so that the results of the research, analyses, or syntheses can be evaluated or replicated; and

(ii) ensures that any information needs and unresolved issues identified in subparagraph (A)(ii) are taken into account in priority-setting for future research conducted by the Secretary.

(4) CONFIDENTIALITY.—

(A) IN GENERAL.—In making use of administrative, clinical, and program data and information developed or collected with respect to the programs established under titles XVIII, XIX, and XXI of the Social Security Act, for purposes of carrying out the requirements of this section or the activities authorized under title IX of the Public Health Service Act (42 U.S.C. 299 et seq.), such data and information shall be protected in accordance with the confidentiality requirements of title IX of the Public Health Service Act.

(B) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to require or permit the disclosure of data provided to the Secretary that is otherwise protected from disclosure under the Federal Food, Drug, and Cosmetic Act, section 1905 of title 18, United States Code, or other applicable law.

(5) EVALUATIONS.—The Secretary shall conduct and support evaluations of the activities carried out under this section to determine the extent to which such activities have had an effect on outcomes and utilization of health care items and services.

(6) IMPROVING INFORMATION AVAILABLE TO HEALTH CARE PROVIDERS, PATIENTS, AND POLICYMAKERS.—Not later than 18 months after the date of enactment of this Act, the Secretary shall identify options that could be undertaken in voluntary collaboration with private and public entities (as appropriate) for the—

(A) provision of more timely information through the programs established under titles XVIII, XIX, and XXI of the Social Security Act, regarding the outcomes and quality of patient care, including clinical and patient-reported outcomes, especially with respect to interventions and conditions for which clinical trials would not be feasible or raise ethical concerns that are difficult to address;

(B) acceleration of the adoption of innovation and quality improvement under such programs; and

(C) development of management tools for the programs established under titles XIX and XXI of the Social Security Act, and with respect to the programs established under such titles, assess the feasibility of using administrative or claims data, to—

(i) improve oversight by State officials;

(ii) support Federal and State initiatives to improve the quality, safety, and efficiency of services provided under such programs; and

(iii) provide a basis for estimating the fiscal and coverage impact of Federal or State program and policy changes.

(b) RECOMMENDATIONS.—

(1) DISCLAIMER.—In carrying out this section, the Director shall—

(A) not mandate national standards of clinical practice or quality health care standards; and

(B) include in any recommendations resulting from projects funded and published by the Director, a corresponding reference to the prohibition described in subparagraph (A).

(2) REQUIREMENT FOR IMPLEMENTATION.—Research, evaluation, and communication activities performed pursuant to this section shall reflect the principle that clinicians and patients should have the best available evidence upon which to make choices in health care items and services, in providers, and in health care delivery systems, recognizing that patient subpopulations and patient and physician preferences may vary.

(3) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to provide the Director with authority to mandate a national standard or require a specific approach to quality measurement and reporting.

(c) RESEARCH WITH RESPECT TO DISSEMINATION.—The Secretary, acting through the Director, may conduct or support research with respect to improving methods of disseminating information in accordance with subsection (a)(3)(C).

(d) LIMITATION ON CMS.—The Administrator of the Centers for Medicare & Medicaid Services may not use data obtained in accordance with this section to withhold coverage of a prescription drug.

(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $50,000,000 for fiscal year 2004, and such sums as may be necessary for each fiscal year thereafter.

SEC. 1014. HEALTH CARE THAT WORKS FOR ALL AMERICANS: CITIZENS HEALTH CARE WORKING GROUP.

(a) FINDINGS.—Congress finds the following:

(1) In order to improve the health care system, the American public must engage in an informed national public debate to make choices about the services they want covered, what health care coverage they want, and how they are willing to pay for coverage.

(2) More than a trillion dollars annually is spent on the health care system, yet—

(A) 41,000,000 Americans are uninsured;

(B) insured individuals do not always have access to essential, effective services to improve and maintain their health; and

(C) employers, who cover over 170,000,000 Americans, find providing coverage increasingly difficult because of rising costs and double digit premium increases.

(3) Despite increases in medical care spending that are greater than the rate of inflation, population growth, and Gross Domestic Product growth, there has not been a commensurate improvement in our health status as a nation.

(4) Health care costs for even just 1 member of a family can be catastrophic, resulting in medical bills potentially harming the economic stability of the entire family.

(5) Common life occurrences can jeopardize the ability of a family to retain private coverage or jeopardize access to public coverage.

(6) Innovations in health care access, coverage, and quality of care, including the use of technology, have often come from States, local communities, and private sector organizations, but more creative policies could tap this potential.

(7) Despite our Nation's wealth, the health care system does not provide coverage to all Americans who want it.

(b) PURPOSES.—The purposes of this section are—

(1) to provide for a nationwide public debate about improving the health care system to provide every American with the ability to obtain quality, affordable health care coverage; and

(2) to provide for a vote by Congress on the recommendations that result from the debate.

(c) ESTABLISHMENT.—The Secretary, acting through the Agency for Healthcare Research and Quality, shall establish an entity to be known as the Citizens' Health Care Working Group (referred to in this section as the ''Working Group'').

(d) MEMBERSHIP.—

(1) NUMBER AND APPOINTMENT.—The Working Group shall be composed of 15 members. One member shall be the Secretary. The Comptroller General of the United States shall appoint 14 members.

(2) QUALIFICATIONS.—

(A) IN GENERAL.—The membership of the Working Group shall include—

(i) consumers of health services that represent those individuals who have not had insurance within 2 years of appointment, that have had chronic illnesses, including mental illness, are disabled, and those who receive insurance coverage through medicare and medicaid; and

(ii) individuals with expertise in financing and paying for benefits and access to care, business and labor perspectives, and providers of health care.

The membership shall reflect a broad geographic representation and a balance between urban and rural representatives.

(B) PROHIBITED APPOINTMENTS.—Members of the Working Group shall not include Members of Congress or other elected government officials (Federal, State, or local). Individuals appointed to the Working Group shall not be paid employees or representatives of associations or advocacy organizations involved in the health care system.

(e) PERIOD OF APPOINTMENT.—Members of the Working Group shall be appointed for a life of the Working Group. Any vacancies shall not affect the power and duties of the Working Group but shall be filled in the same manner as the original appointment.

(f) DESIGNATION OF THE CHAIRPERSON.—Not later than 15 days after the date on which all members of the Working Group have been appointed under subsection (d)(1), the Comptroller General shall designate the chairperson of the Working Group.

(g) SUBCOMMITTEES.—The Working Group may establish subcommittees if doing so increases the efficiency of the Working Group in completing its tasks.

(h) DUTIES.—

(1) HEARINGS.—Not later than 90 days after the date of the designation of the chairperson under subsection (f), the Working Group shall hold hearings to examine—

(A) the capacity of the public and private health care systems to expand coverage options;

(B) the cost of health care and the effectiveness of care provided at all stages of disease;

(C) innovative State strategies used to expand health care coverage and lower health care costs;

(D) local community solutions to accessing health care coverage;

(E) efforts to enroll individuals currently eligible for public or private health care coverage;

(F) the role of evidence-based medical practices that can be documented as restoring, maintaining, or improving a patient's health, and the use of technology in supporting providers in improving quality of care and lowering costs; and

(G) strategies to assist purchasers of health care, including consumers, to become more aware of the impact of costs, and to lower the costs of health care.

(2) ADDITIONAL HEARINGS.—The Working Group may hold additional hearings on subjects other than those listed in paragraph (1) so long as such hearings are determined to be necessary by the Working Group in carrying out the purposes of this section. Such additional hearings do not have to be completed within the time period specified in paragraph (1) but shall not delay the other activities of the Working Group under this section.

(3) THE HEALTH REPORT TO THE AMERICAN PEOPLE.—Not later than 90 days after the hearings described in paragraphs (1) and (2) are completed, the Working Group shall prepare and make available to health care consumers through the Internet and other appropriate public channels, a report to be entitled, ''The Health Report to the American People''. Such report shall be understandable to the general public and include—

(A) a summary of—

(i) health care and related services that may be used by individuals throughout their life span;

(ii) the cost of health care services and their medical effectiveness in providing better quality of care for different age groups;

(iii) the source of coverage and payment, including reimbursement, for health care services;

(iv) the reasons people are uninsured or underinsured and the cost to taxpayers, purchasers of health services, and communities when Americans are uninsured or underinsured;

(v) the impact on health care outcomes and costs when individuals are treated in all stages of disease;

(vi) health care cost containment strategies; and

(vii) information on health care needs that need to be addressed;

(B) examples of community strategies to provide health care coverage or access;

(C) information on geographic-specific issues relating to health care;

(D) information concerning the cost of care in different settings, including institutional-based care and home and community-based care;

(E) a summary of ways to finance health care coverage; and

(F) the role of technology in providing future health care including ways to support the information needs of patients and providers.

(4) COMMUNITY MEETINGS.—

(A) IN GENERAL.—Not later than 1 year after the date on which all the members of the Working Group have been appointed under subsection (d)(1) and appropriations are first made available to carry out this section the Working Group shall initiate health care community meetings throughout the United States (in this paragraph referred to as ''community meetings''). Such community meetings may be geographically or regionally based and shall be completed within 180 days after the initiation of the first meeting.

(B) NUMBER OF MEETINGS.—The Working Group shall hold a sufficient number of community meetings in order to receive information that reflects—

(i) the geographic differences throughout the United States;

(ii) diverse populations; and

(iii) a balance among urban and rural populations.

(C) MEETING REQUIREMENTS.—

(i) FACILITATOR.—A State health officer may be the facilitator at the community meetings.

(ii) ATTENDANCE.—At least 1 member of the Working Group shall attend and serve as chair of each community meeting. Other members may participate through interactive technology.

(iii) TOPICS.—The community meetings shall, at a minimum, address the following questions:

(I) What health care benefits and services should be provided?

(II) How does the American public want health care delivered?

(III) How should health care coverage be financed?

(IV) What trade-offs are the American public willing to make in either benefits or financing to ensure access to affordable, high quality health care coverage and services?

(iv) INTERACTIVE TECHNOLOGY.—The Working Group may encourage public participation in community meetings through interactive technology and other means as determined appropriate by the Working Group.

(D) INTERIM REQUIREMENTS.—Not later than 180 days after the date of completion of the community meetings, the Working Group shall prepare and make available to the public through the Internet and other appropriate public channels, an interim set of recommendations on health care coverage and ways to improve and strengthen the health care system based on the information and preferences expressed at the community meetings. There shall be a 90-day public comment period on such recommendations.

(i) RECOMMENDATIONS.—Not later than 120 days after the expiration of the public comment period described in subsection (h)(4)(D), the Working Group shall submit to Congress and the President a final set of recommendations.

(j) ADMINISTRATION.—

(1) EXECUTIVE DIRECTOR.—There shall be an Executive Director of the Working Group who shall be appointed by the chairperson of the Working Group in consultation with the members of the Working Group.

(2) COMPENSATION.—While serving on the business of the Working Group (including travel time), a member of the Working Group shall be entitled to compensation at the per diem equivalent of the rate provided for level IV of the Executive Schedule under section 5315 of title 5, United States Code, and while so serving away from home and the member's regular place of business, a member may be allowed travel expenses, as authorized by the chairperson of the Working Group. For purposes of pay and employment benefits, rights, and privileges, all personnel of the Working Group shall be treated as if they were employees of the Senate.

(3) INFORMATION FROM FEDERAL AGENCIES.—The Working Group may secure directly from any Federal department or agency such information as the Working Group considers necessary to carry out this section. Upon request of the Working Group, the head of such department or agency shall furnish such information.

(4) POSTAL SERVICES.—The Working Group may use the United States mails in the same manner and under the same conditions as other departments and agencies of the Federal Government.

(k) DETAIL.—Not more than 10 Federal Government employees employed by the Department of Labor and 10 Federal Government employees employed by the Department of Health and Human Services may be detailed to the Working Group under this section without further reimbursement. Any detail of an employee shall be without interruption or loss of civil service status or privilege.

(l) TEMPORARY AND INTERMITTENT SERVICES.—The chairperson of the Working Group may procure temporary and intermittent services under section 3109(b) of title 5, United States Code, at rates for individuals which do not exceed the daily equivalent of the annual rate of basic pay prescribed for level V of the Executive Schedule under section 5316 of such title.

(m) ANNUAL REPORT.—Not later than 1 year after the date of enactment of this Act, and annually thereafter during the existence of the Working Group, the Working Group shall report to Congress and make public a detailed description of the expenditures of the Working Group used to carry out its duties under this section.

(n) SUNSET OF WORKING GROUP.—The Working Group shall terminate on the date that is 2 years after the date on which all the members of the Working Group have been appointed under subsection (d)(1) and appropriations are first made available to carry out this section.

(o) ADMINISTRATION REVIEW AND COMMENTS.—Not later than 45 days after receiving the final recommendations of the Working Group under subsection (i), the President shall submit a report to Congress which shall contain—

(1) additional views and comments on such recommendations; and

(2) recommendations for such legislation and administrative actions as the President considers appropriate.

(p) REQUIRED CONGRESSIONAL ACTION.—Not later than 45 days after receiving the report submitted by the President under subsection (o), each committee of jurisdiction of Congress, the Committee on Finance of the Senate, the Committee on Health, Education, Labor, and Pensions of the Senate, the Committee on Ways and Means of the House of Representatives, the Committee on Energy and Commerce of the House of Representatives, Committee on Education and the Workforce of the House of Representatives, shall hold at least 1 hearing on such report and on the final recommendations of the Working Group submitted under subsection (i).

(q) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—There are authorized to be appropriated to carry out this section, other than subsection (h)(3), $3,000,000 for each of fiscal years 2005 and 2006.

(2) HEALTH REPORT TO THE AMERICAN PEOPLE.—There are authorized to be appropriated for the preparation and dissemination of the Health Report to the American People described in subsection (h)(3), such sums as may be necessary for the fiscal year in which the report is required to be submitted.

SEC. 1015. FUNDING START-UP ADMINISTRATIVE COSTS FOR MEDICARE REFORM.

(a) IN GENERAL.—There are appropriated to carry out this Act (including the amendments made by this Act), to be transferred from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund—

(1) not to exceed $1,000,000,000 for the Centers for Medicare & Medicaid Services; and

(2) not to exceed $500,000,000 for the Social Security Administration.

(b) AVAILABILITY.—Amounts provided under subsection (a) shall remain available until September 30, 2005.

(c) APPLICATION.—From amounts provided under subsection (a)(2), the Social Security Administration may reimburse the Internal Revenue Service for expenses in carrying out this Act (and the amendments made by this Act).

(d) TRANSFER.—The President may transfer amounts provided under subsection (a) between the Centers for Medicare & Medicaid Services and the Social Security Administration. Notice of such transfers shall be transmitted within 15 days to the authorizing committees of the House of Representatives and of the Senate.

SEC. 1016. HEALTH CARE INFRASTRUCTURE IMPROVEMENT PROGRAM.

Title XVIII is amended by adding at the end the following new section:

''HEALTH CARE INFRASTRUCTURE IMPROVEMENT PROGRAM

''SEC. 1897. (a) ESTABLISHMENT.—The Secretary shall establish a loan program that provides loans to qualifying hospitals for payment of the capital costs of projects described in subsection (d).

''(b) APPLICATION.—No loan may be provided under this section to a qualifying hospital except pursuant to an application that is submitted and approved in a time, manner, and form specified by the Secretary. A loan under this section shall be on such terms and conditions and meet such requirements as the Secretary determines appropriate.

''(c) SELECTION CRITERIA.—

''(1) IN GENERAL.—The Secretary shall establish criteria for selecting among qualifying hospitals that apply for a loan under this section. Such criteria shall consider the extent to which the project for which loan is sought is nationally or regionally significant, in terms of expanding or improving the health care infrastructure of the United States or the region or in terms of the medical benefit that the project will have.

''(2) QUALIFYING HOSPITAL DEFINED.—For purposes of this section, the term 'qualifying hospital' means a hospital that—

''(A) is engaged in research in the causes, prevention, and treatment of cancer; and

''(B) is designated as a cancer center for the National Cancer Institute or is designated by the State as the official cancer institute of the State.

''(d) PROJECTS.—A project described in this subsection is a project of a qualifying hospital that is designed to improve the health care infrastructure of the hospital, including construction, renovation, or other capital improvements.

''(e) STATE AND LOCAL PERMITS.—The provision of a loan under this section with respect to a project shall not—

''(1) relieve any recipient of the loan of any obligation to obtain any required State or local permit or approval with respect to the project;

''(2) limit the right of any unit of State or local government to approve or regulate any rate of return on private equity invested in the project; or

''(3) otherwise supersede any State or local law (including any regulation) applicable to the construction or operation of the project.

''(f) FORGIVENESS OF INDEBTEDNESS.—The Secretary may forgive a loan provided to a qualifying hospital under this section under terms and conditions that are analogous to the loan forgiveness provision for student loans under part D of title IV of the Higher Education Act of 1965 (20 U.S.C. 1087a et seq.), except that the Secretary shall condition such forgiveness on the establishment by the hospital of—

''(A) an outreach program for cancer prevention, early diagnosis, and treatment that provides services to a substantial majority of the residents of a State or region, including residents of rural areas;

''(B) an outreach program for cancer prevention, early diagnosis, and treatment that provides services to multiple Indian tribes; and

''(C)(i) unique research resources (such as population databases); or

''(ii) an affiliation with an entity that has unique research resources.

''(g) FUNDING.—

''(1) IN GENERAL.—There are appropriated, out of amounts in the Treasury not otherwise appropriated, to carry out this section, $200,000,000, to remain available during the period beginning on July 1, 2004, and ending on September 30, 2008.

''(2) ADMINISTRATIVE COSTS.—From funds made available under paragraph (1), the Secretary may use, for the administration of this section, not more than $2,000,000 for each of fiscal years 2004 through 2008.

''(3) AVAILABILITY.—Amounts appropriated under this section shall be available for obligation on July 1, 2004.

''(h) REPORT TO CONGRESS.—Not later than 4 years after the date of the enactment of this section, the Secretary shall submit to Congress a report on the projects for which loans are provided under this section and a recommendation as to whether the Congress should authorize the Secretary to continue loans under this section beyond fiscal year 2008.''.

TITLE XI—ACCESS TO AFFORDABLE PHARMACEUTICALS

Subtitle A—Access to Affordable Pharmaceuticals

SEC. 1101. 30-MONTH STAY-OF-EFFECTIVENESS PERIOD.

(a) ABBREVIATED NEW DRUG APPLICATIONS.—Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) is amended—

(1) in paragraph (2)—

(A) by striking subparagraph (B) and inserting the following:

''(B) NOTICE OF OPINION THAT PATENT IS INVALID OR WILL NOT BE INFRINGED.—

''(i) AGREEMENT TO GIVE NOTICE.—An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give notice as required by this subparagraph.

''(ii) TIMING OF NOTICE.—An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall give notice as required under this subparagraph—

''(I) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

''(II) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

''(iii) RECIPIENTS OF NOTICE.—An applicant required under this subparagraph to give notice shall give notice to—

''(I) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

''(II) the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

''(iv) CONTENTS OF NOTICE.—A notice required under this subparagraph shall—

''(I) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

''(II) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.''; and

(B) by adding at the end the following subparagraph:

''(D)(i) An applicant may not amend or supplement an application to seek approval of a drug referring to a different listed drug from the listed drug identified in the application as submitted to the Secretary.

''(ii) With respect to the drug for which an application is submitted, nothing in this subsection prohibits an applicant from amending or supplementing the application to seek approval of a different strength.

''(iii) Within 60 days after the date of the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the Secretary shall issue guidance defining the term 'listed drug' for purposes of this subparagraph.''; and

(2) in paragraph (5)—

(A) in subparagraph (B)—

(i) by striking ''under the following'' and inserting ''by applying the following to each certification made under paragraph (2)(A)(vii)''; and

(ii) in clause (iii)—

(I) in the first sentence, by striking ''unless'' and all that follows and inserting ''unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under subsection (b)(1) or (c)(2) before the date on which the application (excluding an amendment or supplement to the application), which the Secretary later determines to be substantially complete, was submitted.''; and

(II) in the second sentence—

(aa) by striking subclause (I) and inserting the following:

''(I) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on—

''(aa) the date on which the court enters judgment reflecting the decision; or

''(bb) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;'';

(bb) by striking subclause (II) and inserting the following:

''(II) if before the expiration of such period the district court decides that the patent has been infringed—

''(aa) if the judgment of the district court is appealed, the approval shall be made effective on—

''(AA) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

''(BB) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

''(bb) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of title 35, United States Code;'';

(cc) in subclause (III), by striking ''on the date of such court decision.'' and inserting ''as provided in subclause (I); or'';

(dd) by inserting after subclause (III) the following:

''(IV) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity

and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in subclause (II).''; and

(ee) in the matter after and below subclause (IV) (as added by item (dd)), by striking ''Until the expiration'' and all that follows;

(B) by redesignating subparagraphs (C) and (D) as subparagraphs (E) and (F), respectively; and

(C) by inserting after subparagraph (B) the following:

''(C) CIVIL ACTION TO OBTAIN PATENT CERTAINTY.—

''(i) DECLARATORY JUDGMENT ABSENT INFRINGEMENT ACTION.—

''(I) IN GENERAL.—No action may be brought under section 2201 of title 28, United States Code, by an applicant under paragraph (2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (B)(iii) unless—

''(aa) the forty-five day period referred to in such subparagraph has expired;

''(bb) neither the owner of such patent nor the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the patent before the expiration of such period; and

''(cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

''(II) FILING OF CIVIL ACTION.—If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of title 28, United States Code, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

''(III) OFFER OF CONFIDENTIAL ACCESS TO APPLICATION.—For purposes of subclause (I)(cc), the document described in this subclause is a document providing an offer of confidential access to the application that is in the custody of the applicant under paragraph (2) for the purpose of determining whether an action referred to in subparagraph (B)(iii) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

''(ii) COUNTERCLAIM TO INFRINGEMENT ACTION.—

''(I) IN GENERAL.—If an owner of the patent or the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) on the ground that the patent does not claim either—

''(aa) the drug for which the application was approved; or

''(bb) an approved method of using the drug.

''(II) NO INDEPENDENT CAUSE OF ACTION.—Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

''(iii) NO DAMAGES.—An applicant shall not be entitled to damages in a civil action under clause (i) or a counterclaim under clause (ii).''.

(b) APPLICATIONS GENERALLY.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended—

(1) in subsection (b)—

(A) by striking paragraph (3) and inserting the following:

''(3) NOTICE OF OPINION THAT PATENT IS INVALID OR WILL NOT BE INFRINGED.—

''(A) AGREEMENT TO GIVE NOTICE.—An applicant that makes a certification described in paragraph (2)(A)(iv) shall include in the application a statement that the applicant will give notice as required by this paragraph.

''(B) TIMING OF NOTICE.—An applicant that makes a certification described in paragraph (2)(A)(iv) shall give notice as required under this paragraph—

''(i) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

''(ii) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

''(C) RECIPIENTS OF NOTICE.—An applicant required under this paragraph to give notice shall give notice to—

''(i) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

''(ii) the holder of the approved application under this subsection for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

''(D) CONTENTS OF NOTICE.—A notice required under this paragraph shall—

''(i) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

''(ii) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.''; and

(B)(i) by redesignating paragraph (4) as paragraph (5); and

(ii) by inserting after paragraph (3) the following paragraph:

''(4)(A) An applicant may not amend or supplement an application referred to in paragraph (2) to seek approval of a drug that is a different drug than the drug identified in the application as submitted to the Secretary.

''(B) With respect to the drug for which such an application is submitted, nothing in this subsection or subsection (c)(3) prohibits an applicant from amending or supplementing the application to seek approval of a different strength.''; and

(2) in subsection (c)(3)—

(A) in the first sentence, by striking ''under the following'' and inserting ''by applying the following to each certification made under subsection (b)(2)(A)'';

(B) in subparagraph (C)—

(i) in the first sentence, by striking ''unless'' and all that follows and inserting ''unless, before the expiration of 45 days after the date on which the notice described in subsection (b)(3) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under paragraph (2) or subsection (b)(1) before the date on which the application (excluding an amendment or supplement to the application) was submitted.'';

(ii) in the second sentence—

(I) by striking ''paragraph (3)(B)'' and inserting ''subsection (b)(3)'';

(II) by striking clause (i) and inserting the following:

''(i) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on—

''(I) the date on which the court enters judgment reflecting the decision; or

''(II) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;'';

(III) by striking clause (ii) and inserting the following:

''(ii) if before the expiration of such period the district court decides that the patent has been infringed—

''(I) if the judgment of the district court is appealed, the approval shall be made effective on—

''(aa) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

''(bb) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

''(II) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of title 35, United States Code;'';

(IV) in clause (iii), by striking ''on the date of such court decision.'' and inserting ''as provided in clause (i); or'';

(V) by inserting after clause (iii), the following:

''(iv) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in clause (ii).''; and

(VI) in the matter after and below clause (iv) (as added by subclause (V)), by striking ''Until the expiration'' and all that follows; and

(iii) in the third sentence, by striking ''paragraph (3)(B)'' and inserting ''subsection (b)(3)'';

(C) by redesignating subparagraph (D) as subparagraph (E); and

(D) by inserting after subparagraph (C) the following:

''(D) CIVIL ACTION TO OBTAIN PATENT CERTAINTY.—

''(i) DECLARATORY JUDGMENT ABSENT INFRINGEMENT ACTION.—

''(I) IN GENERAL.—No action may be brought under section 2201 of title 28, United States Code, by an applicant referred to in subsection (b)(2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (C) unless—

''(aa) the forty-five day period referred to in such subparagraph has expired;

''(bb) neither the owner of such patent nor the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the patent before the expiration of such period; and

''(cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

''(II) FILING OF CIVIL ACTION.—If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of title 28, United States Code, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

''(III) OFFER OF CONFIDENTIAL ACCESS TO APPLICATION.—For purposes of subclause (I)(cc), the document described in this subclause is a document providing an offer of confidential access to the application that is in the custody of the applicant referred to in subsection (b)(2) for the purpose of determining whether an action referred to in subparagraph (C) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under subsection (b)(2)(A)(iv) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

''(ii) COUNTERCLAIM TO INFRINGEMENT ACTION.—

''(I) IN GENERAL.—If an owner of the patent or the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or this subsection on the ground that the patent does not claim either—

''(aa) the drug for which the application was approved; or

''(bb) an approved method of using the drug.

''(II) NO INDEPENDENT CAUSE OF ACTION.—Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

''(iii) NO DAMAGES.—An applicant shall not be entitled to damages in a civil action under clause (i) or a counterclaim under clause (ii).''.

(c) APPLICABILITY.—

(1) IN GENERAL.—Except as provided in paragraphs (2) and (3), the amendments made by subsections (a) and (b), apply to any proceeding under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) that is pending on or after the date of the enactment of this Act regardless of the date on which the proceeding was commenced or is commenced.

(2) NOTICE OF OPINION THAT PATENT IS INVALID OR WILL NOT BE INFRINGED.—The amendments made by subsections (a)(1) and (b)(1) apply with respect to any certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) submitted on or after August 18, 2003, in an application filed under subsection (b) or (j) of that section or in an amendment or supplement to an application filed under subsection (b) or (j) of that section.

(3) EFFECTIVE DATE OF APPROVAL.—The amendments made by subsections (a)(2)(A)(ii)(I) and (b)(2)(B)(i) apply with respect to any patent information submitted under subsection (b)(1) or (c)(2) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) on or after August 18, 2003.

(d) INFRINGEMENT ACTIONS.—Section 271(e) of title 35, United States Code, is amended by adding at the end the following:

''(5) Where a person has filed an application described in paragraph (2) that includes a certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and neither the owner of the patent that is the subject of the certification nor the holder of the approved application under subsection (b) of such section for the drug that is claimed by the patent or a use of which is claimed by the patent brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of such section was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed.''.

SEC. 1102. FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.

(a) IN GENERAL.—Section 505(j)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) (as amended by section 1101) is amended—

(1) in subparagraph (B), by striking clause (iv) and inserting the following:

''(iv) 180-DAY EXCLUSIVITY PERIOD.—

''(I) EFFECTIVENESS OF APPLICATION.—Subject to subparagraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.

''(II) DEFINITIONS.—In this paragraph:

''(aa) 180-DAY EXCLUSIVITY PERIOD.—The term '180-day exclusivity period' means the 180-day period ending on the day before the date on which an application submitted by an applicant other than a first applicant could become effective under this clause.

''(bb) FIRST APPLICANT.—As used in this subsection, the term 'first applicant' means an applicant that, on the first day on which a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) for the drug.

''(cc) SUBSTANTIALLY COMPLETE APPLICATION.—As used in this subsection, the term 'substantially complete application' means an application under this subsection that on its face is sufficiently complete to permit a substantive review and contains all the information required by paragraph (2)(A).

''(dd) TENTATIVE APPROVAL.—

''(AA) IN GENERAL.—The term 'tentative approval' means notification to an applicant by the Secretary that an application under this subsection meets the requirements of paragraph (2)(A), but cannot receive effective approval because the application does not meet the requirements of this subparagraph, there is a period of exclusivity for the listed drug under subparagraph (F) or section 505A, or there is a 7-year period of exclusivity for the listed drug under section 527.

''(BB) LIMITATION.—A drug that is granted tentative approval by the Secretary is not an approved drug and shall not have an effective approval until the Secretary issues an approval after any necessary additional review of the application.''; and

(2) by inserting after subparagraph (C) the following:

''(D) FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.—

''(i) DEFINITION OF FORFEITURE EVENT.—In this subparagraph, the term 'forfeiture event', with respect to an application under this subsection, means the occurrence of any of the following:

''(I) FAILURE TO MARKET.—The first applicant fails to market the drug by the later of—

''(aa) the earlier of the date that is—

''(AA) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(iii); or

''(BB) 30 months after the date of submission of the application of the first applicant; or

''(bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), at least 1 of the following has occurred:

''(AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.

''(BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed.

''(CC) The patent information submitted under subsection (b) or (c) is withdrawn by the holder of the application approved under subsection (b).

''(II) WITHDRAWAL OF APPLICATION.—The first applicant withdraws the application or the Secretary considers the application to have been

withdrawn as a result of a determination by the Secretary that the application does not meet the requirements for approval under paragraph (4).

''(III) AMENDMENT OF CERTIFICATION.—The first applicant amends or withdraws the certification for all of the patents with respect to which that applicant submitted a certification qualifying the applicant for the 180-day exclusivity period.

''(IV) FAILURE TO OBTAIN TENTATIVE APPROVAL.—The first applicant fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed.

''(V) AGREEMENT WITH ANOTHER APPLICANT, THE LISTED DRUG APPLICATION HOLDER, OR A PATENT OWNER.—The first applicant enters into an agreement with another applicant under this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV), the Federal Trade Commission or the Attorney General files a complaint, and there is a final decision of the Federal Trade Commission or the court with regard to the complaint from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the agreement has violated the antitrust laws (as defined in section 1 of the Clayton Act (15 U.S.C. 12), except that the term includes section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent that that section applies to unfair methods of competition).

''(VI) EXPIRATION OF ALL PATENTS.—All of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired.

''(ii) FORFEITURE.—The 180-day exclusivity period described in subparagraph (B)(iv) shall be forfeited by a first applicant if a forfeiture event occurs with respect to that first applicant.

''(iii) SUBSEQUENT APPLICANT.—If all first applicants forfeit the 180-day exclusivity period under clause (ii)—

''(I) approval of any application containing a certification described in paragraph (2)(A)(vii)(IV) shall be made effective in accordance with subparagraph (B)(iii); and

''(II) no applicant shall be eligible for a 180-day exclusivity period.''.

(b) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as provided in paragraph (2), the amendment made by subsection (a) shall be effective only with respect to an application filed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) after the date of the enactment of this Act for a listed drug for which no certification under section 505(j)(2)(A)(vii)(IV) of that Act was made before the date of the enactment of this Act.

(2) COLLUSIVE AGREEMENTS.—If a forfeiture event described in section 505(j)(5)(D)(i)(V) of that Act occurs in the case of an applicant, the applicant shall forfeit the 180-day period under section 505(j)(5)(B)(iv) of that Act without regard to when the first certification under section 505(j)(2)(A)(vii)(IV) of that Act for the listed drug was made.

(3) DECISION OF A COURT WHEN THE 180-DAY EXCLUSIVITY PERIOD HAS NOT BEEN TRIGGERED.—With respect to an application filed before, on, or after the date of the enactment of this Act for a listed drug for which a certification under section 505(j)(2)(A)(vii)(IV) of that Act was made before the date of the enactment of this Act and for which neither of the events described in subclause (I) or (II) of section 505(j)(5)(B)(iv) of that Act (as in effect on the day before the date of the enactment of this Act) has occurred on or before the date of the enactment of this Act, the term ''decision of a court'' as used in clause (iv) of section 505(j)(5)(B) of that Act means a final decision of a court from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken.

SEC. 1103. BIOAVAILABILITY AND BIOEQUIVALENCE.

(a) IN GENERAL.—Section 505(j)(8) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(8)) is amended—

(1) by striking subparagraph (A) and inserting the following:

''(A)(i) The term 'bioavailability' means the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.

''(ii) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may assess bioavailability by scientifically valid measurements intended to reflect the rate and extent to which the active ingredient or therapeutic ingredient becomes available at the site of drug action.''; and

(2) by adding at the end the following:

''(C) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may establish alternative, scientifically valid methods to show bioequivalence if the alternative methods are expected to detect a significant difference between the drug and the listed drug in safety and therapeutic effect.''.

(b) EFFECT OF AMENDMENT.—The amendment made by subsection (a) does not alter the standards for approval of drugs under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)).

SEC. 1104. CONFORMING AMENDMENTS.

Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended—

(1) in subsections (b)(1)(A)(i) and (c)(1)(A)(i), by striking ''(j)(5)(D)(ii)'' each place it appears and inserting ''(j)(5)(F)(ii)'';

(2) in subsections (b)(1)(A)(ii) and (c)(1)(A)(ii), by striking ''(j)(5)(D)'' each place it appears and inserting ''(j)(5)(F)''; and

(3) in subsections (e) and (l), by striking ''505(j)(5)(D)'' each place it appears and inserting ''505(j)(5)(F)''.

Subtitle B—Federal Trade Commission Review

SEC. 1111. DEFINITIONS.

In this subtitle:

(1) ANDA.—The term ''ANDA'' means an abbreviated drug application, as defined under section 201(aa) of the Federal Food, Drug, and Cosmetic Act.

(2) ASSISTANT ATTORNEY GENERAL.—The term ''Assistant Attorney General'' means the Assistant Attorney General in charge of the Antitrust Division of the Department of Justice.

(3) BRAND NAME DRUG.—The term ''brand name drug'' means a drug for which an application is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act, including an application referred to in section 505(b)(2) of such Act.

(4) BRAND NAME DRUG COMPANY.—The term ''brand name drug company'' means the party that holds the approved application referred to in paragraph (3) for a brand name drug that is a listed drug in an ANDA, or a party that is the owner of a patent for which information is submitted for such drug under subsection (b) or (c) of section 505 of the Federal Food, Drug, and Cosmetic Act.

(5) COMMISSION.—The term ''Commission'' means the Federal Trade Commission.

(6) GENERIC DRUG.—The term ''generic drug'' means a drug for which an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act is approved.

(7) GENERIC DRUG APPLICANT.—The term ''generic drug applicant'' means a person who has filed or received approval for an ANDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act.

(8) LISTED DRUG.—The term ''listed drug'' means a brand name drug that is listed under section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act.

SEC. 1112. NOTIFICATION OF AGREEMENTS.

(a) AGREEMENT WITH BRAND NAME DRUG COMPANY.—

(1) REQUIREMENT.—A generic drug applicant that has submitted an ANDA containing a certification under section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act and a brand name drug company that enter into an agreement described in paragraph (2) shall each file the agreement in accordance with subsection (c). The agreement shall be filed prior to the date of the first commercial marketing of the generic drug that is the subject of the ANDA.

(2) SUBJECT MATTER OF AGREEMENT.—An agreement described in this paragraph between a generic drug applicant and a brand name drug company is an agreement regarding—

(A) the manufacture, marketing or sale of the brand name drug that is the listed drug in the ANDA involved;

(B) the manufacture, marketing, or sale of the generic drug for which the ANDA was submitted; or

(C) the 180-day period referred to in section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act as it applies to such ANDA or to any other ANDA based on the same brand name drug.

(b) AGREEMENT WITH ANOTHER GENERIC DRUG APPLICANT.—

(1) REQUIREMENT.—A generic drug applicant that has submitted an ANDA containing a certification under section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act with respect to a listed drug and another generic drug applicant that has submitted an ANDA containing such a certification for the same listed drug shall each file the agreement in accordance with subsection (c). The agreement shall be filed prior to the date of the first commercial marketing of either of the generic drugs for which such ANDAs were submitted.

(2) SUBJECT MATTER OF AGREEMENT.—An agreement described in this paragraph between two generic drug applicants is an agreement regarding the 180-day period referred to in section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act as it applies to the ANDAs with which the agreement is concerned.

(c) FILING.—

(1) AGREEMENT.—The parties that are required in subsection (a) or (b) to file an agreement in accordance with this subsection shall file with the Assistant Attorney General and the Commission the text of any such agreement, except that such parties are not required to file an agreement that solely concerns—

(A) purchase orders for raw material supplies;

(B) equipment and facility contracts;

(C) employment or consulting contracts; or

(D) packaging and labeling contracts.

(2) OTHER AGREEMENTS.—The parties that are required in subsection (a) or (b) to file an agreement in accordance with this subsection shall file with the Assistant Attorney General and the Commission the text of any agreements between the parties that are not described in such subsections and are contingent upon, provide a contingent condition for, or are otherwise related to an agreement that is required in subsection (a) or (b) to be filed in accordance with this subsection.

(3) DESCRIPTION.—In the event that any agreement required in subsection (a) or (b) to be filed in accordance with this subsection has not been reduced to text, each of the parties involved shall file written descriptions of such agreement that are sufficient to disclose all the terms and conditions of the agreement.

SEC. 1113. FILING DEADLINES.

Any filing required under section 1112 shall be filed with the Assistant Attorney General and the Commission not later than 10 business days after the date the agreements are executed.

SEC. 1114. DISCLOSURE EXEMPTION.

Any information or documentary material filed with the Assistant Attorney General or the

Commission pursuant to this subtitle shall be exempt from disclosure under section 552 of title 5, United States Code, and no such information or documentary material may be made public, except as may be relevant to any administrative or judicial action or proceeding. Nothing in this section is intended to prevent disclosure to either body of the Congress or to any duly authorized committee or subcommittee of the Congress.

SEC. 1115. ENFORCEMENT.

(a) CIVIL PENALTY.—Any brand name drug company or generic drug applicant which fails to comply with any provision of this subtitle shall be liable for a civil penalty of not more than $11,000, for each day during which such entity is in violation of this subtitle. Such penalty may be recovered in a civil action brought by the United States, or brought by the Commission in accordance with the procedures established in section 16(a)(1) of the Federal Trade Commission Act (15 U.S.C. 56(a)).

(b) COMPLIANCE AND EQUITABLE RELIEF.—If any brand name drug company or generic drug applicant fails to comply with any provision of this subtitle, the United States district court may order compliance, and may grant such other equitable relief as the court in its discretion determines necessary or appropriate, upon application of the Assistant Attorney General or the Commission.

SEC. 1116. RULEMAKING.

The Commission, with the concurrence of the Assistant Attorney General and by rule in accordance with section 553 of title 5, United States Code, consistent with the purposes of this subtitle—

(1) may define the terms used in this subtitle;

(2) may exempt classes of persons or agreements from the requirements of this subtitle; and

(3) may prescribe such other rules as may be necessary and appropriate to carry out the purposes of this subtitle.

SEC. 1117. SAVINGS CLAUSE.

Any action taken by the Assistant Attorney General or the Commission, or any failure of the Assistant Attorney General or the Commission to take action, under this subtitle shall not at any time bar any proceeding or any action with respect to any agreement between a brand name drug company and a generic drug applicant, or any agreement between generic drug applicants, under any other provision of law, nor shall any filing under this subtitle constitute or create a presumption of any violation of any competition laws.

SEC. 1118. EFFECTIVE DATE.

This subtitle shall—

(1) take effect 30 days after the date of the enactment of this Act; and

(2) shall apply to agreements described in section 1112 that are entered into 30 days after the date of the enactment of this Act.

Subtitle C—Importation of Prescription Drugs

SEC. 1121. IMPORTATION OF PRESCRIPTION DRUGS.

(a) IN GENERAL.—Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.) is amended by striking section 804 and inserting the following:

"SEC. 804. IMPORTATION OF PRESCRIPTION DRUGS.

''(a) DEFINITIONS.—In this section:

''(1) IMPORTER.—The term 'importer' means a pharmacist or wholesaler.

''(2) PHARMACIST.—The term 'pharmacist' means a person licensed by a State to practice pharmacy, including the dispensing and selling of prescription drugs.

''(3) PRESCRIPTION DRUG.—The term 'prescription drug' means a drug subject to section 503(b), other than—

''(A) a controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802));

''(B) a biological product (as defined in section 351 of the Public Health Service Act (42 U.S.C. 262));

''(C) an infused drug (including a peritoneal dialysis solution);

''(D) an intravenously injected drug;

''(E) a drug that is inhaled during surgery; or

''(F) a drug which is a parenteral drug, the importation of which pursuant to subsection (b) is determined by the Secretary to pose a threat to the public health, in which case section 801(d)(1) shall continue to apply.

''(4) QUALIFYING LABORATORY.—The term 'qualifying laboratory' means a laboratory in the United States that has been approved by the Secretary for the purposes of this section.

''(5) WHOLESALER.—

''(A) IN GENERAL.—The term 'wholesaler' means a person licensed as a wholesaler or distributor of prescription drugs in the United States under section 503(e)(2)(A).

''(B) EXCLUSION.—The term 'wholesaler' does not include a person authorized to import drugs under section 801(d)(1).

''(b) REGULATIONS.—The Secretary, after consultation with the United States Trade Representative and the Commissioner of Customs, shall promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States.

''(c) LIMITATION.—The regulations under subsection (b) shall—

''(1) require that safeguards be in place to ensure that each prescription drug imported under the regulations complies with section 505 (including with respect to being safe and effective for the intended use of the prescription drug), with sections 501 and 502, and with other applicable requirements of this Act;

''(2) require that an importer of a prescription drug under the regulations comply with subsections (d)(1) and (e); and

''(3) contain any additional provisions determined by the Secretary to be appropriate as a safeguard to protect the public health or as a means to facilitate the importation of prescription drugs.

''(d) INFORMATION AND RECORDS.—

''(1) IN GENERAL.—The regulations under subsection (b) shall require an importer of a prescription drug under subsection (b) to submit to the Secretary the following information and documentation:

''(A) The name and quantity of the active ingredient of the prescription drug.

''(B) A description of the dosage form of the prescription drug.

''(C) The date on which the prescription drug is shipped.

''(D) The quantity of the prescription drug that is shipped.

''(E) The point of origin and destination of the prescription drug.

''(F) The price paid by the importer for the prescription drug.

''(G) Documentation from the foreign seller specifying—

''(i) the original source of the prescription drug; and

''(ii) the quantity of each lot of the prescription drug originally received by the seller from that source.

''(H) The lot or control number assigned to the prescription drug by the manufacturer of the prescription drug.

''(I) The name, address, telephone number, and professional license number (if any) of the importer.

''(J)(i) In the case of a prescription drug that is shipped directly from the first foreign recipient of the prescription drug from the manufacturer:

''(I) Documentation demonstrating that the prescription drug was received by the recipient from the manufacturer and subsequently shipped by the first foreign recipient to the importer.

''(II) Documentation of the quantity of each lot of the prescription drug received by the first foreign recipient demonstrating that the quantity being imported into the United States is not more than the quantity that was received by the first foreign recipient.

''(III)(aa) In the case of an initial imported shipment, documentation demonstrating that each batch of the prescription drug in the shipment was statistically sampled and tested for authenticity and degradation.

''(bb) In the case of any subsequent shipment, documentation demonstrating that a statistically valid sample of the shipment was tested for authenticity and degradation.

''(ii) In the case of a prescription drug that is not shipped directly from the first foreign recipient of the prescription drug from the manufacturer, documentation demonstrating that each batch in each shipment offered for importation into the United States was statistically sampled and tested for authenticity and degradation.

''(K) Certification from the importer or manufacturer of the prescription drug that the prescription drug—

''(i) is approved for marketing in the United States and is not adulterated or misbranded; and

''(ii) meets all labeling requirements under this Act.

''(L) Laboratory records, including complete data derived from all tests necessary to ensure that the prescription drug is in compliance with established specifications and standards.

''(M) Documentation demonstrating that the testing required by subparagraphs (J) and (L) was conducted at a qualifying laboratory.

''(N) Any other information that the Secretary determines is necessary to ensure the protection of the public health.

''(2) MAINTENANCE BY THE SECRETARY.—The Secretary shall maintain information and documentation submitted under paragraph (1) for such period of time as the Secretary determines to be necessary.

''(e) TESTING.—The regulations under subsection (b) shall require—

''(1) that testing described in subparagraphs (J) and (L) of subsection (d)(1) be conducted by the importer or by the manufacturer of the prescription drug at a qualified laboratory;

''(2) if the tests are conducted by the importer—

''(A) that information needed to—

''(i) authenticate the prescription drug being tested; and

''(ii) confirm that the labeling of the prescription drug complies with labeling requirements under this Act;

be supplied by the manufacturer of the prescription drug to the pharmacist or wholesaler; and

''(B) that the information supplied under subparagraph (A) be kept in strict confidence and used only for purposes of testing or otherwise complying with this Act; and

''(3) may include such additional provisions as the Secretary determines to be appropriate to provide for the protection of trade secrets and commercial or financial information that is privileged or confidential.

''(f) REGISTRATION OF FOREIGN SELLERS.—Any establishment within Canada engaged in the distribution of a prescription drug that is imported or offered for importation into the United States shall register with the Secretary the name and place of business of the establishment and the name of the United States agent for the establishment.

''(g) SUSPENSION OF IMPORTATION.—The Secretary shall require that importations of a specific prescription drug or importations by a specific importer under subsection (b) be immediately suspended on discovery of a pattern of importation of that specific prescription drug or by that specific importer of drugs that are counterfeit or in violation of any requirement under this section, until an investigation is completed and the Secretary determines that the public is adequately protected from counterfeit and violative prescription drugs being imported under subsection (b).

''(h) APPROVED LABELING.—The manufacturer of a prescription drug shall provide an importer written authorization for the importer to use, at no cost, the approved labeling for the prescription drug.

''(i) CHARITABLE CONTRIBUTIONS.—Notwithstanding any other provision of this section, section 801(d)(1) continues to apply to a prescription drug that is donated or otherwise supplied at no charge by the manufacturer of the drug to a charitable or humanitarian organization (including the United Nations and affiliates) or to a government of a foreign country.

''(j) WAIVER AUTHORITY FOR IMPORTATION BY INDIVIDUALS.—

''(1) DECLARATIONS.—Congress declares that in the enforcement against individuals of the prohibition of importation of prescription drugs and devices, the Secretary should—

''(A) focus enforcement on cases in which the importation by an individual poses a significant threat to public health; and

''(B) exercise discretion to permit individuals to make such importations in circumstances in which—

''(i) the importation is clearly for personal use; and

''(ii) the prescription drug or device imported does not appear to present an unreasonable risk to the individual.

''(2) WAIVER AUTHORITY.—

''(A) IN GENERAL.—The Secretary may grant to individuals, by regulation or on a case-by-case basis, a waiver of the prohibition of importation of a prescription drug or device or class of prescription drugs or devices, under such conditions as the Secretary determines to be appropriate.

''(B) GUIDANCE ON CASE-BY-CASE WAIVERS.—The Secretary shall publish, and update as necessary, guidance that accurately describes circumstances in which the Secretary will consistently grant waivers on a case-by-case basis under subparagraph (A), so that individuals may know with the greatest practicable degree of certainty whether a particular importation for personal use will be permitted.

''(3) DRUGS IMPORTED FROM CANADA.—In particular, the Secretary shall by regulation grant individuals a waiver to permit individuals to import into the United States a prescription drug that—

''(A) is imported from a licensed pharmacy for personal use by an individual, not for resale, in quantities that do not exceed a 90-day supply;

''(B) is accompanied by a copy of a valid prescription;

''(C) is imported from Canada, from a seller registered with the Secretary;

''(D) is a prescription drug approved by the Secretary under chapter V;

''(E) is in the form of a final finished dosage that was manufactured in an establishment registered under section 510; and

''(F) is imported under such other conditions as the Secretary determines to be necessary to ensure public safety.

''(k) CONSTRUCTION.—Nothing in this section limits the authority of the Secretary relating to the importation of prescription drugs, other than with respect to section 801(d)(1) as provided in this section.

''(l) EFFECTIVENESS OF SECTION.—

''(1) COMMENCEMENT OF PROGRAM.—This section shall become effective only if the Secretary certifies to the Congress that the implementation of this section will—

(A) pose no additional risk to the public's health and safety; and

(B) result in a significant reduction in the cost of covered products to the American consumer.

''(2) TERMINATION OF PROGRAM.—

''(A) IN GENERAL.—If, after the date that is 1 year after the effective date of the regulations under subsection (b) and before the date that is 18 months after the effective date, the Secretary submits to Congress a certification that, in the opinion of the Secretary, based on substantial evidence obtained after the effective date, the benefits of implementation of this section do not outweigh any detriment of implementation of this section, this section shall cease to be effective as of the date that is 30 days after the date on which the Secretary submits the certification.

''(B) PROCEDURE.—The Secretary shall not submit a certification under subparagraph (A) unless, after a hearing on the record under sections 556 and 557 of title 5, United States Code, the Secretary—

''(i)(I) determines that it is more likely than not that implementation of this section would result in an increase in the risk to the public health and safety;

''(II) identifies specifically, in qualitative and quantitative terms, the nature of the increased risk;

''(III) identifies specifically the causes of the increased risk; and

''(IV)(aa) considers whether any measures can be taken to avoid, reduce, or mitigate the increased risk; and

''(bb) if the Secretary determines that any measures described in item (aa) would require additional statutory authority, submits to Congress a report describing the legislation that would be required;

''(ii) identifies specifically, in qualitative and quantitative terms, the benefits that would result from implementation of this section (including the benefit of reductions in the cost of covered products to consumers in the United States, allowing consumers to procure needed medication that consumers might not otherwise be able to procure without foregoing other necessities of life); and

''(iii)(I) compares in specific terms the detriment identified under clause (i) with the benefits identified under clause (ii); and

''(II) determines that the benefits do not outweigh the detriment.

''(m) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as are necessary to carry out this section.''.

(b) CONFORMING AMENDMENTS.—The Federal Food, Drug, and Cosmetic Act is amended—

(1) in section 301(aa) (21 U.S.C. 331(aa)), by striking ''covered product in violation of section 804'' and inserting ''prescription drug in violation of section 804''; and

(2) in section 303(a)(6) (21 U.S.C. 333(a)(6), by striking ''covered product pursuant to section 804(a)'' and inserting ''prescription drug under section 804(b)''.

SEC. 1122. STUDY AND REPORT ON IMPORTATION OF DRUGS.

The Secretary, in consultation with appropriate government agencies, shall conduct a study on the importation of drugs into the United States pursuant to section 804 of the Federal Food, Drug, and Cosmetic Act (as added by section 1121 of this Act). Not later than 12 months after the date of the enactment of this Act, the Secretary shall submit to the appropriate committees of the Congress a report providing the findings of such study.

SEC. 1123. STUDY AND REPORT ON TRADE IN PHARMACEUTICALS.

The President's designees shall conduct a study and report on issues related to trade and pharmaceuticals.

TITLE XII—TAX INCENTIVES FOR HEALTH AND RETIREMENT SECURITY

SEC. 1201. HEALTH SAVINGS ACCOUNTS.

(a) IN GENERAL.—Part VII of subchapter B of chapter 1 of the Internal Revenue Code of 1986 (relating to additional itemized deductions for individuals) is amended by redesignating section 223 as section 224 and by inserting after section 222 the following new section:

''SEC. 223. HEALTH SAVINGS ACCOUNTS.

''(a) DEDUCTION ALLOWED.—In the case of an individual who is an eligible individual for any month during the taxable year, there shall be allowed as a deduction for the taxable year an amount equal to the aggregate amount paid in cash during such taxable year by or on behalf of such individual to a health savings account of such individual.

''(b) LIMITATIONS.—

''(1) IN GENERAL.—The amount allowable as a deduction under subsection (a) to an individual for the taxable year shall not exceed the sum of the monthly limitations for months during such taxable year that the individual is an eligible individual.

''(2) MONTHLY LIMITATION.—The monthly limitation for any month is 1/12 of—

''(A) in the case of an eligible individual who has self-only coverage under a high deductible health plan as of the first day of such month, the lesser of—

''(i) the annual deductible under such coverage, or

''(ii) $2,250, or

''(B) in the case of an eligible individual who has family coverage under a high deductible health plan as of the first day of such month, the lesser of—

''(i) the annual deductible under such coverage, or

''(ii) $4,500.

''(3) ADDITIONAL CONTRIBUTIONS FOR INDIVIDUALS 55 OR OLDER.—

''(A) IN GENERAL.—In the case of an individual who has attained age 55 before the close of the taxable year, the applicable limitation under subparagraphs (A) and (B) of paragraph (2) shall be increased by the additional contribution amount.

''(B) ADDITIONAL CONTRIBUTION AMOUNT.—For purposes of this section, the additional contribution amount is the amount determined in accordance with the following table:

''For taxable years beginning in:	***The additional contribution amount is:***
2004	*$500*
2005	*$600*
2006	*$700*
2007	*$800*
2008	*$900*
2009 and thereafter	*$1,000.*

''(4) COORDINATION WITH OTHER CONTRIBUTIONS.—The limitation which would (but for this paragraph) apply under this subsection to an individual for any taxable year shall be reduced (but not below zero) by the sum of—

''(A) the aggregate amount paid for such taxable year to Archer MSAs of such individual, and

''(B) the aggregate amount contributed to health savings accounts of such individual which is excludable from the taxpayer's gross income for such taxable year under section 106(d) (and such amount shall not be allowed as a deduction under subsection (a)).

Subparagraph (A) shall not apply with respect to any individual to whom paragraph (5) applies.

''(5) SPECIAL RULE FOR MARRIED INDIVIDUALS.—In the case of individuals who are married to each other, if either spouse has family coverage—

''(A) both spouses shall be treated as having only such family coverage (and if such spouses each have family coverage under different plans, as having the family coverage with the lowest annual deductible), and

''(B) the limitation under paragraph (1) (after the application of subparagraph (A) and without regard to any additional contribution amount under paragraph (3))—

''(i) shall be reduced by the aggregate amount paid to Archer MSAs of such spouses for the taxable year, and

''(ii) after such reduction, shall be divided equally between them unless they agree on a different division.

''(6) DENIAL OF DEDUCTION TO DEPENDENTS.—No deduction shall be allowed under this section

to any individual with respect to whom a deduction under section 151 is allowable to another taxpayer for a taxable year beginning in the calendar year in which such individual's taxable year begins.

''(7) MEDICARE ELIGIBLE INDIVIDUALS.—The limitation under this subsection for any month with respect to an individual shall be zero for the first month such individual is entitled to benefits under title XVIII of the Social Security Act and for each month thereafter.

''(c) DEFINITIONS AND SPECIAL RULES.—For purposes of this section—

''(1) ELIGIBLE INDIVIDUAL.—

''(A) IN GENERAL.—The term 'eligible individual' means, with respect to any month, any individual if—

''(i) such individual is covered under a high deductible health plan as of the 1st day of such month, and

''(ii) such individual is not, while covered under a high deductible health plan, covered under any health plan—

''(I) which is not a high deductible health plan, and

''(II) which provides coverage for any benefit which is covered under the high deductible health plan.

''(B) CERTAIN COVERAGE DISREGARDED.—Subparagraph (A)(ii) shall be applied without regard to—

''(i) coverage for any benefit provided by permitted insurance, and

''(ii) coverage (whether through insurance or otherwise) for accidents, disability, dental care, vision care, or long-term care.

''(2) HIGH DEDUCTIBLE HEALTH PLAN.—

''(A) IN GENERAL.—The term 'high deductible health plan' means a health plan—

''(i) which has an annual deductible which is not less than—

''(I) $1,000 for self-only coverage, and

''(II) twice the dollar amount in subclause (I) for family coverage, and

''(ii) the sum of the annual deductible and the other annual out-of-pocket expenses required to be paid under the plan (other than for premiums) for covered benefits does not exceed—

''(I) $5,000 for self-only coverage, and

''(II) twice the dollar amount in subclause (I) for family coverage.

''(B) EXCLUSION OF CERTAIN PLANS.—Such term does not include a health plan if substantially all of its coverage is coverage described in paragraph (1)(B).

''(C) SAFE HARBOR FOR ABSENCE OF PREVENTIVE CARE DEDUCTIBLE.—A plan shall not fail to be treated as a high deductible health plan by reason of failing to have a deductible for preventive care (within the meaning of section 1871 of the Social Security Act, except as otherwise provided by the Secretary).

''(D) SPECIAL RULES FOR NETWORK PLANS.—In the case of a plan using a network of providers—

''(i) ANNUAL OUT-OF-POCKET LIMITATION.—Such plan shall not fail to be treated as a high deductible health plan by reason of having an out-of-pocket limitation for services provided outside of such network which exceeds the applicable limitation under subparagraph (A)(ii).

''(ii) ANNUAL DEDUCTIBLE.—Such plan's annual deductible for services provided outside of such network shall not be taken into account for purposes of subsection (b)(2).

''(3) PERMITTED INSURANCE.—The term 'permitted insurance' means—

''(A) insurance if substantially all of the coverage provided under such insurance relates to—

''(i) liabilities incurred under workers' compensation laws,

''(ii) tort liabilities,

''(iii) liabilities relating to ownership or use of property, or

''(iv) such other similar liabilities as the Secretary may specify by regulations,

''(B) insurance for a specified disease or illness, and

''(C) insurance paying a fixed amount per day (or other period) of hospitalization.

''(4) FAMILY COVERAGE.—The term 'family coverage' means any coverage other than self-only coverage.

''(5) ARCHER MSA.—The term 'Archer MSA' has the meaning given such term in section 220(d).

''(d) HEALTH SAVINGS ACCOUNT.—For purposes of this section—

''(1) IN GENERAL.—The term 'health savings account' means a trust created or organized in the United States as a health savings account exclusively for the purpose of paying the qualified medical expenses of the account beneficiary, but only if the written governing instrument creating the trust meets the following requirements:

''(A) Except in the case of a rollover contribution described in subsection (f)(5) or section 220(f)(5), no contribution will be accepted—

''(i) unless it is in cash, or

''(ii) to the extent such contribution, when added to previous contributions to the trust for the calendar year, exceeds the sum of—

''(I) the dollar amount in effect under subsection (b)(2)(B)(ii), and

''(II) the dollar amount in effect under subsection (b)(3)(B).

''(B) The trustee is a bank (as defined in section 408(n)), an insurance company (as defined in section 816), or another person who demonstrates to the satisfaction of the Secretary that the manner in which such person will administer the trust will be consistent with the requirements of this section.

''(C) No part of the trust assets will be invested in life insurance contracts.

''(D) The assets of the trust will not be commingled with other property except in a common trust fund or common investment fund.

''(E) The interest of an individual in the balance in his account is nonforfeitable.

''(2) QUALIFIED MEDICAL EXPENSES.—

''(A) IN GENERAL.—The term 'qualified medical expenses' means, with respect to an account beneficiary, amounts paid by such beneficiary for medical care (as defined in section 213(d) for such individual, the spouse of such individual, and any dependent (as defined in section 152) of such individual, but only to the extent such amounts are not compensated for by insurance or otherwise.

''(B) HEALTH INSURANCE MAY NOT BE PURCHASED FROM ACCOUNT.—Subparagraph (A) shall not apply to any payment for insurance.

''(C) EXCEPTIONS.—Subparagraph (B) shall not apply to any expense for coverage under—

''(i) a health plan during any period of continuation coverage required under any Federal law,

''(ii) a qualified long-term care insurance contract (as defined in section 7702B(b)),

''(iii) a health plan during a period in which the individual is receiving unemployment compensation under any Federal or State law, or

''(iv) in the case of an account beneficiary who has attained the age specified in section 1811 of the Social Security Act, any health insurance other than a medicare supplemental policy (as defined in section 1882 of the Social Security Act).

''(3) ACCOUNT BENEFICIARY.—The term 'account beneficiary' means the individual on whose behalf the health savings account was established.

''(4) CERTAIN RULES TO APPLY.—Rules similar to the following rules shall apply for purposes of this section:

''(A) Section 219(d)(2) (relating to no deduction for rollovers).

''(B) Section 219(f)(3) (relating to time when contributions deemed made).

''(C) Except as provided in section 106(d), section 219(f)(5) (relating to employer payments).

''(D) Section 408(g) (relating to community property laws).

''(E) Section 408(h) (relating to custodial accounts).

''(e) TAX TREATMENT OF ACCOUNTS.—

''(1) IN GENERAL.—A health savings account is exempt from taxation under this subtitle unless such account has ceased to be a health savings account. Notwithstanding the preceding sentence, any such account is subject to the taxes imposed by section 511 (relating to imposition of tax on unrelated business income of charitable, etc. organizations).

''(2) ACCOUNT TERMINATIONS.—Rules similar to the rules of paragraphs (2) and (4) of section 408(e) shall apply to health savings accounts, and any amount treated as distributed under such rules shall be treated as not used to pay qualified medical expenses.

''(f) TAX TREATMENT OF DISTRIBUTIONS.—

''(1) AMOUNTS USED FOR QUALIFIED MEDICAL EXPENSES.—Any amount paid or distributed out of a health savings account which is used exclusively to pay qualified medical expenses of any account beneficiary shall not be includible in gross income.

''(2) INCLUSION OF AMOUNTS NOT USED FOR QUALIFIED MEDICAL EXPENSES.—Any amount paid or distributed out of a health savings account which is not used exclusively to pay the qualified medical expenses of the account beneficiary shall be included in the gross income of such beneficiary.

''(3) EXCESS CONTRIBUTIONS RETURNED BEFORE DUE DATE OF RETURN.—

''(A) IN GENERAL.—If any excess contribution is contributed for a taxable year to any health savings account of an individual, paragraph (2) shall not apply to distributions from the health savings accounts of such individual (to the extent such distributions do not exceed the aggregate excess contributions to all such accounts of such individual for such year) if—

''(i) such distribution is received by the individual on or before the last day prescribed by law (including extensions of time) for filing such individual's return for such taxable year, and

''(ii) such distribution is accompanied by the amount of net income attributable to such excess contribution.

Any net income described in clause (ii) shall be included in the gross income of the individual for the taxable year in which it is received.

''(B) EXCESS CONTRIBUTION.—For purposes of subparagraph (A), the term 'excess contribution' means any contribution (other than a rollover contribution described in paragraph (5) or section 220(f)(5)) which is neither excludable from gross income under section 106(d) nor deductible under this section.

''(4) ADDITIONAL TAX ON DISTRIBUTIONS NOT USED FOR QUALIFIED MEDICAL EXPENSES.—

''(A) IN GENERAL.—The tax imposed by this chapter on the account beneficiary for any taxable year in which there is a payment or distribution from a health savings account of such beneficiary which is includible in gross income under paragraph (2) shall be increased by 10 percent of the amount which is so includible.

''(B) EXCEPTION FOR DISABILITY OR DEATH.—Subparagraph (A) shall not apply if the payment or distribution is made after the account beneficiary becomes disabled within the meaning of section 72(m)(7) or dies.

''(C) EXCEPTION FOR DISTRIBUTIONS AFTER MEDICARE ELIGIBILITY.—Subparagraph (A) shall not apply to any payment or distribution after the date on which the account beneficiary attains the age specified in section 1811 of the Social Security Act.

''(5) ROLLOVER CONTRIBUTION.—An amount is described in this paragraph as a rollover contribution if it meets the requirements of subparagraphs (A) and (B).

''(A) IN GENERAL.—Paragraph (2) shall not apply to any amount paid or distributed from a health savings account to the account beneficiary to the extent the amount received is paid into a health savings account for the benefit of such beneficiary not later than the 60th day after the day on which the beneficiary receives the payment or distribution.

''(B) LIMITATION.—This paragraph shall not apply to any amount described in subparagraph (A) received by an individual from a health savings account if, at any time during the 1-year period ending on the day of such receipt, such individual received any other amount described in subparagraph (A) from a health savings account which was not includible in the individual's gross income because of the application of this paragraph.

''(6) COORDINATION WITH MEDICAL EXPENSE DEDUCTION.—For purposes of determining the amount of the deduction under section 213, any payment or distribution out of a health savings account for qualified medical expenses shall not be treated as an expense paid for medical care.

''(7) TRANSFER OF ACCOUNT INCIDENT TO DIVORCE.—The transfer of an individual's interest in a health savings account to an individual's spouse or former spouse under a divorce or separation instrument described in subparagraph (A) of section 71(b)(2) shall not be considered a taxable transfer made by such individual notwithstanding any other provision of this subtitle, and such interest shall, after such transfer, be treated as a health savings account with respect to which such spouse is the account beneficiary.

''(8) TREATMENT AFTER DEATH OF ACCOUNT BENEFICIARY.—

''(A) TREATMENT IF DESIGNATED BENEFICIARY IS SPOUSE.—If the account beneficiary's surviving spouse acquires such beneficiary's interest in a health savings account by reason of being the designated beneficiary of such account at the death of the account beneficiary, such health savings account shall be treated as if the spouse were the account beneficiary.

''(B) OTHER CASES.—

''(i) IN GENERAL.— If, by reason of the death of the account beneficiary, any person acquires the account beneficiary's interest in a health savings account in a case to which subparagraph (A) does not apply—

''(I) such account shall cease to be a health savings account as of the date of death, and

''(II) an amount equal to the fair market value of the assets in such account on such date shall be includible if such person is not the estate of such beneficiary, in such person's gross income for the taxable year which includes such date, or if such person is the estate of such beneficiary, in such beneficiary's gross income for the last taxable year of such beneficiary.

''(ii) SPECIAL RULES.—

''(I) REDUCTION OF INCLUSION FOR PREDEATH EXPENSES.—The amount includible in gross income under clause (i) by any person (other than the estate) shall be reduced by the amount of qualified medical expenses which were incurred by the decedent before the date of the decedent's death and paid by such person within 1 year after such date.

''(II) DEDUCTION FOR ESTATE TAXES.— An appropriate deduction shall be allowed under section 691(c) to any person (other than the decedent or the decedent's spouse) with respect to amounts included in gross income under clause (i) by such person.

''(g) COST-OF-LIVING ADJUSTMENT.—

''(1) IN GENERAL.—Each dollar amount in subsections (b)(2) and (c)(2)(A) shall be increased by an amount equal to—

''(A) such dollar amount, multiplied by

''(B) the cost-of-living adjustment determined under section 1(f)(3) for the calendar year in which such taxable year begins determined by substituting for 'calendar year 1992' in subparagraph (B) thereof—

''(i) except as provided in clause (ii), 'calendar year 1997', and

''(ii) in the case of each dollar amount in subsection (c)(2)(A), 'calendar year 2003'.

''(2) ROUNDING.—If any increase under paragraph (1) is not a multiple of $50, such increase shall be rounded to the nearest multiple of $50.

''(h) REPORTS.—The Secretary may require—

''(1) the trustee of a health savings account to make such reports regarding such account to the Secretary and to the account beneficiary with respect to contributions, distributions, the return of excess contributions, and such other matters as the Secretary determines appropriate, and

''(2) any person who provides an individual with a high deductible health plan to make such reports to the Secretary and to the account beneficiary with respect to such plan as the Secretary determines appropriate.

The reports required by this subsection shall be filed at such time and in such manner and furnished to such individuals at such time and in such manner as may be required by the Secretary.''.

(b) DEDUCTION ALLOWED WHETHER OR NOT INDIVIDUAL ITEMIZES OTHER DEDUCTIONS.—Subsection (a) of section 62 of such Code is amended by inserting after paragraph (18) the following new paragraph:

''(19) HEALTH SAVINGS ACCOUNTS.—The deduction allowed by section 223.''.

(c) ROLLOVERS FROM ARCHER MSAS PERMITTED.—Subparagraph (A) of section 220(f)(5) of such Code (relating to rollover contribution) is amended by inserting ''or a health savings account (as defined in section 223(d))'' after ''paid into an Archer MSA''.

(d) EXCLUSIONS FOR EMPLOYER CONTRIBUTIONS TO HEALTH SAVINGS ACCOUNTS.—

(1) EXCLUSION FROM INCOME TAX.—Section 106 of such Code (relating to contributions by employer to accident and health plans) is amended by adding at the end the following new subsection:

''(d) CONTRIBUTIONS TO HEALTH SAVINGS ACCOUNTS.—

''(1) IN GENERAL.—In the case of an employee who is an eligible individual (as defined in section 223(c)(1)), amounts contributed by such employee's employer to any health savings account (as defined in section 223(d)) of such employee shall be treated as employer-provided coverage for medical expenses under an accident or health plan to the extent such amounts do not exceed the limitation under section 223(b) (determined without regard to this subsection) which is applicable to such employee for such taxable year.

''(2) SPECIAL RULES.—Rules similar to the rules of paragraphs (2), (3), (4), and (5) of subsection (b) shall apply for purposes of this subsection.

''(3) CROSS REFERENCE.—

''For penalty on failure by employer to make comparable contributions to the health savings accounts of comparable employees, see section 4980G.''.

(2) EXCLUSION FROM EMPLOYMENT TAXES.—

(A) RAILROAD RETIREMENT TAX.—Subsection (e) of section 3231 of such Code is amended by adding at the end the following new paragraph:

''(11) HEALTH SAVINGS ACCOUNT CONTRIBUTIONS.—The term 'compensation' shall not include any payment made to or for the benefit of an employee if at the time of such payment it is reasonable to believe that the employee will be able to exclude such payment from income under section 106(d).''.

(B) UNEMPLOYMENT TAX.—Subsection (b) of section 3306 of such Code is amended by striking ''or'' at the end of paragraph (16), by striking the period at the end of paragraph (17) and inserting ''; or'', and by inserting after paragraph (17) the following new paragraph:

''(18) any payment made to or for the benefit of an employee if at the time of such payment it is reasonable to believe that the employee will be able to exclude such payment from income under section 106(d).''.

(C) WITHHOLDING TAX.—Subsection (a) of section 3401 of such Code is amended by striking ''or'' at the end of paragraph (20), by striking the period at the end of paragraph (21) and inserting ''; or'', and by inserting after paragraph (21) the following new paragraph:

''(22) any payment made to or for the benefit of an employee if at the time of such payment it is reasonable to believe that the employee will be able to exclude such payment from income under section 106(d).''.

(3) EMPLOYER CONTRIBUTIONS REQUIRED TO BE SHOWN ON W–2.—Subsection (a) of section 6051 of such Code is amended by striking ''and'' at the end of paragraph (10), by striking the period at the end of paragraph (11) and inserting '', and'', and by inserting after paragraph (11) the following new paragraph:

''(12) the amount contributed to any health savings account (as defined in section 223(d)) of such employee or such employee's spouse.''.

(4) PENALTY FOR FAILURE OF EMPLOYER TO MAKE COMPARABLE HEALTH SAVINGS ACCOUNT CONTRIBUTIONS.—

(A) IN GENERAL.—Chapter 43 of such Code is amended by adding after section 4980F the following new section:

''SEC. 4980G. FAILURE OF EMPLOYER TO MAKE COMPARABLE HEALTH SAVINGS ACCOUNT CONTRIBUTIONS.

''(a) GENERAL RULE.—In the case of an employer who makes a contribution to the health savings account of any employee during a calendar year, there is hereby imposed a tax on the failure of such employer to meet the requirements of subsection (b) for such calendar year.

''(b) RULES AND REQUIREMENTS.—Rules and requirements similar to the rules and requirements of section 4980E shall apply for purposes of this section.

''(c) REGULATIONS.—The Secretary shall issue regulations to carry out the purposes of this section, including regulations providing special rules for employers who make contributions to Archer MSAs and health savings accounts during the calendar year.''.

(B) CLERICAL AMENDMENT.—The table of sections for chapter 43 of such Code is amended by adding after the item relating to section 4980F the following new item:

''Sec. 4980G. Failure of employer to make comparable health savings account contributions.''.

(e) TAX ON EXCESS CONTRIBUTIONS.—Section 4973 of such Code (relating to tax on excess contributions to certain tax-favored accounts and annuities) is amended—

(1) by striking ''or'' at the end of subsection (a)(3), by inserting ''or'' at the end of subsection (a)(4), and by inserting after subsection (a)(4) the following new paragraph:

''(5) a health savings account (within the meaning of section 223(d)),'', and

(2) by adding at the end the following new subsection:

''(g) EXCESS CONTRIBUTIONS TO HEALTH SAVINGS ACCOUNTS.—For purposes of this section, in the case of health savings accounts (within the meaning of section 223(d)), the term 'excess contributions' means the sum of—

''(1) the aggregate amount contributed for the taxable year to the accounts (other than a rollover contribution described in section 220(f)(5) or 223(f)(5)) which is neither excludable from gross income under section 106(d) nor allowable as a deduction under section 223 for such year, and

''(2) the amount determined under this subsection for the preceding taxable year, reduced by the sum of—

''(A) the distributions out of the accounts which were included in gross income under section 223(f)(2), and

''(B) the excess (if any) of—

''(i) the maximum amount allowable as a deduction under section 223(b) (determined without regard to section 106(d)) for the taxable year, over

''(ii) the amount contributed to the accounts for the taxable year.

For purposes of this subsection, any contribution which is distributed out of the health savings account in a distribution to which section 223(f)(3) applies shall be treated as an amount not contributed.''.

(f) TAX ON PROHIBITED TRANSACTIONS.—

(1) Section 4975 of such Code (relating to tax on prohibited transactions) is amended by adding at the end of subsection (c) the following new paragraph:

''(6) SPECIAL RULE FOR HEALTH SAVINGS ACCOUNTS.—An individual for whose benefit a health savings account (within the meaning of section 223(d)) is established shall be exempt from the tax imposed by this section with respect to any transaction concerning such account (which would otherwise be taxable under this section) if, with respect to such transaction, the account ceases to be a health savings account by reason of the application of section 223(e)(2) to such account.''.

(2) Paragraph (1) of section 4975(e) of such Code is amended by redesignating subparagraphs (E) and (F) as subparagraphs (F) and (G), respectively, and by inserting after subparagraph (D) the following new subparagraph:

''(E) a health savings account described in section 223(d),''.

(g) FAILURE TO PROVIDE REPORTS ON HEALTH SAVINGS ACCOUNTS.—Paragraph (2) of section 6693(a) of such Code (relating to reports) is amended by redesignating subparagraphs (C) and (D) as subparagraphs (D) and (E), respectively, and by inserting after subparagraph (B) the following new subparagraph:

''(C) section 223(h) (relating to health savings accounts),''.

(h) EXCEPTION FROM CAPITALIZATION OF POLICY ACQUISITION EXPENSES.—Subparagraph (B) of section 848(e)(1) of such Code (defining specified insurance contract) is amended by striking ''and'' at the end of clause (iii), by striking the period at the end of clause (iv) and inserting '', and'', and by adding at the end the following new clause:

''(v) any contract which is a health savings account (as defined in section 223(d)).''.

(i) HEALTH SAVINGS ACCOUNTS MAY BE OFFERED UNDER CAFETERIA PLANS.—Paragraph (2) of section 125(d) (relating to cafeteria plan defined) is amended by adding at the end the following new subparagraph:

''(D) EXCEPTION FOR HEALTH SAVINGS ACCOUNTS.—Subparagraph (A) shall not apply to a plan to the extent of amounts which a covered employee may elect to have the employer pay as contributions to a health savings account established on behalf of the employee.''.

(j) CLERICAL AMENDMENT.—The table of sections for part VII of subchapter B of chapter 1 of such Code is amended by striking the last item and inserting the following:

''Sec. 223. Health savings accounts.
''Sec. 224. Cross reference.''.

(k) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 2003.

SEC. 1202. EXCLUSION FROM GROSS INCOME OF CERTAIN FEDERAL SUBSIDIES FOR PRESCRIPTION DRUG PLANS.

(a) IN GENERAL.—Part III of subchapter B of chapter 1 of the Internal Revenue Code of 1986 is amended by inserting after section 139 the following new section:

''SEC. 139A. FEDERAL SUBSIDIES FOR PRESCRIPTION DRUG PLANS.

''Gross income shall not include any special subsidy payment received under section 1860D–22 of the Social Security Act. This section shall not be taken into account for purposes of determining whether any deduction is allowable with respect to any cost taken into account in determining such payment.''.

(b) ALTERNATIVE MINIMUM TAX RELIEF.—Section 56(g)(4)(B) of such Code is amended by inserting ''or 139A'' after ''section 114''.

(c) CONFORMING AMENDMENT.—The table of sections for part III of subchapter B of chapter 1 of such Code is amended by inserting after the item relating to section 139 the following new item:

''Sec. 139A. Federal subsidies for prescription drug plans.''.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years ending after the date of the enactment of this Act.

SEC. 1203. EXCEPTION TO INFORMATION REPORTING REQUIREMENTS RELATED TO CERTAIN HEALTH ARRANGEMENTS.

(a) IN GENERAL.—Section 6041 of the Internal Revenue Code of 1986 (relating to information at source) is amended by adding at the end the following new subsection:

''(f) SECTION DOES NOT APPLY TO CERTAIN HEALTH ARRANGEMENTS.—This section shall not apply to any payment for medical care (as defined in section 213(d)) made under—

''(1) a flexible spending arrangement (as defined in section 106(c)(2)), or

''(2) a health reimbursement arrangement which is treated as employer-provided coverage under an accident or health plan for purposes of section 106.''.

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to payments made after December 31, 2002.

And the Senate agree to the same.

That the House recede from its disagreement to the amendment of the Senate to the title of the bill and agree to the same with an amendment as follows:

In lieu of the matter proposed to be inserted by the Senate amendment to the title of the bill insert the following: ''An Act to amend title XVIII of the Social Security Act to provide for a voluntary prescription drug coverage program under the medicare program, to modernize, strengthen, and improve the medicare program, to amend the Internal Revenue Code of 1986 to allow a deduction to individuals for amounts contributed to health savings accounts, to amend the Federal Food, Drug, and Cosmetic Act with respect to abbreviated applications for the approval of new drugs and the importation of prescription drugs, and for other purposes.''.

And the Senate agree to the same.

BILLY TAUZIN,
WILLIAM THOMAS,
MICHAEL BILIRAKIS,
NANCY L. JOHNSON,
TOM DELAY,
Managers on the Part of the House.

CHUCK GRASSLEY,
ORRIN HATCH,
DON NICKLES,
BILL FRIST,
JON KYL,
MAX BAUCUS,
JOHN BREAUX,
Managers on the Part of the Senate.

JOINT EXPLANATION STATEMENT OF THE COMMITTEE OF CONFERENCE

The managers on the part of the House and the Senate at the conference on the disagreeing votes of the two Houses on the amendment of the Senate to the bill (H.R. 1) to amend title XVIII of the Social Security Act to provide for a voluntary program for prescription drug coverage under the Medicare Program, to modernize the Medicare Program to amend the Internal Revenue Code of 1986 to allow a deduction to individuals for amounts contributed to health savings security accounts and health savings accounts, to provide for the disposition of unused health benefits in cafeteria plans and flexible spending arrangements, and for other purposes, submit the following joint statement to the House and the Senate in explanation of the effect of the action agreed upon by the managers and recommended in the accompanying conference report:

The Senate amendment to the text of the bill struck all of the House bill after the enacting clause and inserted a substitute text.

The House recedes from its disagreement to the amendment of the Senate with an amendment that is a substitute for the Hose bill and the Senate amendment. The differences between the House bill, the Senate amendment, and the substitute agreed to in conference are noted below, except for clerical corrections, conforming changes made necessary by agreements reached by the conferees, and minor drafting and clarifying changes.

MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003

Short Title; Amendments to Social Security Act; References to BIPA and Secretary; Table of Contents. (Section 1 of Conference Agreement; Section 1 of House bill; Section 1 of Senate bill).

Present Law

No provision.

House Provision

The provision specifies the title of the Act as the ''Medicare Prescription Drug and Modernization Act of 2003''. The provision also includes a table of contents.

Senate Provision

The provision specifies the title of the Act as the ''Prescription Drug and Medicare Improvement Act of 2003''. The provision also includes a table of contents.

Conference Agreement

The provision specifies the title of the Act as the ''Medicare Prescription Drug, Improvement and Modernization Act of 2003''. The provision also includes a table of contents.

TITLE I—MEDICARE PRESCRIPTION DRUG BENEFIT

Voluntary Prescription Drug Benefit Program (Section 101 of Conference agreement, Section 101 of House bill; Section 101 of Senate bill).

Present Law

Medicare does not cover most outpatient prescription drugs. Beneficiaries who are inpatients of hospitals or skilled nursing facilities may receive drugs as part of their treatment. Medicare payments made to the facilities cover these costs. Medicare also makes payments to physicians for drugs or biologicals which cannot be self-administered. This means that coverage is generally limited to drugs or biologicals administered by infusion or injection. However, if the injection is generally self-administered (e.g., insulin), it is not covered.

Despite the general limitation on coverage for outpatient drugs, the law specifically authorizes coverage for the following: (1) drugs used in immunosuppressive therapy (such as cyclosporin) following discharge from a hospital for a Medicare covered organ transplant; (2) erythropoietin (EPO) for the treatment of anemia for persons with chronic renal failure who are on dialysis; (3) drugs taken orally during cancer chemotherapy providing they have the same active ingredients and are used for the same indications as chemotherapy drugs which would be covered if they were not self-administered and were administered as incident to a physician's professional service; and (4) hemophilia clotting factors for hemophilia patients competent to use such factors to control bleeding without medical supervision, and items related to the administration of such factors. The program also pays for supplies (including drugs) that are necessary for the effective use of covered durable medical equipment, including those which must be put directly into the equipment (e.g., tumor chemotherapy agents used with an infusion pump). Medicare also covers pneumococcal pneumonia vaccines, hepatitis B vaccines, and influenza virus vaccines.

The Committee on Ways and Means, the Committee on Energy and Commerce and the

Senate Finance Committee have held numerous hearings on providing prescription drug benefits to seniors, modernizing the program by making benefits, cost sharing and the delivery of care more rational, and strengthening Medicare financially for current and future generations.

The typical senior now takes more than 20 prescriptions a year to improve their health or manage their diseases. While seniors are taking more drugs than any other demographic group, they are often paying the highest prices because about twenty five percent of seniors have no prescription drug coverage. Similarly, low-income beneficiaries must often make unacceptable choices between life-saving medicines and other essentials.

The addition of a prescription drug benefit to Medicare, while providing seniors additional choices in how they receive their health services, is a critical modernization of the program.

Legislation to achieve these goals passed the House in 2000 (H.R. 4680, the Medicare Rx 2000 Act), in 2002 (H.R. 4954, the Medicare Modernization and Prescription Drug Act), and in 2003 (H.R. 1, the Medicare Prescription Drug and Modernization Act). The Senate passed legislation (S.1, the Prescription Drug and Medicare Improvement Act) to modernize the program and provide prescription drugs in 2003.

The conference report is the culmination of this legislative process.

House Bill

The provision would establish a new Voluntary Prescription Drug Benefit Program under a new Part D of Title XVIII of the Social Security Act. Effective January 1, 2006, a new optional benefit would be established under a new Part D. Beneficiaries could purchase either ''standard coverage'' or actuarially equivalent coverage. In 2006, ''standard coverage'' would have a $250 deductible, 20% cost-sharing for costs between $251 and $2,000, then no coverage until the beneficiary had out-of-pocket costs of $3,500 when full coverage would be provided.

The out-of-pocket limit would be higher for higher income beneficiaries. Low-income subsidies would be provided for persons with incomes below 150% of poverty. Coverage would be provided through prescription drug plans (PDPs) or Medicare Advantage (MA) Rx plans or Enhanced Fee-For-Service (EFFS) Rx plans. The program would rely on private plans to provide coverage and to bear some of the financial risk for drug costs; federal subsidies would be provided to encourage participation. Plans would determine payments and would be expected to negotiate prices. The new Medicare Benefits Administration (MBA), within the Department of Health and Human Services (HHS) would administer the benefit.

Senate Bill

Effective January 1, 2006, a new optional benefit would be established under a new Part D. Beneficiaries could purchase either ''standard coverage'' or actuarially equivalent coverage. In 2006, ''standard coverage'' would have a $275 deductible, 50% cost-sharing for costs between $276 and $4,500, then no coverage until the beneficiary had out-of-pocket costs of $3,700; and 10% cost-sharing thereafter. Individuals with incomes below 160% of poverty would receive additional assistance. The bill would rely on private plans to provide coverage and to bear a portion of the financial risk for drug costs. Federal subsidies would be provided to encourage participation. (A fallback mechanism would be provided in areas where private risk bearing plans were not available. Under the fallback mechanism, Medicare would contract with a private plan to provide the benefit in the area; the plan would not be at financial risk, except for a small portion of management fees tied to performance). Coverage would be provided through Medicare Prescription Drug Plans (PDPs) or MedicareAdvantage plans (MAs). A new Center for Medicare Choices (CMC) would be established within the Department of Health and Human Services (HHS) to administer the Part D benefit and the new MA program.

Conference Agreement

The provision establishes a new voluntary prescription drug benefit under a new Part D of Title XVIII of the Social Security Act. Effective January 1, 2006, a new optional benefit will be established under a new Part D. Beneficiaries could purchase either ''standard coverage'' or alternative coverage with actuarially equivalent benefits. In 2006, ''standard coverage'' will have a $250 deductible, 25% coinsurance for costs between $251 and $2,250, and catastrophic coverage after out of pocket expenses of $3,600. Once the beneficiary reached the catastrophic limit, the program would pay all costs except for nominal cost-sharing. Low-income subsidies would be provided for persons with incomes below 150% of poverty. Coverage would be provided through prescription drug plans or Medicare Advantage prescription drug (MA–PD) plans. The program will rely on private plans to provide coverage and to bear some of the financial risk for drug costs; federal subsidies will be provided to encourage participation. Plans will determine premiums through a bid process and will compete based on premiums and negotiated prices.

PART D—VOLUNTARY PRESCRIPTION DRUG BENEFIT PROGRAM

Subpart 1—Eligible Beneficiaries and Prescription Drug Benefits.

Eligibility, Enrollment and Information (New Section 1860D–1 of conference agreement; New Section 1860D–1 and New Section 1860D–5 of House bill; new sections 1860D–1, 1860D–2, 1860D–3, and 1860D–4 of Senate bill).

Present Law

People generally enroll in Part B when they turn 65. Persons who have applied for Social Security or railroad retirement benefits automatically receive a Medicare card when they turn 65. Persons who have not applied for Social Security or railroad retirement benefits must file an application for Medicare benefits. An individual who becomes entitled to Medicare Part A is automatically enrolled in Part B unless he or she specifically opts out of this coverage. An aged person not entitled to Part A may still enroll in Part B.

House Bill

The new Section 1860D–1 would specify that each individual entitled to Medicare Part A or enrolled in Medicare Part B would be entitled to obtain qualified prescription drug coverage. The benefit is completely voluntary. MA organizations and EFFS plans would be required to offer plans that included qualified prescription drug coverage. An individual enrolled in an MA Rx plan or EFFS Rx plan would obtain their drug coverage through the plan. An individual not enrolled in either an MA or EFFS plan could enroll in a new prescription drug plan (PDP). The provision would specify that an individual eligible to make an election to enroll in a PDP, or with an MA Rx or EFFS Rx plan, would do so in accordance with regulations issued by the Administrator of the new Medicare Benefits Administration (MBA). Enrollments and changes in enrollment could occur only during a specified election period. The election periods would generally be the same as those established for MA and EFFS programs including annual coordinated election periods and special election periods. An individual discontinuing an MA election during the first year of eligibility would be permitted to enroll in a PDP at the same time as the election of coverage under the original fee-for-service plan.

The provision would establish initial election periods. A six month election period, beginning on October 1, 2005, would be established for persons entitled to Part A or enrolled under Part B on that date. For persons first entitled to Part A or enrolled in Part B after that date, an initial election period, which was the same as that for initial part B enrollment, would be established. The Administrator would be required to establish special election periods for persons in special circumstances to ensure no or little disruption in coverage. Specifically these would apply to: persons having and involuntarily losing prescription drug coverage; in cases of enrollment delays or non-enrollment attributable to government action; in the case of an individual meeting exceptional circumstances specified by the Administrator (including circumstances identified by the Administrator for MA enrollment); and in cases of individuals who become eligible for Medicaid drug coverage.

General information on PDP, MA Rx and EFFS Rx plans would be made available during election periods. The Administrator could provide information on individuals eligible to enroll in plans to plan sponsors and organizations.

The provision would provide that elections would take effect at the same time that elections take effect for MA plans. However, no election could take effect before January 1, 2006. The Administrator would provide for the termination of an election in the case of termination of Part A and Part B coverage or termination of an election for cause (including failure to pay the required premium).

The new Section 1860D–5 would require the Administrator to establish a process for the selection of a PDP plan or an MA Rx or EFFS Rx plan that provided qualified prescription drug coverage. The process would include the conduct of annual coordinated election periods under which individuals could change the qualifying plans through which they obtained coverage. The process would also include the active dissemination of information to promote an informed selection among qualifying plans (based on price, quality, and other features) in a manner consistent with and in coordination with the dissemination of information under MA. Further, the process would provide for the coordination of elections through filing with an entity offering a MA Rx or EFFS Rx plan or a PDP sponsor in a manner consistent with that provided under MA. The plan would have to inform each enrollee at the beginning of the year of the enrollee's annual out-of-pocket threshold.

In order to ensure no duplication of coverage, the section would specify that an MA Rx or EFFS Rx enrollee could only elect to receive drug coverage through the plan.

SENATE BILL

Under the New Section 1860D–1, the Administrator would provide for and administer a voluntary prescription drug delivery program under which each Part D eligible individual enrolled in Part D would be provided access to drug coverage. In general, MedicareAdvantage enrollees would obtain drug benefits through their MedicareAdvantage plan. Other Part D enrollees would receive their drug coverage through enrollment in a Medicare Prescription Drug Plan offered in the geographic area in which the beneficiary resides. MedicareAdvantage enrollees in MSA plans would also receive drug coverage through enrollment in a Medicare Prescription Drug

plan. MedicareAdvantage enrollees in private fee-for-service plans would receive drug benefits through such plan if the plan provided qualified prescription drug coverage; otherwise they would enroll in a Medicare Prescription Drug plan. The program would begin January 1, 2006.

Under the New Section 1860D–2, the Administrator would establish an enrollment process, which would be similar to that for Part B. An initial open enrollment period would be established. For beneficiaries eligible as of November 1, 2005, this would be the 6–month period beginning November 1, 2005. Persons becoming eligible after this date would have an initial 7-month enrollment period similar to that established for Part B.

The New Section 1860D–3 would require the Administrator to establish a process through which a Part D eligible individual who was not enrolled in a MedicareAdvantage Plan (except for an MSA plan or private-fee-for-service plan not offering qualified drug coverage) could enroll in a Medicare Prescription Drug plan serving the geographic area where the beneficiary resides. The beneficiary could make an annual election to change enrollment to another plan. A beneficiary in Part D who failed to enroll in a plan would be enrolled in a plan designated by the Administrator.

The Administrator would use rules similar to the rules established for enrollment, disenrollment and termination of enrollment with MedicareAdvantage plans. Included would be requirements relating to establishment of special election periods and application of the guaranteed issue and renewal provisions. The Administrator would also coordinate enrollments, disenrollments, and terminations of enrollments under Part C with those under Part D.

The enrollment process established by the Administrator would ensure that beneficiaries who enrolled in the first open enrollment period (beginning November 2005) would be permitted to elect an eligible entity prior to January 1, 2006, in order to assure coverage was effective on that date.

In general, persons enrolled in MedicareAdvantage Plans would receive drug coverage through their MedicareAdvantage Plans and be subject to their enrollment rules. Persons enrolled in MSA plans or private-fee-for-service plans not offering qualified drug coverage would be subject to Part D enrollment rules.

The Administrator would be authorized to provide information about eligible beneficiaries to eligible entities with contracts under Part D. Such information would be provided as the Administrator determined necessary to facilitate enrollment with such entities and for only so long and to the extent necessary to carry out this objective.

The new Section 1860D–4 would require the Administrator to broadly disseminate information to beneficiaries regarding Part D coverage. Current beneficiaries would be provided such information at least 30 days prior to beginning of the first enrollment period.

Information activities would be similar to those performed for MedicareAdvantage and be coordinated with such activities. Comparative plan information would include a comparison of benefits, monthly beneficiary obligation, quality and performance, beneficiary cost-sharing, consumer satisfaction surveys, and other information specified by the Secretary.

Conference agreement

The New Section 1860D–1 of the conference agreement specifies that each individual entitled to Medicare Part A or enrolled in Medicare Part B would be entitled to obtain qualified prescription drug coverage through enrollment in a prescription drug plan. A beneficiary enrolled in a Medicare Advantage (MA) plan providing qualified prescription drug coverage (MA–PD plan) will obtain coverage through that plan. MA enrollees may not enroll in a prescription drug plan (PDP) under Part D except for: (1) Enrollees in private-fee-for service MA plans not offering qualified prescription drug coverage; and (2) Enrollees in Medicare medical savings accounts (MSAs). Coverage first begins January 1, 2006.

The Secretary is required to establish a process for enrollment, disenrollment, termination, and change of enrollment of eligible beneficiaries in prescription drug plans. The Secretary is required to use rules similar to, and coordinated with rules established for MA–PD plans relating to: residency requirements, exercise of choice, coverage election periods (including initial periods, annual coordinated election periods, special election periods, and election periods for exceptional circumstances); coverage periods (relating to effectiveness of elections and changes of elections); guaranteed issue and renewal; and marketing material and application forms.

The agreement establishes a default election process for full-benefit dual eligible beneficiaries, that is, persons eligible for both Medicare and full benefits (including prescription drugs) under the state's Medicaid program. The Secretary will enroll any full-benefit dual eligible who has not enrolled in a prescription drug plan or MA–PD plan, in a plan that has a premium equal to or below the premium subsidy amount available to persons with incomes below 135% of poverty. If more than one plan is available, the Secretary will enroll the beneficiary on a random basis among all such plans in the PDP region. Nothing prevents the beneficiary from declining enrollment or changing such enrollment.

The provision would establish a six-month initial enrollment period, beginning November 15, 2005, for all persons who are eligible beneficiaries on that date; it is the same period established for enrollment period established for MA plans for that year. An initial enrollment period will apply for individuals becoming eligible after that date; in no case can such period be less than six months, which follows the current enrollment process for Part B. Conferees intend the enrollment process to be administratively simple to encourage enrollment in the new plans.

The Secretary will establish enrollment periods for special circumstances. These include the involuntary loss of creditable prescription drug coverage such as under a group health plan, or a reduction in coverage such that it no longer meets the actuarial equivalence test. Failure to pay the required premium does not meet the definition of involuntary loss of coverage. A special enrollment period is also established for persons who discontinue their enrollment in a MA–PD plan during their first year of eligibility.

The Secretary is authorized to provide each PDP sponsor and MA organization such identifying information about eligible individuals as the Secretary determines to be necessary to facilitate efficient marketing of plans and enrollment of beneficiaries in plans. The Secretary may provide such information only to the extent necessary to carry out these activities and such PDP sponsor or MA organization may only use it to facilitate marketing and enrollment of beneficiaries in PDP and MA–PD plans. Conferees intend this provision to facilitate outreach to beneficiaries to ensure participation in the program. A consistent barrier to encouraging enrollment in the existing Medicare+Choice program is the high cost of marketing to individuals. With Secretarial assistance, Conferees expect these costs to be reduced so that plans can readily identify eligible beneficiaries and target information effectively.

The Secretary is required to conduct activities that are designed to broadly disseminate information to eligible beneficiaries and prospective eligible beneficiaries. It must be available at least 30 days prior to the initial enrollment period. The information dissemination requirements are similar to and are to be coordinated with the activities the Secretary is required to perform for MA plans.

The Conferees expect that in carrying out the annual dissemination of information requirement that the Secretary will conduct a significant public information campaign to educate beneficiaries about the new Medicare drug benefit to ensure the broad dissemination of accurate and timely information. In particular, the Conferees expect that in carrying out this public information campaign that HHS will place a priority on, and make a best and concerted effort to, ensuring that the lower income seniors are aware of the additional benefits available to them and how to enroll. Therefore, the public information campaign should include a program of outreach, information, appropriate mailings, and enrollment assistance with and through appropriate state and federal agencies, including State health insurance counseling and assistance programs, in coordination with other federal programs of assistance to low-income individuals, to maximize enrollment of eligible individuals. In addition, special outreach efforts shall be made for disadvantaged and hard-to-reach populations, including targeted efforts in historically underserved populations, and working with low-income assistance sites and a broad array of public, voluntary, and private community organizations serving Medicare beneficiaries. Materials and information shall be made available in languages other than English, where appropriate.

It is also critical that eligibility determination forms and paperwork should be as simple as possible, with mail-in or electronic filings possible. In addition, face-to-face interviews should not be required except where necessary. The Secretary shall encourage multi-year enrollment (provided eligible individuals will be required to report disqualifying income and asset changes on a timely basis). It is the desire of the Conferees that, within three years after program enactment, the Secretary shall report on best practices in the successful enrollment of low-income beneficiaries.

The Secretary is also required to disseminate comparative information to beneficiaries for the annual open enrollment period. Comparative information is to include information on benefits and formularies under a plan; monthly beneficiary premium; quality and performance; beneficiary cost-sharing; and consumer satisfaction surveys. The Secretary is not required to provide information on quality and performance or consumer satisfaction during the first plan year or the next plan year if the information is not available. The Secretary is also required to provide information concerning the methodology for determining late enrollment penalties.

To promote informed decisions, comparative information is to include information on benefits and formularies under a plan; monthly beneficiary premium; quality and performance; beneficiary cost-sharing; and consumer satisfaction surveys. The Secretary is not required to provide information on quality and performance or consumer satisfaction during the first plan year or the next plan year if the information is not available. The Secretary is also required to provide information concerning the methodology for determining late enrollment penalties.

Prescription Drug Benefits (New Section 1860D–2 of conference agreement; New Section 1860D–2 of House bill; New Sections 1860D–6, 1860D, and 1860D–1 of Senate bill).

Present Law

No provision.

House Bill

a. *Benefits.* The new Section 1860D–2 would specify the requirements for qualified prescription drug coverage. Qualified coverage would be defined as either ''standard coverage'' or actuarially equivalent coverage. In both cases, access would have to be provided to negotiated prices.

For 2006, ''standard coverage'' would be defined as having a $250 deductible; 20% coinsurance up to the initial coverage limit ($2,000); catastrophic coverage would begin after an individual incurred $3,500 in out of pocket costs. Beginning in 2007, the annual dollar amounts would be increased by the annual percentage increase in average per capita aggregate expenditures for covered outpatient drugs for Medicare beneficiaries for the 12–month period ending in July of the previous year.

Plans would be permitted to substitute cost-sharing requirements, for costs up to the initial coverage limit that were actuarially consistent with an average expected 20% coinsurance for costs up to the initial coverage limit. They could also apply tiered copayments, provided such copayments were actuarially consistent with the average 20% cost-sharing requirements.

The provision would specify incurred costs that would count toward meeting the catastrophic limit. Costs would be treated as incurred costs only if they were paid by the individual (or by another family member on behalf of the individual), paid on behalf of a low-income individual under the subsidy provisions, under the Medicaid program, or under a state pharmaceutical assistance program. Any costs for which the individual was reimbursed by insurance or otherwise would not count toward incurred costs. The Administrator would be authorized to establish procedures, in coordination with the Secretary of the Treasury and the Secretary of Labor, for determining whether costs were being reimbursed by insurance or other third-party arrangement. The procedures would provide for alerting entities in which such individuals were enrolled. Entities could also periodically ask enrolled individuals about such arrangements. A material misrepresentation by an individual (as defined in standards set by the Administrator through a process established by the Administrator) would constitute grounds for termination of Part D enrollment.

The provision would permit a PDP or MA Rx or EFFS Rx plan to offer, subject to approval by the Administrator, alternative coverage providing certain requirements were met. The actuarial value of total coverage would have to be at least equal to the actuarial value of standard coverage. The unsubsidized value of the coverage (i.e. the value of the coverage exceeding subsidy payments) would have to be equal to the unsubsidized value of standard coverage. The coverage would be designed (based on actuarially representative patterns of utilization) to provide for payment of incurred costs up to the initial coverage limit of at least the same percentage of costs provided under standard coverage. Further, stop loss protection would be the same as that under standard coverage.

Both standard coverage and actuarially equivalent coverage would have to offer access to negotiated prices. Coverage offered by a PDP plan sponsor or a MA or EFFS entity would be required to provide beneficiaries with access to negotiated prices (including applicable discounts). Access would be provided even when no benefits were payable because of the application of cost-sharing or initial coverage limits. Insofar as a state elected to use these negotiated prices for its Medicaid program, the Medicaid drug payment provisions would not apply. (Further, the negotiated prices would not be taken into account in making ''best price'' determinations under Medicaid.) The PDP sponsor or MA or EFFS entity would be required to disclose to the Administrator the extent to which manufacturer discounts or rebates or other remunerations or price concessions were made available to the sponsor or organization and passed through to enrollees through pharmacies and other dispensers. Manufacturers would be required to disclose pricing information to the Administrator under the same conditions currently required for Medicaid.

Qualified prescription drug coverage could include coverage exceeding that specified for standard coverage or actuarially equivalent coverage. However, any additional coverage would be limited to covered outpatient drugs. The Administrator could terminate a contract with a PDP sponsor or MA or EFFS entity if a determination was made that the sponsor or organizations engaged in activities intended to discourage enrollment of classes of eligible Medicare beneficiaries obtaining coverage through the plan on the basis of their higher likelihood of utilizing prescription drug coverage.

b. *Income-Related Out-of-Pocket threshold.* The provision would increase the annual out-of-pocket threshold for each enrollee whose adjusted gross income exceeded a specified income threshold. The portion of income exceeding this income threshold ($60,000 in 2006), but below an income threshold limit ($200,000 in 2006), would be considered in making this calculation. The increase would be calculated as follows. First, the ratio of the annual out-of- pocket limit to the income limit would be calculated and expressed as a percent. For 2006, this would be $3,500 divided by $60,000 equaling 5.8%. This percentage would be multiplied by any excess income over $60,000, or, if less, by the difference between income threshold limit and the income threshold ($140,000 in 2006). Thus, the catastrophic out-of-pocket limit would be $5,820 for an enrollee with an income of $100,000 and $11,620 for persons with incomes at $200,000 or above. Beginning in 2007, the income threshold and income threshold limits would be increased by the percentage increase in the consumer price index (CPI) for all urban consumers, rounding to the nearest $100.

The income used for making the income determination would be adjusted gross income. (Individuals filing joint returns would each be treated separately with each person considered to have an adjusted gross income equal to one-half of the total.) The determination would be the most recent return information disclosed by the Secretary of the Treasury to the Secretary of HHS, (as provided for under Section 106 of this Act) before the beginning of the year. The Secretary, in coordination with the Secretary of the Treasury, would provide a procedure under which an enrollee could elect to use more recent information, including information for a taxable year ending in the current calendar year. The process would require: (1) the enrollee to provide the Secretary with the relevant portion of the more recent return; (2) the Medicare Beneficiary Ombudsman offering assistance to the enrollees in presenting such information and the toll-free number being a point of contact for beneficiaries to inquire how to present the information; (3) verification by the Secretary of the Treasury; and (4) payment by the Secretary to the enrollee equal to the benefit payments that would have been payable under the plan if more recent information had been used. If such payments were made, the PDP sponsor would pay the Secretary the requisite amount, less the applicable reinsurance that would have applied. The payment would be credited to the Prescription Drug Account.

The Secretary would be required to provide, through the annual Medicare handbook, general information on the calculation of out-of-pocket thresholds. The Secretary would periodically transmit to the Secretary of the Treasury the names and TINs of enrollees in PDPs or MA Rx or EFFS Rx plans and request that the Secretary of the Treasury disclose information as provided for under Section 106 of this Act. The Secretary would disclose to entities offering the plan the amount of the out-of-pocket threshold that would apply to a specified taxpayer. Individuals could opt out of the Secretarial disclosure requirements, if they elected to have the maximum out-of-pocket threshold applied in a year. Criminal and civil penalties would apply to any unauthorized disclosure of information obtained pursuant to Section 106. In disclosing such information, stringent new confidentiality protections would apply.

c. *Covered Drugs.* Covered outpatient drugs would be defined to include: (1) a drug which could only be dispensed subject to a prescription and which was described in subparagraph (A)(i) or (A)(ii) of Section 1927(k)(2) of the Social Security Act (relating to drugs covered under Medicaid); (2) a biological product described in paragraph B of such subsection; (3) insulin described in subparagraph C of such section and medical supplies associated with the injection of insulin; and (4) vaccines licensed under section 351 of the Public Health Service Act. Drugs excluded from Medicaid coverage would be excluded from the definition except for smoking cessation drugs. The definition would include any use of a covered outpatient drug for a medically accepted indication. Drugs, which could be paid for under Medicare Part B, would not be covered under Part D. A plan could elect to exclude a drug, which would otherwise be covered, if the drug was excluded under the formulary and the exclusion was not successfully appealed under the new Section 1860D–3. In addition, a PDP or MA Rx or EFFS Rx plan could exclude from coverage, subject to reconsideration and appeals provisions, any drug, which would not meet Medicare's definition of medically necessary or was not prescribed in accordance with the plan or Part D.

Senate Bill

a. *Benefits.* Under the new Section 1860D–6 of the Senate bill, plans would be required to offer ''qualified coverage.'' ''Qualified coverage'' would be either ''standard coverage'' or ''actuarially equivalent coverage.'' Both would require access to negotiated prices. In 2006, standard coverage would be defined as having a $275 deductible, 50% cost-sharing for drug costs between $276 and the initial coverage limit of $4,500, then no coverage, except that beneficiaries would have access to negotiated drug prices, until the beneficiary had out-of-pocket costs of $3,700 ($5813 in total spending); and 10% cost-sharing thereafter. These amounts would be increased in future years by the percentage increase in average per capita expenditures for covered drugs for the year ending the previous July.

Out-of-pocket costs counting toward the limit would include costs paid by the individual (or by another individual such as a family member), paid on behalf of a low-income individual under the low-income provisions, paid under Medicaid, or paid under a

state pharmaceutical assistance program. Any costs for which the individual was reimbursed by insurance or otherwise could not be counted. The Administrator would be authorized to establish procedures, in coordination with the Secretary of the Treasury and the Secretary of Labor, for determining whether costs were being reimbursed by insurance or other third-party arrangement. The procedures would provide for alerting entities in which such individuals were enrolled. Entities could also periodically ask enrolled individuals about such arrangements. A material misrepresentation by an individual (as defined in standards set by the Administrator through a process established by the Administrator) would constitute grounds for termination of Part D enrollment.

Entities could offer more generous drug coverage, if approved by the Administrator, but only if they also offered a plan providing standard coverage. Entities could offer a plan design different from standard coverage provided certain conditions were met. The actuarial value of total coverage would have to be at least equal to the actuarial value of standard coverage. The unsubsidized value of coverage would have to be at least equal to the unsubsidized value of standard coverage. Further, the coverage would be designed, based on a representative pattern of utilization, to cover the same percentage of costs up to the initial benefit limit as provided under the standard plan. The limitation on the deductible and out-of-pocket expenditures would be the same as under standard coverage. The entity would have to apply for and receive approval from the Administrator for an alternative benefit design.

The Administrator would establish processes for determining the actuarial value of prescription drug coverage. The processes would take into account any effect that providing actuarially equivalent rather than standard coverage would have on utilization.

Qualified drug plans would be required to provide beneficiaries with access to negotiated prices (including all discounts, direct or indirect subsidies, rebates, other price concessions, or direct or indirect remunerations), regardless of the fact that no benefits may be payable. The entity would be required to issue a card or other technology for this purpose. The Administrator would be required to provide for development of national standards relating to a standardized format for the card or other technology. The standards would be compatible with those provided for under the administrative simplification and electronic prescribing requirements of Title XI. The standards would be implemented no later than January 1, 2008.

The bill would exempt any prices negotiated by a Medicare Prescription Drug plan, MedicareAdvantage plan, or qualified retiree program from Medicaid's determination of ''best price'' for purposes of the Medicaid drug rebate program.

b. *Income-Related Out-of-Pocket Threshold.* No provision.

c. *Covered Drugs.* The New Section 1860 D would define covered drugs as drugs, biological products, and insulin (including syringes, and necessary medical supplies associated with the administration of insulin, as defined by the Administrator) which are covered under Medicaid and vaccines licensed under Section 351 of the Public Health Service Act. Coverage would be extended to any use of a covered drug for a medically accepted indication. The term would not include drugs or classes of drugs, or their medical uses, which could be excluded from coverage under Medicaid, except for smoking cessation agents. The term would not include drugs currently covered under Medicare Part A or Medicare Part B to the extent payment is available under those Parts. A drug prescribed for an individual, which would ordinarily be a covered drug, would not be covered if a plan's formulary excluded the drug and the exclusion was not successfully resolved. Further, a Medicare Prescription Drug plan or a MedicareAdvantage plan could exclude drugs which did not meet Medicare's definition of ''reasonable and necessary'' under Section 1862(a) of the Act or which were not prescribed in accordance with the requirements of the plan or Part D.

New Section 1860D–1 would specify that the program would provide coverage for all therapeutic categories and classes of covered drugs (though not necessarily for all drugs within such categories and classes).

Conference Agreement

a. *Benefits.* The New Section 1860D–2 specifies the requirements for qualified prescription drug coverage. Qualified coverage would be defined as either ''standard prescription drug coverage'' or ''alternative prescription drug coverage'' with at least actuarially equivalent benefits. In both cases, access would have to be provided to negotiated prices.

Qualified drug plans would be required to provide beneficiaries with access to negotiated prices (including all discounts, direct or indirect subsidies, rebates, other price concessions, or direct or indirect remunerations), regardless of the fact that no benefits may be payable. The entity would be required to issue a card or other technology for this purpose. The Administrator would be required to provide for development of national standards relating to a standardized format for the card or other technology. The standards would be compatible with those provided for under the administrative simplification and electronic prescribing requirements of Title XI.

Plans are permitted to provide supplemental prescription coverage consisting of either certain reductions in cost-sharing (i.e. reduction in deductible, reduction in coinsurance percentage, and increase in initial coverage limit) or coverage of drugs which are excluded because of application of the Medicaid definition of covered drugs. A PDP sponsor may not offer a plan that provides supplemental benefits unless it also offers a basic plan in the area.

For 2006, ''standard prescription drug coverage'' is defined as having a $250 deductible; 25% coinsurance up to the initial coverage limit ($2,250); and catastrophic coverage after an individual incurred $3,600 in out of pocket expenses. Once the beneficiary reached the catastrophic limit, the program would pay all costs except for nominal cost-sharing.

Once the beneficiary reached the catastrophic (''stop loss'') limit, the program would pay all costs, except for nominal cost-sharing. Low-income beneficiaries would have no cost- sharing. The cost-sharing is equal to the greater of: (1) a copayment of $2 for a generic drug or preferred multiple source and $5 for any other drug; or (2) five percent coinsurance. Nothing is to be construed as preventing a PDP sponsor or MA organization from reducing the cost-sharing for preferred or generic drugs. Beginning in 2007, the annual dollar amounts would be increased by the annual percentage increase in average per capita aggregate expenditures for covered outpatient drugs for Medicare beneficiaries for the 12–month period ending in July of the previous year.

Plans would be permitted to substitute cost-sharing requirements, for costs up to the initial coverage limit that were actuarially consistent with an average expected 25% coinsurance for costs up to the initial coverage limit. They could also apply tiered copayments, provided such copayments were actuarially consistent with the average 25% cost-sharing requirements.

The agreement specifies incurred costs that count toward meeting the catastrophic limit. Costs are only considered incurred if they are incurred for the deductible, cost-sharing, benefits not paid because of application of the initial coverage limit. Incurred costs do not include amounts for which no benefits are provided because of the application of a formulary. Costs would be treated as incurred costs only if they were paid by the individual (or by another family member on behalf of the individual), paid on behalf of a low-income individual under the subsidy provisions, or under a state pharmaceutical assistance program (SPAP). Conferees intend SPAP spending to fill in beneficiary cost sharing and deductibles and have that spending count against the catastrophic. State liability will be limited to spending below the catastrophic limit, and for which there is no coverage. The state pharmacy assistance programs could use money saved from the Medicare drug benefit to extend their assistance to persons with incomes above 150% of poverty. For example, 200% of poverty or even 300% of poverty.

Any costs for which the individual was reimbursed by insurance or otherwise would not count toward incurred costs. The Secretary is authorized to establish procedures, in coordination with the Secretary of the Treasury and the Secretary of Labor, for determining whether costs were being reimbursed by insurance or other third-party arrangement. The procedures would provide for alerting entities in which such individuals were enrolled. Entities could also periodically ask enrolled individuals about such arrangements. A material misrepresentation by an individual (as defined in standards set by the Secretary through a process established by the Secretary) would constitute grounds for termination of Part D enrollment.

The provision permits a prescription drug plan or MA–PD plan to offer, subject to approval by the Secretary alternative prescription drug coverage providing certain requirements are met. The actuarial value of total coverage would have to be at least equal to the actuarial value of standard coverage. The unsubsidized value of the coverage (i.e. the value of the coverage exceeding subsidy payments) would have to be equal to the unsubsidized value of standard coverage. The coverage would be designed (based on actuarially representative patterns of utilization) to provide for payment of incurred costs up to the initial coverage limit of at least the same percentage of costs provided under standard coverage. Further, stop loss protection would be the same as that under standard coverage. The deductible could not exceed that under standard coverage.

Under the conference agreement, prescription drug plans and MA–PD plans are permitted to offer alternative coverage that is at least actuarially equivalent to the standard Part D benefit, provided that the alternative coverage includes an initial deductible that is no more than the deductible in the standard plan and provides the same threshold for catastrophic coverage under the standard Part D benefit. Within these requirements plans may change the cost sharing for the drug benefit, implement different formularies, and the benefit limit can be modified while still maintaining actuarial equivalence.

For beneficiaries who desire additional drug coverage beyond that offered in the basic Medicare benefit, MA–PD and PDP

plans may also provide supplemental prescription drug coverage. Supplemental policies may be offered by a plan to its own enrollees and may provide for a reduction in the annual deductible, reductions in coinsurance or cost-sharing required, or increases in drug coverage above the benefit limit. However, the conferees recognize that the conditions under which the government provides reinsurance subsidies may create significant disincentives for private sector plans to provide supplemental prescription drug coverage.

To address this concern, the conference agreement clarifies the Secretary's current Medicare demonstration authority to include Part C and Part D with the intent that this authority be used to conduct demonstration projects to allow private sector plans maximum flexibility to design alternative prescription drug coverage. CMS's authority to conduct Medicare demonstrations is provided in section 402 of the Social Security Amendments of 1967 (42 U.S.C. §1395b–1). Under section 402(b), the Secretary is authorized to waive requirements in Title XVIII that relate to reimbursement and payment. Consistent with the Secretary's current-law demonstration authority, the Conference committee intends that any demonstration of benefit flexibility be limited to evaluate innovations in drug benefit design and to not increase total prescription drug outlays as a result of the demonstrations.

Under this authority, CMS could alter the payments to prescription drug plans, Medicare Advantage plans and regional PPOs, or some subset thereof. A number of subsections of 402 could be used as authority to demonstrate the impact of providing additional drug coverage to filling in the gap in coverage or for providing benefit flexibility, as long as the provisions being waived could reasonably be characterized as related to payment provisions.

Specifically, CMS should demonstrate the effect of filling in the gap in coverage by reimbursing participating plans a capitated payment that is actuarially equivalent to the amount that plans would otherwise receive from the government in the form of specific reinsurance when an individual plan enrollee reaches the catastrophic attachment point ($3,600). In order to demonstrate the impact of plans offering flexible benefits, CMS could alter reinsurance payments for MA plans, regional PPOs, or prescription drug plans participating in a waiver program. For example, it is expected that CMS would change the reinsurance payment methodology for a group of plans and compare spending under this alternative methodology to those plans that continue to receive payments as outlined in Title I. However, all plans would be required to at least offer the required benefits, including those required under Part D. CMS is not permitted to waive the minimum benefits provided by the plans. The conferees anticipate that CMS would use this authority to demonstrate that paying MA plans, regional PPOs or PDPs a capitated payment in lieu of specific reinsurance for prescription drug coverage increases plan efficiency and improves the quality of the services.

Consistent with current law, CMS also is also permitted to develop and engage in demonstrations to determine whether payments for non-Medicare services would result in more economical provision and more effective utilization of Medicare services provided by MA plans, regional PPOs, or prescription drug plans as long as the additional services are incident to Medicare covered services, and provided by entities that meet certain requirements (MA plans and regional PPOs would meet these conditions). Under this subsection, CMS could demonstrate that paying MA plans or regional PPOs a payment to provide non-Medicare benefits (including prescription drug coverage or preventative services not provided under Part C or Part D) results in more economical provision and more effective utilization of comprehensive health care services. Any additional benefits must be determined to be budget neutral, and it is the intention of the Conference committee that any demonstration authority be used in a manner as to not increase Medicare outlays.

The conferees fully expect that the Secretary will use this demonstration authority to conduct projects to evaluate new methods of providing reinsurance payments that remove disincentives for private sector plans to offer additional prescription drug benefits to their enrollees. In order to meet the budget neutrality requirement, it may be necessary to implement such a demonstration after implementation of the new Part D benefit for one to two years. Using the results of this type of demonstration, the Conferees would expect the Secretary to submit to Congress any recommend changes in the drug payment methodology under this Part. Both standard coverage and alternative coverage would have to offer access to negotiated prices.

Coverage offered by a PDP plan sponsor or a MA–PD entity would be required to provide beneficiaries with access to negotiated prices. Access would be provided even when no benefits were payable because of the application of cost-sharing or an initial coverage limits. Negotiated prices are to take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered Part D drugs, and include dispensing fees. The negotiated prices would not be taken into account in making ''best price'' determinations under Medicaid. Under the current Medicaid best price policy, the largest discount a pharmaceutical manufacturer negotiates in the private market must be passed along to the Medicaid program as well. As GAO and CBO have noted, because manufacturers can only influence market share and volume in the private sector, not Medicaid, the ''best price'' policy has led to less discounting by manufacturers.

The PDP sponsor or MA–PD entity is required to disclose to the Secretary the aggregate negotiated price concessions made available to the sponsor or organization and passed through in the form of lower subsidies, lower monthly beneficiary premiums, and lower prices through pharmacies and other dispensers. Manufacturers would be required to disclose pricing information to the Secretary, but that information would remain confidential.

b. Income-Related Out-of-Pocket Threshold. No provision.

c. Covered Drugs. Covered outpatient drugs are defined to include: (1) a drug which could only be dispensed subject to a prescription and which was described in subparagraph A of Section 1927(k)(2) of the Social Security Act (relating to drugs covered under Medicaid); (2) a biological product described in paragraph B of such subsection; (3) insulin described in subparagraph C of such section and medical supplies associated with the injection of insulin (as defined in regulations of the Secretary); and (4) vaccines licensed under section 351 of the Public Health Service Act. It is the intent of conferees that the definition of insulin, and medical supplies associated with the administration of insulin, as a covered prescription drug shall include medical supplies that the Secretary determines to be reasonable and necessary, such as insulin, insulin syringes, and insulin delivery devices that are not otherwise covered under the durable medical equipment benefit. Drugs excluded from Medicaid coverage are excluded from the definition except for smoking cessation drugs. The definition would include any use of a covered outpatient drug for a medically accepted indication. Drugs, which can be paid for under Medicare Part B, are not covered under Part D. A PDP plan or MA–PD plan could exclude from coverage, subject to reconsideration and appeals provisions, any drug which would not meet Medicare's definition of medically necessary or was not prescribed in accordance with the plan or Part D.

Access to a Choice of Qualified Prescription Drug Coverage (New Section 1860D–3 of Conference agreement; New Section 1860D–5 of House bill; New Section 1860d–13 of Senate bill).

Present Law

No provision.

House Bill

New section 1860D–5 would require the Administrator to assure that all eligible individuals residing in the U.S. would have a choice of enrollment in at least two qualifying plan options, at least one of which was a PDP, in their area of residence. The requirement would not be satisfied if only one PDP sponsor or one MA or EFFS organization offered all the qualifying plans in the area. If necessary to ensure such access, the Administrator would be authorized to provide partial underwriting of risk for a PDP sponsor to expand its service area under an existing prescription drug plan to adjoining or additional areas, or to establish such a plan, including offering such plan on a regional or nationwide basis. The assistance would be available only so long as, and to the extent, necessary to assure the guaranteed access. However, the Administrator could never provide for the full underwriting of financial risk for any PDP sponsor. Additionally, the Administrator would be directed to seek to maximize the assumption of financial risk by PDP sponsors and entities offering MA Rx or EFFS Rx plans. The Administrator would be required to report to Congress annually on the exercise of this authority and recommendations to minimize the exercise of such authority.

Senate Bill

New Section 1860D–13 of the Senate bill would require the Administrator to approve at least 2 contracts to offer a Medicare Prescription drug Plan in an area. If the Administrator determined that at least 2 plans were not going to be available in the subsequent year, the Administrator would reduce the amount of risk required by plans in a region. This would be achieved by adjusting the percentages applicable to risk corridors established under the bill. Alternatively, the reinsurance percentage could be increased. The Administrator could not provide for the full underwriting of financial risk for any entity and could not provide for the underwriting of any financial risk for a public entity. The Administrator would seek to maximize the assumption of financial risk to ensure fair competition among plans. The authority would be used only so long as, and to the extent necessary, to assure access. The authority could not be used if 2 or more qualified bids were submitted in an area by qualified entities.

Not later than September 1 of each year, beginning in 2005, the Administrator would make a determination as to whether there were 2 approved bids. If not, the Administrator would enter into an annual fallback contract with an entity to provide Part D enrollees in the area with standard coverage (including access to negotiated prices) for the following year.

In the case of an area with only one competitively bid contract, the plan (at the

plan's option) could be offered under the rules established for risk-bearing plans. Beneficiaries could enroll with such plan or with the fallback plan.

Conference Agreement

New Section 1860D–3 of the conference agreement requires the Secretary to assure that each beneficiary has available a choice of enrollment in at least 2 qualifying plans in the area in which the beneficiary resides. At least one plan has to be a prescription drug plan. The requirement is not satisfied for an area if only one PDP sponsor or one MA organization offering a MA–PD plan offers all the qualifying plans for the area. A qualifying plan is defined as a prescription drug plan or an MA–PD plan that provides either: (1) basic prescription drug coverage; or (2) qualified prescription drug coverage, so long as there is no MA monthly supplemental beneficiary premium applied (due to the application of a credit against the premium of a rebate). In any case where plans are not available, the beneficiary is given the opportunity to enroll in a fallback plan.

The conference agreement permits the Secretary, in order to assure access, to approve limited risk contracts as specified under the new Section 1860D–11. Only if access is still not provided, will the Secretary provide for the offering of a fallback plan.

Beneficiary Protections for Qualified Prescription Drug Coverage (New Section 1860D–4 of conference agreement; New Section 1860D–3 of House bill; New Section 1860D–5 and Section 121 of Senate bill).

Present Law

a. Beneficiary Protections. Medicare+Choice plans are required to meet a number of beneficiary protection requirements. They are required to disclose plan information to enrollees. They are required to have procedures relating to coverage decisions, reconsiderations, and appeals. Further, they are required to assure the confidentiality and accuracy of enrollee records.

Marketing material used by Medicare+Choice plans must be approved by the Secretary.

b. Electronic Prescription Program. Part C (Administrative Simplification) in Title XI of the Social Security Act requires the Secretary to develop transaction and security standards to support the growth of electronic record keeping and claims processing in the nation's health care system.

Section 1171 defines health care clearinghouse, health care provider, health plan, personally identifiable health information, and standard setting organization. Section 1172 specifies that the administrative simplification standards apply to individual and group health plans, health care clearinghouses, and health care providers who transmit health information electronically in a standard format in connection with one of the transactions specified in Section 1173, or who rely on third-party billing services to conduct such transactions. The Secretary is required either to adopt standards that have already been developed by standard setting organizations or to develop different standards, provided they substantially reduce administrative costs to health plans and providers. If no standard has been adopted by a standard setting organization, the Secretary must develop a new standard based on the recommendations of various specified organizations and agencies.

Section 1173 instructs the Secretary to adopt the following standards: (1) uniform electronic formats for various common transactions between health care providers and health plans (e.g., health claims, eligibility and enrollment); (2) code sets for data elements in standard electronic transactions; (3) unique health identifiers for individuals, employers, plans, and providers; (4) security standards to safeguard confidential patient information against unauthorized access, use, or disclosure; and (5) electronic signatures to verify the authenticity of transactions. Section 1174 provides a timetable for the adoption of the administrative simplification standards and permits the Secretary to modify the standards as frequently as once every 12 months.

Section 1175 requires health plans and providers that process electronic transactions to use standard formats and data elements. Plans and providers may transmit and receive such data either directly or by contracting with a clearinghouse to convert nonstandard data elements into standard transactions. Most entities covered by the administrative simplification standards have 24 months to comply. Small health plans have 36 months to comply.

Section 1176 establishes civil monetary penalties of up to $25,000 per person for violations of the standards. Section 1177 establishes criminal penalties for wrongfully obtaining or disclosing personally identifiable health information. Penalties range from a $50,000 fine and/or 1 year in prison, up to a $250,000 fine and/or up to 10 years in prison if the offense is committed with the intent to sell, transfer, or use the information for commercial advantage, personal gain, or to inflict malicious harm. Section 1178 specifies that the standards preempt contrary provisions in state law pertaining to health information. However, the standards may not preempt or limit state laws that are necessary to prevent fraud and abuse, regulate health insurance companies, or report on health care delivery and costs. Also, the standards may not limit the authority of the state to collect and report for public health purposes.

House Bill

a. Beneficiary Protections. The New Section 1860D–1 would establish guaranteed issue and community-rating requirements. The provision would specify that individuals electing qualified prescription drug coverage under a PDP plan or MA Rx or EFFS Rx plan could not be denied enrollment based on health status or other factors. MA provisions relating to priority enrollment (where capacity limits have been reached) and limitations on terminations of elections would apply to PDP sponsors. The provision would require PDP sponsors to make drug coverage available to all eligible individuals residing in the area without regard to their health or economic status or their place of residence in the area.

The New Section 1860D–3 would specify required beneficiary protections. Plans would have to comply with guaranteed issue and community-rated premium requirements specified in the new Section 1860D–1, access to negotiated prices as specified in the new Section 1860D–2, and the non-discrimination provisions specified in the new Section 1860D–6.

PDP plan sponsors would be required to disclose, to each enrolling beneficiary, information about the plan's benefit structure. The plan would have to disclose information on: (1) access to specific covered drugs, including access through pharmacy networks; (2) how any formulary used by the sponsor functioned; (3) copayment and deductible requirements (including any applicable tiered copayment requirements); and (4) grievance and appeals procedures. In addition, beneficiaries would have the right to obtain more detailed plan information. Plans would be required to have a mechanism for providing specific information to enrollees on request. The sponsor would be required to make available, through an Internet web site and, on request, in writing, information on specific changes in the formulary. Plans would be required to furnish to enrollees, at least monthly, a detailed explanation of benefits when drug benefits were provided, including information on benefits compared to the initial coverage limit and the applicable out-of-pocket threshold.

PDP sponsors and entities offering an MA Rx or EFFS Rx plan would be required to permit the participation of any pharmacy that met the plan's terms and conditions. A PDP and an MA Rx or EFFS Rx plan could reduce copayments for its enrolled beneficiaries below the otherwise applicable level for drugs dispensed through in-network pharmacies; in no case could the reduction result in an increase in subsidy payments made by the Administrator to the plan. PDP sponsors and entities offering an MA Rx or EFFS Rx plan would be required to secure participation in its network of a sufficient number of pharmacies that dispense drugs directly to patients (other than by mail order) to assure convenient access. The Administrator would establish convenient access rules that were no less favorable to enrollees than rules for convenient access established by the Secretary of Defense on June 1, 2003, for purposes of the TRICARE Retail Pharmacy program. The rules would include adequate emergency assess for enrolled beneficiaries. Sponsors would permit enrollees to receive benefits through a community pharmacy, rather than through mail-order, with any differential in cost paid by enrollees. Pharmacies could not be required to accept insurance risk as a condition of participation.

PDP sponsors and entities offering an MA Rx or EFFS Rx plan would be required to issue (and reissue as appropriate) a card or other technology that could be used by an enrolled beneficiary to assure access to negotiated prices for drugs when coverage was not otherwise provided under the plan. The Administrator would provide for the development of uniform standards relating to a standardized format for the card or other technology. These standards would be compatible with the administrative simplification requirements of Title XI of the Social Security Act.

The provision would specify that if a PDP sponsor or an MA or EFFS entity used a formulary, it would have to meet certain requirements. It would be required to establish a pharmaceutical and therapeutic committee to develop and review the formulary. The committee would include at least one physician and one pharmacist, independent and free of conflict with respect to the committee, both with expertise in the care of elderly or disabled persons. The majority of members would be physicians or pharmacists. The committee would be required, when developing and reviewing the formulary, to base clinical decisions on the strength of scientific evidence and standards of practice. This would include assessing peer-reviewed medical literature, such as randomized clinical trials, pharmacoeconomic studies, outcomes research data, and such other information the committee determined appropriate. The committee would also take into account whether including a particular covered drug had therapeutic advantages in terms of safety and efficacy. The formulary would have to include drugs within each therapeutic category and class of covered outpatient drugs, although not necessarily all drugs within such categories or classes. When establishing such classes, the committee would take into account the standards published in the United States Pharmacopeia Drug Information. It would be required to make available to plan enrollees, through the Internet or otherwise, the bases for the exclusion of coverage of any drug on the formulary. The

committee would be required to establish policies and procedures to educate and inform health care providers and enrollees concerning the formulary. Any removal of a drug from the formulary, and any change in the preferred or tier cost-sharing status of a drug, could not occur until appropriate notice had been provided to beneficiaries and physicians. The plan would provide for periodic evaluation and analysis of treatment protocols and procedures. Further, the PDP sponsor or entity offering a MA Rx or EFFS Rx plan would be required to have, as part of its appeals process, a process for appeals of coverage denials based on application of the formulary.

The PDP sponsor would be required to have (directly, or indirectly through arrangements) an effective cost and drug utilization management program; quality assurance measures including a medication therapy management program; and a program to control waste, fraud, and abuse. Utilization management programs would be required to include medically appropriate incentives to use generic drugs and therapeutic interchange where appropriate. Medication therapy management programs would be designed to assure, for beneficiaries at risk for potential medication problems such as beneficiaries with complex or chronic diseases (such as diabetes, asthma, hypertension, and congestive heart failure) or multiple prescriptions, that drugs under the plan were appropriately used to optimize therapeutic outcomes through improved medication use and to reduce the risk of adverse events, including adverse drug interactions. The program would be developed in cooperation with licensed pharmacists and physicians. The PDP sponsor would be required, when establishing fees for pharmacists and other providers, to take into account the resources and time associated with the medication therapy management program. The sponsor or entity would disclose the amount of such fees to the Administrator upon request; the fees would be confidential.

Each PDP sponsor and entity offering a MA Rx or EFFS Rx plan would ensure that each pharmacy or other dispenser informed enrolled beneficiaries at the time of purchase, of any price differential between their prescribed drug and the price of the lowest cost generic drug covered under the plan that was therapeutically equivalent and bioequivalent.

Each PDP sponsor would be required to have meaningful procedures for the hearing and resolving of any grievances between the organization (including any entity or individual through which the organization provided covered benefits) and enrollees. Enrollees would be afforded access to expedited determinations and reconsiderations, in the same manner afforded under MA. A beneficiary in a plan that provided for tiered cost-sharing could request coverage of a nonpreferred drug on the same conditions applicable to preferred drugs, if the prescribing physician determined that the preferred drug for the treatment of the same condition was not as effective for the enrollee or had adverse effects for the enrollee.

In general, PDP plan sponsors would be required to meet the requirements for independent review and appeals of coverage denials and tiered cost-sharing in the same manner that such requirements applied to MA organizations. An individual enrolled in a PDP plan could appeal to obtain coverage for a drug not on the formulary if the prescribing physician determined that the formulary drug for treatment of the same condition was not as effective for the individual or had adverse effects for the individual. The PDP sponsor would be required to meet requirements related to confidentiality and accuracy of enrollee records in the same manner that such requirements applied to MA organizations.

b. Electronic Prescription Program. PDP sponsors and entities offering an MA Rx or EFFS Rx plan would be required, effective January 1, 2007, to have in place an electronic prescription program. The program would have to be consistent with national standards developed by the Administrator. The program would be required to provide for electronic transmittal of prescriptions (except in emergencies and exceptional cases). It would also have to provide for the electronic transmittal of information to the prescribing health professional of information that included: (1) information (to the extent available and feasible) on the drugs being prescribed for that patient and other information relating to the medical history or condition of the patient that may be relevant to the appropriate prescription for the patient; (2) cost-effective alternatives (if any) for the prescribed drug; and (3) information on drugs included in the applicable formulary. To the extent feasible, the program would permit the prescribing health professional to provide, and be provided, information on an interactive real time basis.

The Administrator would provide for the development of uniform standards relating to the electronic prescription drug program. These standards would be compatible with the administrative simplification requirements of Title XI of the Social Security Act. The Administrator would be required to establish an advisory task force that included representatives of physicians, hospitals, pharmacies, beneficiaries, pharmacy benefit managers, individuals with expertise in information technology, and pharmacy benefit experts of the Departments of Veterans Affairs and Defense and other appropriate Federal agencies to provide recommendations to the administrator on such standards, including recommendations relating to: (1) the range of available computerized prescribing software and hardware and their costs to develop and implement; (2) the extent to which such standards and systems could be readily implemented by physicians, pharmacies, and hospitals; (3) efforts to develop uniform standards and a common software platform for the secure electronic communication of medication history, eligibility, benefit, and prescription information; (4) efforts to develop and promote universal connectivity and interoperability for the secure electronic exchange of such information; (5) the cost of implementing such systems; (6) implementation issues as they relate to the administrative simplification provisions of Title XI and current Federal and State prescribing laws and regulations and their impact on implementation of computerized prescribing. The Administrator would constitute the task force by April 1, 2004; it would submit recommendations to the Administrator by January 1, 2005. The Administrator would provide for the development and promulgation of national standards by January 1, 2006. The standards would be issued by a standards organization accredited by the American National Standards Institute and be compatible with administrative simplification standards.

Senate Bill

a. Beneficiary Protections. Eligible entities offering Medicare Prescription Drug Plans would be required to disclose plan information comparable to that required for MedicareAdvantage plans. Entities would have to disclose information on access, operation of any formulary, beneficiary cost-sharing, and grievance and appeals procedures. Further, upon request of an individual, they would be required to disclose general information on coverage, utilization, and grievance procedures. An eligible entity would be required to have a mechanism for providing specific information to enrollees, upon request, including information on coverage of specific drugs and changes in its formulary. Entities would be required to provide easily understandable explanation of benefits and a notice of benefits in relation to the initial coverage limit and the annual out-of-pocket limit. The MedicareAdvantage requirements relating to approval of marketing materials would apply to information provided by entities on drug plans.

The bill would include several provisions designed to assure beneficiary access to drugs. Eligible entities would be required to have in place procedures to ensure that beneficiaries were not charged more than the negotiated price of a covered drug. The procedures would include the issuance of a card or other technology that could be used by a beneficiary to assure access to negotiated prices for which coverage was not otherwise provided under the plan. Entities would be required to secure the participation in the network of a sufficient number of pharmacies that dispensed drugs directly to patients (other than by mail order) to ensure convenient access for beneficiaries. The Administrator would be required to establish standards to ensure convenient access, including emergency access. The standards would take into account reasonable distances to pharmacy services in both urban and rural areas and to pharmacy services and access to pharmacy services of the Indian health service and Indian tribes and tribal organizations.

An entity would be required to establish a point-of-service method of operation under which the plan would provide access to any or all pharmacies not participating in the network and could charge beneficiaries, through adjustments in cost sharing, the additional costs associated with this option. This additional cost sharing would not count toward the program's cost-sharing requirements or benefit limits. Entities would be required to permit enrollees receiving benefits (which may include a 90-day supply of drugs or biologicals) through a community pharmacy, rather than through mail order and may permit a differential amount to be paid by enrollees.

New Section 1860D–6 would permit entities to use a variety of cost control mechanisms including formularies, tiered copayments, selective contracting with drug providers, and mail order pharmacies. Under New Section 1860D–5, plans electing to use a formulary would be required to establish a pharmacy and therapeutic committee to develop and review the formulary. The pharmacy and therapeutics committee would include at least one academic expert, at least one practicing physician, and at least one practicing pharmacist, all of whom must have expertise in the care of elderly or disabled persons. The committee would base clinical decisions on the strength of scientific evidence and standards of practice. The committee would establish policies and procedures to educate and inform health care providers concerning the formulary. Drugs could not be removed from the formulary until after appropriate notice had been provided to beneficiaries, physicians, and pharmacists. An enrollee would have the right to appeal to obtain coverage for a drug not on the formulary if the prescribing physician determined that the formulary drug was not as effective for treatment of the same condition for the individual or had adverse effects for the individual. If a plan offered tiered cost-sharing for covered drugs, an enrollee would have the right to request that a nonpreferred drug be treated on terms applicable

for a preferred drug if the prescribing physician determined that the preferred drug was not as effective for treatment of the same condition for the individual or had adverse effects for the individual.

The formulary would be required to include drugs within all therapeutic categories and classes of covered drugs (although not necessarily for all drugs within such categories and classes). For purposes of defining therapeutic categories and classes, the Administrator would be required to use the following compendia: American Hospital Formulary Service Drug Information, United States Pharmacopeia-Drug Information, the DRUGEX Information System, and American Medical Association Drug Evaluations.

Eligible entities would be required to have a cost-effective drug utilization management program (including incentives to reduce costs when appropriate). They would be required to have a program to control fraud, abuse, and waste. Further, they would be required to have quality assurance measures, including a medication therapy management program, to reduce medical errors and adverse drug interactions. The medication therapy management program would be designed to assure that drugs for beneficiaries with chronic diseases (such as diabetes, asthma, hypertension, hyperlipidemia, and congestive heart failure) or multiple prescriptions were appropriately used to optimize therapeutic outcomes and reduce the risk of adverse events including adverse drug interactions. The program could include enhanced beneficiary understanding of appropriate use through education, counseling and other appropriate means; increased adherence with prescription regimens through refill reminders, special packaging and other appropriate means; and detection of patterns of overuse and underuse of drugs. The program would be developed in cooperation with pharmacists and physicians. Associated costs would be taken into account by the entity when establishing fees for pharmacists and others providing services under the medication therapy management program.

Pharmacies or other dispensers would be required to assure that beneficiaries were informed at the time of purchase of any difference between the price of the prescribed drug and the lowest cost generic drug that is therapeutically equivalent and bioequivalent and that is available at the pharmacy or other dispenser. Entities would also be required to have meaningful procedures for hearing and resolving grievances, comparable to those established for MedicareAdvantage plans. In addition, eligible entities would be required to meet MedicareAdvantage requirements relating to coverage determinations. Entities would be required to safeguard the privacy of individually identifiable beneficiary information, maintain such records in an accurate and timely manner, ensure timely access by beneficiaries, and otherwise comply with laws relating to patient privacy.

Eligible entities would be required to conduct consumer satisfaction surveys with respect to the plan and entity. The Administrator would establish uniform requirements for such survey.

b. Electronic Prescription Program. The provision would establish a new Part D in Title XI of the Social Security Act. The new Section 1180 would mandate the development or adoption of standards for transactions and data elements for such transactions, to enable the electronic transmission of medication history, eligibility, benefit and other prescription information. In developing the standards, the Secretary would be required to consult with representatives of physicians, hospitals, pharmacists, standard setting organizations, pharmacy benefit managers, beneficiaries, information exchange networks, technology experts, and representatives of the Departments of Veterans Affairs and Defense and other interested parties. The standards developed or adopted by the Secretary would be consistent with the objective of improving patient safety and improving the quality of care.

Standards would be required to comply with certain requirements. Patients could request a written prescription and not be charged for such request. The standards would accommodate the electronic transmittal of a patient's medication history, eligibility, benefit and other prescription information among prescribing and dispensing professionals at the point of care. The information that could be transmitted using the standards would include: information on the drugs prescribed for the patient; cost-effective alternatives (if any) to the drug prescribed; information on eligibility and benefits (including the drugs included in the applicable formulary and any requirements for prior authorization); information on potential drug interactions; and other information to improve the quality of care and to reduce medical errors. The standards would be designed so that, to the extent practicable, they did not impose an undue administrative burden on the practice of medicine, pharmacy, or other health professions.

The standards developed or adopted by the Secretary would be consistent with Federal regulations (concerning the privacy of individually identifiable health information) promulgated under section 264(c) of the 1996 Health Insurance Portability and Accountability Act (HIPAA), and would be compatible with HIPAA's Administrative Simplification standards.

The Secretary would be required to adopt standards for the appropriate data elements needed for the electronic exchange of prescription drug information among prescribers, insurers, and other entities.

The Secretary would have to adopt the standards by Jan. 1, 2006, and would be permitted to modify them, but in a manner that minimized the disruption and cost of compliance. Individuals that transmit or receive prescriptions electronically would be required to comply with the standards. However, individuals would not be required to transmit or receive electronic prescriptions. The standards would preempt state electronic prescription laws. Entities covered by the standards would have 24 months to comply. Small health plans, as defined by the Secretary, would have an additional 12 months to comply.

The Secretary would be required to consult with the Attorney General to ensure that the standards resulted in the secure electronic transmission of prescriptions for controlled substances.

Conference Agreement

a. Beneficiary Protections. New Section 1860D–4 establishes beneficiary protection requirements for qualified prescription drug plans. PDP plan sponsors are required to disclose, to each enrolling beneficiary, information about the plan's benefit structure. The plan will disclose information on: (1) access to specific covered drugs (including access through pharmacy networks); (2) how any formulary (including a tiered formulary) used by the sponsor functions, including how a beneficiary might obtain information on the formulary; (3) copayment and deductible requirements (including any applicable tiered copayment requirements; and (4) grievance and appeals procedures. In addition, beneficiaries will have the right to obtain more detailed plan information. Plans will be required to have a mechanism for providing specific information to enrollees on request. The sponsor will be required to make available, through an Internet website, information on specific changes in the formulary (including tiered or preferred status). Sponsors will be required to furnish to enrollees, a detailed explanation of benefits when drug benefits were provided, including information on benefits compared to the initial coverage limit and the applicable out-of-pocket threshold.

PDP sponsors are required to permit the participation of any pharmacy that meets the plan's terms and conditions. The conference report would require plans to accept any and all pharmacies willing to agree to the terms and conditions of the plan. A PDP could reduce copayments for its enrolled beneficiaries below the otherwise applicable level for drugs dispensed through in-network pharmacies; in no case could the reduction result in an increase in subsidy payments made by the Secretary to the plan. The PDP sponsor is required to secure participation in its network of a sufficient number of pharmacies that dispense drugs directly to patients (other than by mail order) to assure convenient access. The Secretary will establish convenient access rules that are no less favorable to enrollees than rules for convenient access established in the statement of work solicitation (#MDA906–03–R–0002) by the Department of Defense on March 13, 2003, for purposes of the TRICARE Retail Pharmacy program. The conference report adopts the House language, with the clarification that the minimum in-network pharmacy for each plan offered by a PDP or MA plan in a geographic area must provide access to pharmacies that is not less restrictive than the TRICARE access standards. These standards require that 90 percent of plan enrollees in urban areas will have access to a retail pharmacy within 2 miles; that 90 percent of suburban plan enrollees will have access to a retail pharmacy within 5 miles; and that 70 percent of rural plan enrollees will have access to a pharmacy within 15 miles. PDP sponsors or MA sponsors can offer broader networks than those meeting the TRICARE access standards.

Plan sponsors cannot create any pharmacy networks that are more restrictive than the TRICARE access standards. PDP plan sponsors or MA sponsors cannot include mail order only pharmacies. The rules would include adequate emergency access for enrolled beneficiaries. The rules may include standards with respect to access for enrollees in long-term care facilities. Sponsors will permit enrollees to receive benefits (which may include a 90-day supply) through a community pharmacy, rather than through mail-order, with any differential in charge paid by enrollees. In addition, the conference report clarifies that pharmacies could not accept insurance risk.

PDP sponsors are required to issue (and reissue as appropriate) a card or other technology that could be used by an enrolled beneficiary to assure access to negotiated prices for drugs. The Secretary will provide for the development, adoption, or recognition of standards relating to a standardized format for the card or other technology. These standards are to be compatible with the administrative simplification requirements of Title XI of the Social Security Act. The standards will be implemented by such date the Secretary determines to be sufficient to ensure PDP sponsors utilize such standards beginning January 1, 2006, and developed in consultation with the National Counsel for Prescription Drug Programs (NCPDP) and other standard setting organizations.

The provision would specify that if a PDP sponsor used a formulary, it would have to meet certain requirements. A pharmaceutical and therapeutic committee would

develop and review the formulary. The committee would include at least one practicing physician and one practicing pharmacist, independent and free of conflict with respect to the committee, both with expertise in the care of elderly or disabled persons. The majority of members would be physicians or pharmacists. The committee would be required, when developing and reviewing the formulary, to base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, such as randomized clinical trials, pharmacoeconomic studies, outcomes research data, and such other information the committee determined appropriate. The committee would also take into account whether including a particular covered drug in the formulary (or in a particular tier in a formulary) had therapeutic advantages in terms of safety and efficacy. The formulary would have to include drugs within each therapeutic category and class of covered Part D drugs, although not necessarily all drugs within such categories or classes.

The Secretary is required to request the United States Pharmacopeia to develop a list of categories and classes that may be used by plans. The Secretary's request would also include the revision of such classification from time to time to reflect changes in therapeutic uses of covered drugs and the addition of new covered drugs. The plan sponsor cannot change therapeutic categories and classes in a formulary other than at the beginning of a plan year, except as the Secretary may permit to take into account new therapeutic uses and newly approved covered drugs. Each sponsor is required to establish policies and procedures to educate and inform health care providers and enrollees concerning the formulary. Any removal of a drug from the formulary, and any change in the preferred or tier cost-sharing status of a drug, could not occur until appropriate notice had been provided to the Secretary, beneficiaries, and physicians, pharmacies, and pharmacists. The plan must provide for periodic evaluation and analysis of treatment protocols and procedures.

The PDP sponsor would be required to have (directly, or indirectly through arrangements) a cost-effective drug utilization management program; quality assurance measures, a medication therapy management program; and a program to control fraud, waste, and abuse. A medication therapy management program is a program of drug therapy management and medication administration, that may be furnished by a pharmacist and that is designed to assure with respect to targeted beneficiaries that drugs under the plan are appropriately used to optimize therapeutic outcomes through improved medication use and to reduce the risk of adverse events, including adverse drug interactions. Targeted individuals are those with multiple chronic diseases (such as diabetes, asthma, hypertension, hyperlipidemia, and congestive heart failure) or are taking multiple drugs or are likely to incur annual costs that exceed a specified level. The program would be developed in cooperation with licensed practicing pharmacists and physicians. Such plans would be coordinated with disease management programs to the extent beneficiaries are enrolled in such programs. The PDP sponsor would be required, when establishing fees for pharmacists and other providers, to take into account the resources and time associated with the medication therapy management program. The sponsor or entity would disclose the amount of such fees to the Administrator upon request; the fees would be confidential.

The Secretary will be required to conduct consumer satisfaction surveys in order to provide comparative information during the enrollment period.

Each PDP sponsor is required to have meaningful procedures for the hearing and resolving of any grievances between the sponsor (including any entity or individual through which the sponsor provided covered benefits) and enrollees. Enrollees will be afforded access to expedited determinations and reconsiderations, in the same manner afforded under MA. A beneficiary in a plan that provides for tiered cost-sharing can request coverage of a non-preferred drug on the same conditions applicable to preferred drugs, if the prescribing physician determines that that the preferred drug for the treatment of the same condition is not as effective for the enrollee or has adverse effects for the enrollee. A PDP is required to have an exceptions process consistent with guidelines established by the Secretary.

In general, PDP plan sponsors will be required to meet the requirements for independent review and appeals of coverage denials and tiered cost-sharing in a similar manner that such requirements applied to MA organizations for fee-for-service benefits. An individual enrolled in a PDP plan may appeal to obtain coverage for a drug not on the formulary only if the prescribing physician determines that all covered Part D drugs on any tier of the formulary for treatment of the same condition would not as effective for the individual or would have adverse effects for the individual or both. The PDP sponsor will be required to meet requirements related to confidentiality and accuracy of enrollee records in the same manner that such requirements applied to MA organizations.

Each PDP sponsor will provide that each pharmacy that dispenses a covered drug shall inform enrolled beneficiaries at the time of purchase (or at the time of delivery in the case of mail order drugs) of any price differential between the price to the enrollee and the price of the lowest cost generic drug covered under the plan that is therapeutically equivalent and bioequivalent and available at the pharmacy. The Secretary is permitted to waive this requirement.

b. Electronic Prescription Program. The conference agreement requires the Secretary to develop electronic prescription standards. The standards apply to prescriptions for covered part D drugs and required information that are transmitted electronically under an electronic prescription drug program conducted by a PDP or MA plan. The program must provide for the electronic transmittal of information on eligibility and benefits (including formulary drugs, any tiered formulary structure, and prior authorization requirements), information on the drug being prescribed and other drugs listed in the patient's medication history (including drug-drug interactions), and information on the availability of lower-cost, therapeutically appropriate alternative drugs. The conferees intend for prescribing health care professionals to have ready access to neutral and unbiased information on the full range of covered outpatient drugs available. Disclosure of information must meet the requirements of the HIPAA privacy rule and, to the extent feasible, be on an interactive, real-time basis. The conferees do not intend for the provision relating to ''interactive, real-time'' transmission of information to preclude an individual or entity from complying with the standards under this part by virtue of such individual's or entity's inability to transmit information on an interactive, real-time basis.

The standards must be consistent with the objectives of improving patient safety and the quality and efficiency of patient care. To the extent practicable, the standards must be designed so that they do not impose an undue administrative burden on prescribing physicians and pharmacists. The standards must also be compatible with the HIPAA Administrative Simplification standards and other health information technology standards, and must permit the electronic exchange of drug labeling and drug listing information maintained by the FDA and the National Library of Medicine. Finally, the standards must accommodate the messaging of information about appropriate prescribing of drugs and allow a beneficiary (consistent with their prescription drug plan) to designate a particular pharmacy to dispense a prescribed drug.

The conference agreement requires the Secretary to promulgate initial standards by September 1, 2005, taking into account recommendations from the National Committee on Vital and Health Statistics (NCVHS). The NCVHS is required to develop such recommendations in consultation with standard setting organizations, practicing physicians, hospitals, pharmacies, practicing pharmacists, pharmacy benefit managers, state boards of pharmacy and medicine, and appropriate federal agencies. Prior to the promulgation of final standards, the Secretary must enter into voluntary agreements with physicians, pharmacies, hospitals, and PDP sponsors and MA plans to conduct a pilot project to test the initial standards. The pilot project must be conducted during the 1-year period that begins on January 1, 2006, except that pilot testing is not required where there is adequate industry experience. The Secretary must then evaluate the pilot project and report to Congress not later than April 1, 2007. Based on the evaluation and not later then April 1, 2008, the Secretary must promulgate final standards to take effect within one year. The electronic prescriptions standards shall supercede any contrary state laws.

The agreement requires the Secretary, in consultation with the Attorney General, to provide a safe harbor from both criminal sanctions under Section 1128(b)(1 and 2) of the Act and the self-referral prohibition under Section 1877 of the Act with respect to the provision of nonmonetary remuneration necessary and used solely to receive and transmit electronic prescription information in accordance with Part D standards. Nonmonetary remuneration includes hardware, software, or information technology and training services. This safe harbor is to apply: (1) in the case of a hospital by the hospital to members of its medical staff; (2) in the case of a medical group practice by the practice to prescribing health care professionals who are members of the practice; and (3) in the case of a PDP sponsor or MA organization, by the sponsor or organization to pharmacists and pharmacies participating in its network and to prescribing health processionals.

The conferees intend for electronic prescribing to serve as a vehicle to reduce medical errors and improve efficiencies in the health care system, but not for it to be used as a marketing platform or other mechanism to unduly influence the clinical decisions of physicians.

Subpart 2—Prescription Drug Plans; PDP Sponsors; Financing

PDP Regions; Submission of Bids; Plan Approval (New Section 1860D–11 of Conference Agreement; New Section 1860D–6 and New section 1860D–4 of House bill; New Section 1860D–7, 1860D–12, and 1860D–13 of Senate bill).

Present Law

a. PDP Regions. No provision.
b. Submission of Bids. No provision.
c. Plan Approval. No provision.
d. Fallback. No provision

House Bill

a. PDP Regions. The Administrator would designate at least 10 service areas in the U.S., consistent with EFFS regions, to the extent practicable.

b. Submission of Bids. The new Section 1860D–6 would require each PDP sponsor to submit to the Administrator specified information in the same manner as such information was submitted by MA organizations. The information to be submitted would be information on the qualified drug coverage to be provided, the actuarial value of the coverage, and information on the bid and premium for the coverage. The PDP sponsor would have to include an actuarial certification of:(1) the actuarial basis for the bid and premium; (2) the portion of the bid and premium attributable to benefits in excess of the standard coverage; (3) the reduction in the premium resulting from reinsurance subsidies; (4) the reduction in the bid resulting from direct and reinsurance subsidy payments; and (5) such other information required by the Administrator.

c. Plan Approval. The Administrator would review the submitted information for purposes of conducting negotiations with the plan. The Administrator would approve the premium only if it accurately reflected the actuarial value of the benefits and the 73% average subsidy provided for under the new Section 1860D–8. The Administrator would apply actuarial principles to approval of a premium in a manner similar to that used for establishing the monthly Part B premium. These requirements would not apply to private fee-for-service plans.

d. Fallback. No provision

Senate Bill

a. PDP Regions. New Section 1860D–10 would require the Administrator to establish by April 15, 2005, and periodically review, service areas in which plans could offer benefits. The

Administrator would establish service areas so that they maximized the availability of Medicare Prescription Drug Plans to eligible beneficiaries and minimized the ability of entities offering plans to favorably select beneficiaries. In establishing the service areas, the Administrator would establish at least 10 service areas, which would have to include at least one state. The Administrator could not divide states so that portions of a state were in different service areas.

To the extent possible, the Administrator would include multi-state metropolitan statistical areas (MSAs) in a single service area. The Secretary could divide MSAs where it is necessary to establish service areas of such size and geography as to maximize plan participation. The Administrator could conform service areas to those established for preferred provider organizations under MedicareAdvantage.

Under the New Section 1860D–12, plan service areas could either be, the entire area of one of the service areas established by the Administrator or the entire area covered by Medicare. Entities could submit separate bids for multiple service areas, provided each bid was for a single service area.

b. Submission of bids. The new Section 1860D–12 of the Senate bill would require entities to submit bids to the Administrator on an annual basis. The bid would be submitted at such time in the previous year as specified by the Administrator. The bid would contain information on proposed plans including benefits, actuarial value of the qualified prescription drug coverage, the service area for the plan, and the monthly premium. Premium information would have to include an actuarial certification of the basis for the premium, the portion of the premium attributable to benefits in excess of standard coverage, and the reduction in bids attributable to reinsurance payments. Entities would also be required to provide information on whether the entity planned to use any funds in the plan stabilization reserve fund that were available to the entity for the purpose of stabilizing or reducing the monthly premium.

c. Plan Approval. The new Section 1860D–13 would prohibit the Administrator from approving a plan unless the premium, for both standard coverage and for any additional benefits, accurately reflected the actuarial value of the benefits less the actuarial value of reinsurance payments and any stabilization funds used. The bid submitted by an entity for a qualified plan must reasonably and equitably reflect the cost of benefits provided under that plan. The Administrator would have the authority to negotiate the terms and conditions of the proposed monthly premiums and other terms and conditions of proposed plans. The Administrator could disapprove, or limit enrollment in, a proposed plan based on costs to beneficiaries, the quality of coverage and benefits, the adequacy of the plan network, average aggregate projected costs of covered drugs and other factors determined appropriate by the Administrator. The Administrator could approve a plan only if it provided the required benefits and was not designed to result in a favorable selection of beneficiaries. The Administrator would approve at least 2 contracts to offer a Medicare Prescription Drug plan in an area. Contracts would be awarded for 2 years.

d. Fallback. Under New Section 1860D–13, the Administrator, not later than September 1 of each year, beginning in 2005, would make a determination as to whether there were 2 approved bids. If not, the Administrator would enter into an annual contract with an entity to provide Part D enrollees in the area with standard coverage (including access to negotiated prices) for the following year. The Administrator could enter into only 1 contract for each such area. A single entity could be awarded contracts for more than one such area. The Administrator could not enter into such a contract if the Administrator received two or more qualified bids after exercise of the authority to reduce risk for entities. Entities would be required to meet beneficiary protection requirements.

Beneficiary premiums for a fallback plan would be set at the premium amount that would apply if the plan premium equaled the national weighted average premium for the area, as adjusted for geographic differences in drug prices. The Administrator would establish a methodology for making this calculation, which could take into account geographic differences in utilization and the results of the ongoing study on spending and utilization required under the Act. The contract with the plan would provide for payments to the plans for the negotiated costs of covered drugs and payment of prescription management fees tied to performance management fees established by the Administrator. Performance requirements established by the Administrator would include the following; (1) the entity contained costs to taxpayers and to beneficiaries; (2) the entity provided quality clinical care; and (3) the entity provided quality services. The fallback plan would not be permitted to engage in any marketing or branding of the contract. Entities that submitted bids to be a qualified risk-bearing entity could not submit a bid to be a fallback plan.

Conference Agreement

a. PDP Regions. New Section 1860D–11 of the conference agreement provides for the establishment of PDP regions. The service area for a plan includes an entire PDP region. The Secretary shall establish, and may revise PDP regions in a manner that is consistent with the requirements for establishment and revision of MA regions. To the extent practicable, PDP regions shall be the same as MA regions. The Secretary may establish different regions if the Secretary determines that it would improve access to drug benefits. The Secretary will establish PDP regions for the territories. A plan can be offered in more than one PDP region, including all PDP regions.

b. Submission of Bids. Each PDP sponsor is required to submit to the Secretary specified information at the same time and in a similar manner as such information is submitted by MA organizations. The information to be submitted is: (1) information on the prescription drug coverage to be provided; (2) the actuarial value of the qualified prescription drug coverage in the region for a beneficiary with a national average risk profile; (3) information on the bid including the basis for the actuarial value, the portion of the bid attributable to basic coverage and if applicable, the portion attributable to supplemental benefits, and assumptions regarding reinsurance subsidy payments and administrative expenses; (4) service area; (5) level of risk assumed including whether the sponsor requires a modification of risk level and if so the extent of the modification; and (6) such other information required by the Secretary. A modification of risk levels applies to all PDP plans offered by a PDP sponsor in a region; it may include an increase in the federal percentage assumed in the risk corridor or decrease in the size of risk corridors. The Secretary is to establish requirements for information submission in a manner that promotes the offering of plans in more than one PDP region.

The Secretary is to establish processes and methods for determining the actuarial valuation of prescription drug coverage including: (1) an actuarial valuation of standard coverage; (2) actuarial valuations relating to alternative coverage; (3) use of generally accepted actuarial principles and methodologies; (4) applying the same methodology for determinations of alternative coverage as is used for determinations of standard coverage; and (5) actuarial valuation of reinsurance subsidies. The processes and methods are to take into account the effect that providing alternative coverage (rather than standard coverage) has on drug utilization.

PDP sponsors and MA organizations are responsible for the submission of required actuarial valuations for plans they offer. They may use actuarial opinions certified by independent, qualified actuaries.

c. Plan Approval. The Secretary will review the submitted information for purposes of conducting negotiations with the plan. The Secretary has the authority to negotiate the terms and conditions of the plans. The authority is similar to the authority the Director of the Office of Personnel Management has with respect to Federal Employee Health Benefits (FEHB) plans.

After review and negotiation, the Secretary will approve or disapprove the plan. The Secretary may only approve a plan if certain requirements are met. The plan must comply with Part D requirements, including for actuarial determinations. The Secretary must determine that the portion of the bid that is related to basic coverage is supported by the actuarial bases provided and reasonably and equitably reflects the revenue requirements (as the term is used under Section 1302(8)(c) of the Public Health Service Act) for benefits provided under the plan, less the sum of the actuarial value of the reinsurance payments provided. Similarly, the Secretary must determine that the portion of the bid that is related to supplemental

coverage is supported by the actuarial bases provided and reasonably and equitably reflects the revenue requirements for coverage provided under the plan.

The Secretary can only approve a plan, if the plan and the benefits (including any formulary and tiered formulary structure) are not likely to discourage enrollment by certain beneficiaries.

The agreement provides that the Secretary may only approve a limited risk plan for a PDP region if the access requirements for the region would otherwise not be met except for the approval of a limited risk or fallback plan. Only the minimum number of limited risk plans necessary for a region to meet access requirements may be approved. The Secretary shall provide priority to those with the highest level of risk. In no case can the reduction of risk provide for no (or a de minimus) level of financial risk. There is no limit on the number of full risk plans that may be approved.

d. Fallback. The New Section 1860D–3, discussed above, establishes access requirements. If access is not provided, including through a limited risk plan, the conference agreement establishes a fallback process. The Secretary is required to establish a separate process for the solicitation of bids from eligible fallback entities for the offering in all fallback service areas in or more PDP regions of a fallback prescription drug plan during the contract period. A single fallback entity may not offer all fallback plans throughout the United States. Except as otherwise provided, the general provision relating to approval or disapproval of bids under New Section 1860D–11(e) applies with respect to fallback plans. The Secretary can only approve one fallback plan for all fallback service areas in any PDP region for a contract period. Competitive contracting provisions apply. The Secretary shall approve fallback plans so that if there are any fallback service areas in the region for the year, they are offered at the same time as prescription drug plans would otherwise be offered.

The fallback entity could not submit a bid for a prescription drug plan for any region for the first year of a contract period. A fallback service area is an area within a PDP region in which, after applying the provisions relating to limited risk plans, the access requirements will not be met. Fallback prescription drug plans are permitted to offer only standard prescription drug coverage, pass on negotiated discounts and meet such other requirements specified by the Secretary. The fallback plan would not be permitted to engage in any marketing or branding of the contract.

Under a fallback contract, the Secretary would pay actual costs of Part D covered drugs taking into account negotiated price concessions. Payment would also be made for prescription management fees tied to performance management requirements, established by the Secretary. Performance requirements established by the Secretary would include the following; (1) the entity contained costs to the Medicare Prescription Drug Account and to beneficiaries; (2) the entity provided quality clinical care, including reduction in adverse drug interactions; and (3) the entity provided timely and accurate delivery of services, including pharmacy and beneficiary support services; and (4) efficient and effective benefit administration and claims adjudication services. Beneficiary premiums under fallback plans would be uniform and equal to 26 percent of the Secretary's estimate of the average monthly per capita actuarial cost (including administrative costs) to the entity offering the fallback plan.

In general, contract requirements for fallback plans would be the same as those established for prescription drug plans. A contract for a fallback plan would be for 3 years (and be renewable after a subsequent bidding process). However, a contract could not apply in an area in any year unless the area was a fallback service area.

The Secretary will submit an annual report to Congress that describes the instances in which limited risk plans and fallback plans are offered. The secretary will include such recommendations as may be appropriate to limit the need for the provision of such plans and to maximize the assumption of financial risk.

In order to promote competition, the Secretary is prohibited from interfering with the negotiations between drug manufacturers and pharmacies and PDP sponsors. Further, the Secretary may not require a particular formulary or require a particular price structure for the reimbursement of covered drugs. Conferees expect PDPs to negotiate price concessions directly with manufacturers.

PDP sponsors shall permit State pharmaceutical assistance programs and prescription plans under Section 1860D–24 to coordinate benefits with the plan. Fees may not be imposed that are unrelated to coordination. Conferees want to ensure the new Medicare plans are required to coordinate with State plans to ensure those plans can efficiently enroll seniors without unnecessary constraints. Conferees want to ensure a seamless transition for both States and beneficiaries.

Requirements for and contracts with prescription drug plan (PDP) sponsors (new Section 1860D–12 of Conference agreement; (New Section 1860D–4 of House Bill; New Sections 1860D–7, 1860D–10, 1860D–12, and 1860D–13 of Senate Bill).

Present Law

Medicare+Choice plans are required to meet a number of financial and organizational requirements. In general they are required to be organized and licensed under state law, except that a special exception may be established for provider-sponsored organizations. In addition, entities must assume full financial risk for required services.

House Bill

New Section 1860D–4 would specify organizational plan requirements for entities seeking to become PDP plan sponsors. In general, the section would require a PDP sponsor to be licensed under state law as a risk bearing entity eligible to offer health insurance or health benefits coverage in each state in which it offers a prescription drug plan. Alternatively it could meet solvency standards established by the Administrator for entities not licensed by the state. Plans would be required to assume full financial risk on a prospective basis for covered benefits except: (1) as covered by federal subsidy payments and reinsurance payments for high cost enrollees; or (2) as covered by federal incentive payments to encourage plans to expand service areas for existing plans or establish new plans. The entity could obtain reinsurance or make other arrangements for the cost of coverage provided to enrollees.

PDP plan sponsors would be required to enter into a contract with the Administrator under which the sponsor agreed to comply both with the applicable requirements and standards and the terms and conditions of payment. The contract could cover more than one plan. Contracts would be for at least one year. The Administrator would have the same authority to negotiate the terms and conditions of the plans as the Director of the Office of Personnel Management has with respect to Federal Employee Health Benefits (FEHB) plans. The Administrator would be required to take into account subsidy payments for covered benefits in negotiating the terms and conditions regarding premiums. The Administrator would designate at least 10 service areas, consistent with EFFS regions.

The new section would incorporate, by reference, many of the contract requirements applicable to MA plans including minimum enrollment, contract periods, allowable audits to protect against fraud and abuse, intermediate sanctions, and contract terminations. Pro rata user fees could be established to help finance enrollment activities; in no case could the amount of the fee exceed 20% of the maximum fee permitted for an MA or EFFS plan.

The new Section would permit the Administrator to waive the state licensure requirements under circumstances similar to those permitted under Part C for provider sponsored organizations. In such cases, plans would be required to meet financial solvency and capital adequacy standards established by the Administrator. The Administrator would establish such standards by regulation by October 1, 2004.

The standards established under Part D would supersede any state law or regulation (other than state licensing laws or laws relating to plan solvency). In addition, states would be prohibited from imposing premium taxes or similar taxes with respect to premiums paid to PDP sponsors or payments made to such sponsors by the Administrator.

Senate Bill

Under the New Section 1860D–7, an entity eligible to offer a Medicare Prescription Drug Plan would be organized and licensed under state law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each state it offers a plan. Alternatively, the Administrator could waive the requirement that the entity be licensed in the state, if the Administrator determined that grounds for approval of the application had been met. By January 1, 2005, the Administrator would, in consultation with the National Association of Insurance Commissioners, establish and publish solvency standards for non-licensed entities.

Entities would be required to assume financial risk on a prospective basis for costs of benefits in excess of amounts received from premium payments and reinsurance payments. Entities would be permitted to obtain private reinsurance for the portion of the costs for which they were at risk.

Beneficiaries could not elect a Medicare Prescription Drug Plan unless the Administrator had entered into a contract with the eligible entity for the plan. A contract with an entity could cover more than one plan.

The New Section 1860D–12 would require the Administrator, by January 1, 2005, to establish by regulation standards to implement Part D. Such standards would be periodically reviewed and revised as appropriate. Significant new regulatory requirements could only be implemented at the beginning of a calendar year. The standards would supersede any state law and regulation to the extent such law or regulation was inconsistent with such standards and in the same manner those standards were superseded for Medicare Advantage plans. Standards specifically superseded include those relating to benefits (including requirements relating to cost- sharing and the structure of formularies), premiums, requirements relating to inclusion or treatment of providers, coverage determinations (including related grievance and appeals processes), and requirements relating to marketing materials and summaries and schedules of benefits for a plan.

States would be prohibited from imposing a premium or similar tax with respect to

premiums paid to the Administrator for Medicare Prescription Drug Plans and any payments made by the Administrator to eligible entities offering such a plan.

Conference Agreement

The conference agreement establishes organizational requirements for PDP sponsors under the New Section 1860D–12. In general, the section would require a PDP sponsor to be licensed under state law as a risk bearing entity eligible to offer health insurance or health benefits coverage in each state in which it offers a prescription drug plan. Alternatively it could meet solvency standards established by the Secretary for entities not licensed by the state. To the extent an entity is at risk, it must assume financial risk on a prospective basis for covered benefits that is not covered by direct subsidy payments. The entity could obtain insurance or make other arrangements for the cost of coverage provided to enrollees.

PDP plan sponsors would be required to enter into a contract with the Secretary under which the sponsor agreed to comply both with the applicable requirements and standards and the terms and conditions of payment. The contract could cover more than one plan. The Secretary may not enter into a contract with a PDP sponsor if the entity submitted a bid for the year (as the first year of the contract period) to offer a fallback plan in any region or offered a fallback plan in the region during the previous year. An entity is to be treated as submitting a bid if it is acting as a subcontractor of a PDP sponsor that is offering a plan; however this does not apply to a MA organization insofar as it is acting as a PDP sponsor.

The new section would incorporate, by reference, many of the contract requirements applicable to MA plans including minimum enrollment, contract periods, protections against fraud and abuse, intermediate sanctions, and contract terminations. Pro rata user fees may be established to help finance enrollment activities.

The new Section 1860D–12 permits the Secretary, in order to expand choice, to waive the state licensure requirement under circumstances similar to those permitted under Part C for provider sponsored organizations. In such cases, plans would be required to meet financial solvency and capital adequacy standards established by the Secretary. The Secretary, in consultation with the National Association of Insurance Commissioners, would establish and publish such standards by January 1, 2005. The Secretary may periodically review and revise the standards; however, the Secretary may not implement significant new regulatory requirements except at the beginning of a calendar year.

The standards established under Part D supersede state laws or regulations in the same manner that such laws or regulations are superseded for purposes of MA organizations and plans. In addition, states are prohibited from imposing premium taxes with respect to premiums for PDP plans.

Premiums; Late Enrollment Penalty (New Section 1860D–13 of the Conference agreement; New Section 1860D–1 and New Section 1860D–6 of House Bill; New Sections 1860D–2, 1860D–6, 1860D–14, 1860D–15, 1860D–17, and 1860D–18 of Senate bill).

Present Law

Persons who delay enrollment in Part B after their initial enrollment period are subject to a premium penalty. Certain persons, including a working individual and/or spouse of a working individual, may be able to delay enrollment in Medicare Part B without being subject to the delayed enrollment penalty.

House Bill

New Section 1860D–1 would specify that PDP sponsors and MA or EFFS organizations providing qualified prescription drug coverage could not deny, limit, or condition the coverage or provision of benefits or increase the premium based on any health-related status factor in the case of persons who maintained continuous prescription drug coverage since the date they first qualified to elect drug coverage under Part D. Individuals who did not maintain continuous coverage could be subject to an adjusted premium or a pre-existing condition exclusion in a manner reflecting the additional actuarial risk involved. Such risk would be established through an appropriate actuarial opinion. The Administrator would provide a mechanism for assisting sponsors and entities in identifying eligible individuals who had, or had not, maintained continuous coverage.

The provision would specify that an individual would be considered to have had continuous prescription drug coverage if the individual established that he or she had coverage under one of the following (and coverage in one plan occurred no more than 63 days after termination of coverage in another plan): (1) qualified prescription drug coverage under a PDP or MA Rx or EFFS Rx plan; (2) Medicaid prescription drug coverage; (3) prescription drug coverage under a group health plan, but only if benefits were at least equivalent to benefits under a qualified PDP; (4) prescription drug coverage under a Medigap plan, but only if the policy was in effect on January 1, 2006, and only if the benefits were at least equivalent to benefits under a qualified PDP; (5) state pharmaceutical assistance program, but only if benefits were at least equivalent to benefits under a qualified PDP; and (6) veterans coverage for prescription drugs, but only if benefits were at least equivalent to benefits under a qualified PDP. Individuals could apply to the Administrator to waive the requirement that such coverage be at least equivalent to benefits under a qualified prescription drug plan. They could make such application if they could establish that they were not adequately informed that the coverage did not provide such level of coverage.

New Section 1860D–6 would specify that the bid and premium for a PDP could not vary among individuals enrolled in the plan in the same service area, provided they were not subject to late enrollment penalties. A PDP sponsor would permit each enrollee to have their premiums withheld from their Social Security checks in the same manner as is currently done for Part B premiums. Beneficiaries could also make payment of the premium through an electronic funds transfer mechanism. The amount would be credited to the Medicare Prescription Drug Trust Fund. Reductions in Part B premiums attributable to enrollment in MA or EFFS plans could be used to reduce the premium otherwise applicable.

Under certain conditions, the PDP sponsor or entity offering an MA Rx or EFFS Rx plan in an area would be required to accept, for an individual eligible for a low-income premium subsidy, the reference premium amount (premium for standard coverage) as payment in full for the premium for qualified prescription coverage. This requirement would apply if there was no standard coverage available in the area.

Senate Bill

New section 1860D–2 would specify that persons enrolling in Part D after their initial enrollment period would be subject to delayed enrollment penalties. The actuarially sound increase for each 12-month period of delayed enrollment would be determined by the Administrator.

Eligible beneficiaries with creditable drug coverage could elect to continue to receive such coverage, not enroll in Part D, and subsequently enroll in Part D without penalty if the plan terminates, ceases to provide, or reduces the value of the prescription drug coverage under the plan to below the actuarial value of standard prescription drug coverage. Subject to certain conditions, creditable drug coverage would include drug coverage through Medicaid or through a Section 1115 waiver for persons who are not dual eligibles, a group health plan, state pharmaceutical assistance program, Veterans' programs, and Medigap. Entities offering creditable coverage would be required to disclose whether coverage equals or exceeds the actuarial value of standard coverage. A special enrollment period would apply for persons losing creditable coverage. In general, it would be the 63-day period beginning on the date the individual lost such coverage. Entitlement would begin the first day of the first month following enrollment.

The New Section 1860D–14 would require the Administrator to compute a monthly standard coverage premium for each Medicare Prescription Drug plan and for each Medicare Advantage plan. This would equal the value of standard coverage or actuarially equivalent coverage if the plan provided no additional benefits. If the plan offered additional benefits, the calculation would reflect only the value of standard coverage or, alternatively the approved plan premium for the required qualified coverage plan offered by the entity.

The New Section 1860D–15 would require the Administrator, each year, beginning in 2006, to compute a monthly national average premium equal to the average of the monthly standard coverage premium for each Medicare Prescription Drug plan and each Medicare Advantage plan. The calculation would be a weighted average based on the number of enrollees in the plan in the previous year. The Administrator would establish a methodology for making an adjustment to take into account differences in prices among different areas. In making this calculation, the Administrator could take into account geographic differences in utilization. Any adjustment would be budget neutral.

The Administrator would establish procedures for making the calculation for 2005.

New Section 1860D–17 would specify that if the plan's monthly approved premium for standard coverage was equal to the national monthly weighted average premium for such coverage, the beneficiary would pay: (1) the applicable percentage, established for the area, of the monthly national average. If the plan's monthly approved premium was less than the national average the beneficiary would pay: (1) the applicable percentage for the area, minus, (2) the difference between the national average and the plan's premium. If the plan's monthly premium was greater than the national average, the beneficiary would pay: (1) the applicable percentage for the area, plus (2) the difference between the national average and the plan's premium. The applicable percentage for an area would be 30% divided by 100% minus a percentage equal to: total reinsurance payments that will be made in a year (including such payments to qualified retiree plans) divided by such amount plus total payments that would be made to plans, including Medicare Advantage plans, in the year for standard coverage (or actuarially equivalent coverage).

New Section 1860D–18 would specify that premiums would be collected in the same manner as Part B premiums. The collections would be credited to the Prescription Drug Account. The Administrator would establish procedures whereby the sponsor of employment-based retiree coverage could pay the premium. The Administrator would transmit

the information necessary for collection to the Commissioner of Social Security.

New section 1860D–6 would specify that premiums for a plan would not vary within a region. However, this requirement would not apply to enrollees who were enrolled in a plan pursuant to a contract between the plan and the employer or other group plan that provided employment-based retiree health coverage, if the premium amount was the same for all such enrollees under such agreement.

Conference Agreement

The conference agreement establishes a new section 1860D–13 which sets requirements for beneficiary premiums. The monthly beneficiary premium for a prescription drug plan is defined as the base beneficiary premium, as adjusted. The base beneficiary premium equals the product of the beneficiary premium percentage and the national average monthly bid amount. The beneficiary premium percentage is equal to: (1) 26%, divided by (2) 100% minus a percentage equal to total reinsurance payments divided by the sum of such reinsurance payments and total payments the Secretary estimates will be paid to prescription drug plans in a year that are attributable to the standardized bid amount (taking into account amounts paid by the Secretary and enrollees and the application of risk adjustment). The national average monthly bid amount is a weighted average of standardized bid amounts for each prescription drug plan and each MA–PD plan. It does not take into account bids submitted for MSA plans, MA private fee-for-service plans, specialized MA plans for special needs beneficiaries, PACE programs, and reasonable cost reimbursement contracts. Once the base beneficiary premium is calculated, it is adjusted up or down, as appropriate, to reflect differences between it and the geographically-adjusted national average monthly bid amount. It is further increased for any supplemental benefits and decreased if the individual is entitled to a low-income subsidy. The premium is uniform for all persons enrolled in the plan, except for those receiving low-income subsidies or those subject to a late enrollment penalty.

Late enrollment penalties would be applied to beneficiaries who failed to maintain creditable coverage for a period of 63 days (within a continuous period of eligibility), beginning on the day after the individual's initial enrollment period and ending on the date of enrollment in a prescription drug plan or MA–PD plan. The amount of the penalty is equal to the amount that is the greater of what the Secretary determines is actuarially sound or 1 percent of the national average monthly beneficiary basic premium (not geographically adjusted) for each uncovered month.

The provision specifies that an individual is considered to have had creditable prescription drug coverage if the individual establishes that he or she had coverage under one of the following: (1) prescription drug plan or MA–PD; (2) Medicaid; (3) group health plan, including a Federal Employees Health Benefits (FEHB) plan and a qualified retiree prescription drug plan; (4) state pharmaceutical assistance program; (5) veterans coverage of prescription drugs; (6) prescription drug coverage under a Medigap plan; (7) military coverage including TRICARE; and 8) other coverage the Secretary determines is appropriate. Coverage meets the definition of creditable coverage only if the actuarial value of prescription drug coverage equals or exceeds the actuarial value of such coverage under standard prescription drug coverage. Individuals could apply to the Secretary to waive the requirement that such coverage be at least equivalent to benefits under a qualified prescription drug plan if they could establish that they were not adequately informed that the coverage did not provide such level of coverage. The Secretary will establish procedures for the documentation of creditable prescription drug coverage. Entities offering creditable coverage would be required to provide disclosure that the coverage does not meet the requirement and the fact that the eligible individual could face late enrollment penalties.

Beneficiary premium payments may be paid directly to the PDP sponsor or MA organization. Alternatively the beneficiary has the option of having the amount withheld from his or her Social Security payment or having payment made through an electronic funds transfer mechanism. Payments withheld are to be paid to the PDP sponsor; however, in the case of late enrollment penalties only that portion attributable to increased actuarial costs is to be paid to the plan.

Premium and Cost-Sharing Subsidies for Low-Income Subsidy Individuals (New Section 1860D–14 of the Conference agreement; New section 1860D–7 of House bill; New Section 1860D–19 of Senate bill).

Present Law

Some low-income aged and disabled Medicare beneficiaries are also eligible for full or partial coverage under Medicaid. Medicaid is a federal-state program, which provides health insurance coverage to certain low-income individuals. Within broad federal guidelines, each state sets its own eligibility criteria, including income eligibility standards. Persons meeting the state standards are entitled to full coverage under Medicaid. Persons entitled to full Medicaid protection generally have all of their health care expenses met by a combination of Medicare and Medicaid. For these ''dual eligibles,'' Medicare pays first for services both programs cover. Medicaid picks up Medicare cost-sharing charges and provides protection against the costs of services generally not covered by Medicare. Perhaps the most important service for the majority of dual eligibles is prescription drugs. These dual eligibles typically have comprehensive drug coverage with only nominal cost-sharing.

Federal law specifies several population groups that are entitled to more limited Medicaid protection. These are qualified Medicare beneficiaries (QMBs), specified low income beneficiaries (SLMBs), and certain qualified individuals. QMBs and SLMBs are not entitled to Medicaid's prescription drug benefit unless they are also entitled to full Medicaid coverage under their state's Medicaid program. Qualifying individuals are never entitled to Medicaid drug coverage (because, by definition, they are not eligible for full Medicaid benefits).

Qualified Medicare Beneficiaries (QMBs) are aged or disabled persons with incomes at or below the federal poverty level. In 2003, the monthly level is $769 for an individual and $1,030 for a couple. ($9,228 per year for an individual and $12,360 per year for a couple). The qualifying levels are higher than the HHS federal poverty guidelines because, by law, $20 per month of unearned income, rounded to the next dollar, is disregarded in the calculation. QMBs must also have assets below $4,000 for an individual and $6,000 for a couple. QMBs are entitled to have their Medicare cost-sharing charges, including the Part B premium, paid by the Federal-state Medicaid program. Medicaid protection is limited to payment of Medicare cost-sharing charges (i.e., the Medicare beneficiary is not entitled to coverage of Medicaid plan services unless the individual is otherwise entitled to Medicaid).

Specified Low-Income Medicare Beneficiaries (SLMBs) are persons who meet the QMB criteria, except that their income is over the QMB limit. The SLMB limit is 120% of the federal poverty level. In 2003, the monthly income limits are $918 for an individual and $1,232 for a couple ($11,016 per year for an individual and $14,784 for a couple). Medicaid protection is limited to payment of the Medicare Part B premium (i.e., the Medicare beneficiary is not entitled to coverage of Medicaid plan services unless the individual is otherwise entitled to Medicaid.)

Qualifying Individuals (QI–1s) are persons who meet the QMB criteria, except that their income is between 120% and 135% of poverty. The monthly income limit for QI–1 for an individual is $1,031 and for a couple $1,384 ($12,372 per year for an individual and $16,608 for a couple). Medicaid protection for these persons is limited to payment of the monthly Medicare Part B premium. In general, Medicaid payments are shared between the federal government and the states according to a matching formula. However, expenditures under the QI–1 program are paid 100% by the federal government (from the Part B trust fund) up to the state's allocation level. A state is only required to cover the number of persons which would bring its spending on these population groups in a year up to its allocation level. This temporary program, originally slated to end September 30, 2002, was extended through March 31, 2004 by P.L. 108–89.

Eligibility determinations for Medicaid, QMB, SLMB, and QI–1 programs are made by the states.

House Bill

The New Section 1860D–7 would provide income-related subsidies for low-income individuals. Low-income persons would receive a premium subsidy (based on the value of standard coverage). Individuals with incomes below 135% of poverty would have a subsidy equal to 100% of the value of standard drug coverage provided under the plan. For individuals between 135% and 150% of poverty, there would be a sliding scale premium subsidy ranging from 100% of such value at 135% of poverty to 0% of such value at 150% of poverty. For those with incomes under 135% of poverty, beneficiary cost-sharing for spending up to the initial coverage limit would be reduced to an amount not to exceed $2 for a multiple source or generic drug and $5 for a non-preferred drug. Sponsors and entities could not charge individuals receiving cost-sharing subsidies more than $5 per prescription. (Beginning in 2007, these amounts would be increased by the percentage increase in per capita beneficiary drug costs.) Sponsors and entities could reduce to zero the cost-sharing otherwise applicable for generic drugs.

In 2006, persons eligible for low-income subsidies would have to have resources at or below three times the level applicable for the Supplemental Security Income program (i.e. $6,000 for an individual and $9,000 for a couple). Beginning in 2007, these amounts would be increased by the annual percentage increase in the consumer price index.

The determination of whether an individual was a subsidy eligible individual, and the amount of the subsidy, would be made by the State Medicaid program or the Social Security Administration. Such funds as necessary would be appropriated to the Social Security Administration. Individuals not in the 50 states or the District of Columbia could not be subsidy eligible individuals but could be eligible for financial assistance with drug costs under new Section 1935(e) added by Section 103.

The premium subsidy amount would be defined as the benchmark premium amount for the qualified prescription drug coverage that the beneficiary selects whether offered by a

PDP plan or an MA Rx or EFFS Rx plan in the area. The benchmark premium amount for a plan means the premium amount for enrollment under the plan (without regard to any subsidies or late enrollment penalties) for standard coverage (or alternative coverage if the actuarial value was equivalent). If a plan provided alternative coverage with a higher actuarial value than that for standard coverage, the benchmark amount would bear the same ratio to the total premium as the actuarial value of standard coverage was to the actuarial value of alternative coverage.

The Administrator would provide a process whereby the Administrator would notify the PDP sponsor or MA Rx or EFFS Rx entity that an individual was eligible for a subsidy and the amount of the subsidy. The sponsor or entity would reduce the premiums or cost-sharing otherwise imposed by the amount of the subsidy. The Administrator would periodically, and on a timely basis, reimburse the sponsor or entity for the amount of the reductions.

Part D benefits would be primary to any coverage available under Medicaid. The Administrator would be required to develop and implement a plan for the coordination of Part D benefits and Medicaid benefits. Particular attention would be given to coordination of payments and preventing fraud and abuse. The Administrator would be required to involve the Secretary, the States, the data processing industry, pharmacists, pharmaceutical manufacturers, and other experts in the development and administration of the plan.

Senate Bill

Medicaid beneficiaries eligible for medical and drug benefits under their state Medicaid program (including the medically needy) would continue to receive drug benefits through Medicaid. Persons meeting the definition of QMB, SLMB, or QI–1, and not eligible for Medicaid medical and drug benefits, as well as other persons below 160% of the federal poverty level, would receive their drug benefits through Part D. They would receive assistance for the Part D premium and cost-sharing charges.

QMBs, SLMBs and QI–1s would have a 100% premium subsidy for premiums provided the plan premium was at or below the national weighted average premium (or the lowest premium in the area if none was below the national weighted average).

The benefit package for the QMB population would be defined as having a zero deductible, cost-sharing of 2.5% for costs below the initial coverage limit; 5.0% cost-sharing for costs above the initial coverage limit and below the annual catastrophic limit, and 2.5% cost-sharing for costs above the catastrophic limit. The benefit package for the SLMB and QI–1 population would be defined as having a zero deductible, 5.0% cost-sharing for costs below the initial coverage limit; 10.0% cost-sharing for costs above the initial coverage limit and below the annual catastrophic limit, and 2.5% cost-sharing for costs above the catastrophic limit. Plans could waive or reduce cost-sharing otherwise applicable.

Persons with incomes below 160% of poverty, not otherwise eligible for low-income benefits would have a sliding scale premium subsidy ranging from 100% of the premium at 135% of poverty to 0% at 160% of poverty with no additional premium costs provided the plan premium was at or below the national weighted average premium (or the lowest premium in the area if none was below the national weighted average). The benefit package for this population would be defined as having a $50 deductible in 2006 (indexed in subsequent years by the annual percentage increase in average per capita Medicare drug expenditures), 10.0% cost-sharing for costs below the initial coverage limit; 20.0% cost-sharing for costs above the initial coverage limit and below the annual catastrophic limit, and 10.0% cost-sharing for costs above the catastrophic limit. Plans could waive or reduce cost-sharing otherwise applicable.

QMBs, SLMBs and QI–1s and other Part D enrollees with incomes below 160% of poverty could enroll in MedicareAdvantage and receive their low-income assistance through such plans.

Beginning November 1, 2005, eligibility for low-income individuals would be determined by states. The Administrator would implement a process to notify the eligible entity or MedicareAdvantage plan that the individual was eligible for a cost-sharing subsidy and the amount of the subsidy. The entity would reduce the applicable cost-sharing and submit information to the Administrator on the amount of the reduction. The Administrator would periodically and on a timely basis reimburse the entity or organization for the amount of the reductions.

Beginning January 1, 2009, to the extent a state had not already eliminated application of an asset test, it would be required to permit individuals to make a self-declaration that assets did not exceed $10,000 for an individual or $20,000 for a couple. In subsequent years, these amounts would be increased by the increase in the consumer price index. The Secretary would develop a model declaration form.

Conference Agreement

New Section 1860D–14 of the conference agreement provides premium and cost-sharing subsidies for low-income subsidy-eligible individuals. There are groups of subsidy eligible individuals. The first group is composed of persons who: (1) are enrolled in a prescription drug plan or MA–PD plan; (2) have incomes below 135% of poverty; and (3) have resources in 2006 below $6,000 for an individual and $9,000 for a couple (increased in future years by the percentage increase in the CPI), or (4) who is a full benefit dual eligible, regardless whether that person meets other eligibility standards. The second group of subsidy eligible individuals are persons meeting the same requirements, except that the income level is 150% of poverty and an alternative resources standard may be used; this alternative standard in 2006 is $10,000 for an individual and $20,000 for a couple (increased in future years by the percentage increase in the CPI.)

Individuals with incomes below 135% of poverty, and resources meeting the requirement for the first group, would have a premium subsidy equal to 100% of the low-income benchmark premium amount, but in no case higher than the actual premium amount for basic coverage under the plan. The low-income benchmark premium amount for a region equals either: (1) the weighted average of the basic premiums, if all prescription drug plans are offered by the same PDP sponsor; or (2) the weighted average of premiums for prescription drug plans and MA–PD plans, if plans in the region are offered by more than one PDP sponsor. Other low-income subsidy eligible persons will have a sliding scale premium subsidy ranging from 100% of such value at 135% of poverty to 0% of such value at 150% of poverty. Persons below 135% of poverty would have a premium subsidy for any late enrollment penalty equal to 80 percent for the first 60 months and 100 percent thereafter.

Beneficiaries in both groups are entitled to cost-sharing subsidies. Individuals with incomes below 135% of poverty, and resources meeting the requirement for the first group will have no deductible, cost-sharing for all costs up to the out-of-pocket threshold of $2 for a generic drug or preferred multiple source and $5 for brand name or non-preferred drug. Institutionalized dual eligibles will have no cost sharing. Full benefit dual eligibles with incomes under 100 percent of poverty will have cost sharing up to the out-of-pocket threshold of up to $1 for a generic drug or preferred multiple source and $3 for a brand name or nonpreferred drug. Other low-income subsidy eligible persons will have a $50 deductible, 15 percent cost-sharing for all costs up to the out-of-pocket limit, and cost-sharing for costs above the out-of-pocket threshold of $2 for a generic drug or preferred multiple source and $5 for brand name or non-preferred drug. The deductible and cost-sharing amounts are increased each year beginning in 2007 by the annual percentage increase in per capita beneficiary expenditures for Part D covered drugs except for $1 and $3 cost-sharing, which will increase by the percentage increase in CPI.

Eligibility determinations are to be made under the state Medicaid plan for the state or by the Commissioner of Social Security. Conferees believe that more beneficiaries will enroll in the new Part D benefit if given the option to apply at the Social Security office as well as the welfare office. Low-income subsidy applications, information, and application assistance shall be available to beneficiaries in all Social Security offices and State Medicaid offices. It is the intent of the conferees that while enrollment at the SSA offices is important, both Medicaid programs and the Social Security Administration should engage in outreach activities to encourage eligible individuals to apply for subsidies under this section. The determinations shall remain effective for a period determined by the Secretary, not to exceed one year. Redeterminations or appeals are to be made in the same manner as such redeterminations and appeals are made by state Medicaid plans or the Commissioner for the supplemental security income program, whichever is appropriate.

Full dual eligible persons are to be treated as subsidy eligible persons; the Secretary may provide that other Medicaid beneficiaries be treated as subsidy eligible. Otherwise, income is to be determined in the same manner as determinations are made for the QMB program; however, Section 1902(r)(2) which permits the use of less restive methodologies does not apply for determining whether an individual is a low-income subsidy eligible individual. However, Section 1902(r)(2) continues to apply to all state Medicaid eligibility determinations. The Secretary is to develop a model simplified application form and process for determining and verifying eligibility. The Commissioner may only require submission of statements from financial institutions for an application for low-income subsidies to be considered complete. No other documentary evidence may be required with the submission of the application. The Secretary is permitted to verify information submitted on the application.

The Secretary will provide a process whereby the Secretary will notify the PDP sponsor or MA organization that an individual is eligible for a subsidy and the amount of the subsidy. The sponsor or entity would reduce the premiums or cost-sharing otherwise imposed by the amount of the subsidy. The Administrator will periodically, and on a timely basis, reimburse the sponsor or entity for the amount of the reductions. Reimbursement for cost-sharing subsidies may be computed on a capitated basis.

The residents of the territories are not eligible for low-income subsidies. However, they may be eligible for financial assistance

under the new section 1935(e), as added by Section 103.

Subsidies for All Medicare Beneficiaries for Qualified Prescription Drug Coverage (New Section 1860D–15 of Conference agreement; New Section 1860D–8 of House bill; New Sections 1860D–20, 1860D–11, and 1860D–16 of Senate bill).

House Bill

a. Subsidies. New Section 1860D–8 would provide for subsidy payments to qualifying entities. The stated purpose of such payments would be to reduce premiums for all beneficiaries consistent with an overall subsidy level of 73%, reduce adverse selection among plans, and promote the participation of PDP sponsors. Such payments would be made as direct subsidies and through reinsurance. The section would constitute budget authority in advance of appropriations and represent the obligation of the Administrator to provide for subsidy payments specified under the section.

Direct subsidies would be made for individuals enrolled in a PDP, MA Rx or EFFS Rx plan, and equal to 43% of the national weighted average monthly bid amount. Each year, the Administrator would compute a national average monthly bid amount equal to the average of the benchmark bid amounts for each drug plan (not including those offered by private-fee-for service entities) adjusted to add back in the value of reinsurance subsidies. The benchmark bid amount would be defined as the portion of the bid attributable to standard coverage or actuarial equivalent coverage. The bid amount would be a weighted average with the weight for each plan equal to the average number of beneficiaries enrolled in the plan for the previous year. (The Administrator would establish a procedure for determining the weighted average for 2005).

Reinsurance payments would be made for specified costs incurred in providing prescription drug coverage for individuals enrolled in either a PDP plan, or a MA Rx or EFFS Rx plan. The Administrator would provide for reinsurance payments to PDP sponsors, and entities offering MA Rx or EFFS Rx plans. Reinsurance payments would be provided for 30% of an individual's allowable drug costs over the initial reinsurance threshold ($1,000 in 2006) but not over the initial coverage limit ($2,000 in 2006). Reinsurance, not to exceed 80% would also be provided for costs over the out-of-pocket threshold ($3,500 in 2006). In the aggregate, reinsurance payments would equal 30% of total payments made by qualifying entities for standard coverage.

For purposes of calculating reinsurance payments, allowable costs would be defined as the portion of gross covered prescription drug costs that were actually paid by the plan (net of discounts, chargebacks, and average percentage rebates), but in no case more than the part of such costs that would have been paid by the plan if the drug coverage under the plan were standard coverage. Gross covered drug costs would be defined as costs (including administrative costs) incurred under the plan for covered prescription drugs dispensed during the year, including costs related to the deductible, whether paid by the enrollee or the plan, regardless of whether coverage under the plan exceeded standard coverage and regardless of when the payment for the drugs was made.

The Administrator would be required to estimate the total reinsurance subsidy payments that would be made during the year (including those made to qualified retiree plans) and total benefit payments to be made by qualifying entities for standard coverage during the year. The Administrator would proportionately adjust payments such that total subsidy payments during the year were equal to 30% of total payments made by qualifying plans for standard coverage during the year. The Administrator could, in a budget neutral manner, adjust direct subsidy payments in order to avoid risk selection. The payment method would be determined by the Administrator who could use an interim payment system based on estimates. Payments would be made from the Medicare Prescription Drug Trust Fund.

b. Risk corridors. No provision.

Senate Bill

a. Subsidies. New Section 1860D–20 of the Senate bill would provide for reinsurance payments on behalf of: (1) persons enrolled in a PDP; (2) MA plan (except for MSA plan or private fee-for-service plan not providing qualified coverage); (3) persons eligible for but not enrolled in Part D and covered under a qualified retiree plan; (4) persons eligible for but not enrolled in Part D and covered under a qualified state pharmaceutical assistance program. Qualified retiree plans and state pharmaceutical assistance programs would have to provide coverage at least equal to the actuarial value of standard coverage. Reinsurance payments would be made to plans in the case of individuals whose spending exceeded the out-of-pocket limit. Payments to plans would equal 80% (65% in the case of persons in a state pharmaceutical assistance program) of allowable drug costs exceeding the limit. Allowable costs would be equal to actual costs above the limit. Entities would be required to notify the Administrator of the total actual costs (if any) incurred for providing benefits for an individual after the individual exceeded the out-of-pocket threshold. Administrative costs, costs for coverage in excess of the standard benefit, and discounts, direct or indirect subsidies, rebates, or other price concessions or direct or indirect remunerations would not be included. Payment methods would be determined by the Administrator. Such methods could include the use of interim payments.

Any plan sponsor that was not an employer would be required to redistribute reinsurance payments to employers contributing to the plan maintained by the sponsor; the payments would be allocated proportionately among all employers contributing to the plan.

The New Section 1860D–11 would require the Administrator to establish an appropriate method for adjusting payments to plans to take into account variations in costs based on the differences in actuarial risk of different enrollees being served. Any risk adjustment would be designed in a budget neutral manner. The Administrator could take into account similar methodologies used to adjust payments for Medicare Advantage organizations. The Administrator would be required to publish such risk adjusters not later than April 15 each year (beginning in 2005) to be used for computing payments to plans for standard coverage.

New Section 1860D–16 would require the Administrator to pay each entity offering a Medicare Prescription Drug Plan an amount equal to the full monthly approved premium, with appropriate risk adjusters. Payment terms would be determined by the Administrator and be based on terms used for Medicare Advantage plans. Payments to plans would be adjusted to account for differences in actuarial risk of different enrollees being served.

b. Risk corridors. New section 1860D–16 would require entities to notify the Administrator for each year (beginning in 2007) of the total actual costs the entity incurred in providing standard coverage in the preceding year. Total actual costs would reflect total payments made to pharmacies and other entities for coverage and the aggregate amount of discounts, direct or indirect subsidies, rebates, or other price concessions or direct or indirect remunerations made to the entity. The notification would not include spending for administrative costs, amounts spent for coverage in excess of standard coverage, or amounts for which the entity subsequently received reinsurance payments.

The provision would establish risk corridors, which would be defined as specified percentages above and below a target amount. The target amount would be defined as the total of plan premiums minus a percentage (negotiated between the Administrator and the entity) for administrative costs. No payment adjustment would be made if allowable costs were not more than the first threshold upper limit or less than the first threshold lower limit for the year, i.e. if the plans were within the first risk corridor. A portion of any plan spending above or below these levels would be subject to risk adjustments. If allowable costs exceeded the first threshold upper limit, then payments would be increased. If allowable costs were below the first threshold lower limit, payments would be reduced.

During 2006 and 2007, plans would be at full risk for drug spending within 2.5% above or below the target. Plans would be at risk for 25% of spending exceeding 2.5% (first threshold upper limit) and below 5% of the target (second threshold upper limit). That is their payments would equal 75% of the allowable costs for spending in this range. They would be at risk for 10% of the spending exceeding 5% of the target. That is their payments would equal 90% of the allowable costs for spending in this range. Conversely, if plans fell below the target, they would share the savings with the government. They would have to refund 75% of the savings if costs fell between 2.5% and 5% below the target level, and 90% of any amounts below 5% of the target.

A special transition corridor would be established in the first two years. The Administrator would make a payment adjustment if the Administrator determined that 60% or more of all participating plans (including Medicare Advantage plans) representing at least 60% of covered beneficiaries had allowable costs that were more than 2.5% above the target. Risk corridor payments would equal 90% of any spending greater than 2.5% of the target but below 5% of the target.

For 2008–2011, the risk corridors would be modified. Plans would be at full risk for drug spending within 5.0% above or below the target level. Plans would be at risk for 50% of spending exceeding 5.0% and below 10.0% of the target level. They would be at risk for 10% of the spending exceeding 10% of the target level. Payments would be increased by 50% of allowable costs exceeding the first threshold upper limit and 90% for costs exceeding the second threshold upper limit. Conversely, if plans fell below the target, they would share the savings with the government. They would have to refund 50% of the savings if costs fell between 5% and 10% below the target level, and 90% of any amounts below 90% of the target. For years after 2011, the Administrator would establish risk corridors. The first threshold risk percentage could not be less than 5% and the second threshold risk percentage could not be less than 10%.

Administrative costs would be not be included in the calculation of whether or nor plan spending fell within a particular risk corridor. Administrative costs would be negotiated separately, on a plan by plan basis, with the Administrator. Administrative costs would be subject to performance risk.

For purposes of making risk corridor calculations, allowable costs would be based on actual costs reported by the plan.

The Administrator could require disclosure of any data as needed to administer the benefit. The Administrator would have the right to inspect and audit any books and records of the entity pertaining to amounts reported for drug spending. Information could be used by officers and employees of the Department of Health and Human Services, but only to the extent necessary to carry out this section.

The Administrator would be required to establish a stabilization reserve fund, within the Prescription Drug Account. Amounts in this fund would be made available to eligible entities beginning with their 2008 contract year. Payments to the fund would be determined as follows. If the target amount for a plan for any year 2006–2010 exceeded applicable costs by more than 3% for the year, the entity would pay the Administrator the amount of such excess; the Administrator would deposit such amount in the fund on behalf of the entity. Applicable costs would be defined as the sum of allowable costs and the amount by which monthly payments were reduced through application of the risk corridor provisions. At appropriate intervals, the Administrator would notify a participating entity of the balances in any of its stabilization accounts. Beginning in 2008, entities would be permitted to use account funds to stabilize or reduce plan premiums. The accounts would expire after 5 years. Any amounts not used by an eligible entity or that was deposited for use by an entity that no longer had a Part D contract would revert to the use of the Prescription Drug Account.

Conference agreement

a. Subsidies. New Section 1860D–15 of the conference agreement provides for subsidy payments to qualifying entities. Such payments would reduce premiums for all beneficiaries consistent with an overall subsidy level of 74% for basic coverage, to reduce adverse selection among plans, and to promote the participation of PDP sponsors and MA organizations. Such payments would be made as direct subsidies and through insurance.

The direct monthly per capita subsidy amount is equal to the plan's standardized bid amount adjusted for health status and risk and reduced by the base beneficiary premium as adjusted to reflect the difference between the bid and the national average bid.

Reinsurance payments, equal to 80% of allowable costs, would also be provided for an enrollee whose costs exceeded the annual out-of-pocket threshold ($3,600 in 2006). For purposes of calculating reinsurance payments, allowable costs would be defined as the portion of gross covered prescription drug costs that were actually paid by the plan (net of discounts, chargebacks, and average percentage rebates), but in no case more than the part of such costs that would have been paid by the plan if the drug coverage under the plan were basic coverage or, in the case of supplemental coverage, standard coverage. Gross covered drug costs would be defined as costs (not including administrative costs) incurred under the plan for covered prescription drugs dispensed during the year, including costs related to the deductible, whether paid by the enrollee or the plan, regardless of whether coverage under the plan exceeded basic coverage and regardless of when the payment for the drugs was made.

The Secretary is required to establish an appropriate method for adjusting the standardized bid amount to take into account variations in costs for basic coverage based on the differences in actuarial risk of different enrollees being served. Any risk adjustment would be designed in a budget neutral manner. The Secretary may take into account similar methodologies used to adjust payments for MA organizations. The Secretary would require PDP sponsors and MA organizations offering MA–PD plans to submit data. The Secretary is required to publish such risk adjusters at the same time as risk adjusters are published for MA organizations.

The Secretary is required to establish an appropriate method for adjusting the national average monthly bid amount per capita subsidy amount to take into account differences. If the Secretary determines that price variations are de minimis, no adjustment is to be made. Any adjustments must be applied in a budget neutral manner.

The Secretary is to establish payment methods, which may include interim payments. Payments are conditional upon the PDP sponsor and MA organization furnishing necessary information to the Secretary. Information may be used by officers and employees of HHS only for the purposes of and to the extent necessary to carry out the section.

c. Risk corridors. New Section 1860D–15 of the conference agreement provides for the establishment of risk corridors, which are defined as specified percentages above and below a target amount. The target amount is defined as total payments paid to the plan, taking into account the amount paid by the Secretary and enrollees, based on the standardized bid amount, risk adjusted, and reduced by total administrative expenses assumed in the bid. No payment adjustments will be made if adjusted allowable costs for the plan are at least equal to the first threshold lower limit of the first risk corridor but not greater than the first threshold upper limit of the risk corridor for the year, i.e. if the plans are within the first risk corridor. A portion of any plan spending above or below these levels is subject to risk adjustment. If adjusted allowable costs exceed the first threshold upper limit, then payments are increased. If adjusted allowable costs are below the first threshold lower limit, then payments are reduced. Adjusted allowable costs are reduced by reinsurance and subsidy payments. Payment adjustments would not affect beneficiary premiums.

During 2006 and 2007, plans would be at full risk for adjusted allowable risk corridor costs within 2.5% above or below the target. Plans with adjusted allowable costs above this level would receive increased payments. If their costs were between 2.5% of the target (first threshold upper limit) and 5% of the target (second threshold upper limit), they would be at risk for 25% of the increased amount; that is their payments would equal 75% of adjusted allowable costs for spending in this range. If their costs were above 5% of the target they would be at risk for 25% of the costs between the first and second threshold upper limits and 20% of the costs above that amount. That is their payments would equal 80% of the adjusted allowable costs over the second threshold upper limit. Conversely, if plans fell below the target, they would share the savings with the government. They would have to refund 75% of the savings if costs fell between 2.5% and 5% below the target level, and 80% of any amounts below 5% of the target.

A higher risk sharing percentage would apply in 2006 and 2007 if the Secretary determines that 60 percent of prescription drug plans and MA–PD plans, representing at least 60 percent of beneficiaries enrolled in such plans have adjusted allowable costs that are more than the first threshold upper limit. In this case, payment to plans would equal 90 percent of adjusted allowable costs between the first and second upper threshold limits.

For 2008–2011, the risk corridors would be modified. Plans would be at full risk for drug spending within 5% above or below the target level. Plans would be at risk for 50% of spending exceeding 5% and below 10% of the target level. Additionally, they would be at risk for 20% of any spending exceeding 10% of the target level. Payments would be increased by 50% of adjusted allowable costs exceeding the first threshold upper limit and 80% for any costs exceeding the second threshold upper limit. Conversely, if plans fell below the target, they would share the savings with the government. They would have to refund 50% of the savings if costs fell between 5% and 10% below the target level, and 80% of any amounts below 10% of the target. For years after 2011, the Administrator would establish risk corridors. The first threshold risk percentage could not be less than 5% and the second threshold risk percentage could not be less than 10% of the target amount. Conferees intend the risk corridors to create incentives for plans to enter the market.

If allowable risk corridor costs are less than the first threshold lower limit, but not greater than the first threshold upper limit for the plan year, then no payment adjustment is made.

Plans are at full financial risk for all spending for supplemental prescription drug coverage.

The subsidy and risk corridor provisions would not apply to fallback plans.

Medicare Prescription Drug Account in the Federal Supplementary Insurance Trust Fund (New Section 1860D–16 of Conference Agreement; New Section 1860D–9 of House Bill; New Section 1860D–25 of Senate Bill).

Present Law

Medicare Part B is financed by a combination of enrollee premiums and federal general revenues. Income from these sources is credited to the Federal Supplementary Insurance Trust Fund. Payments are made from the Trust Fund for Part B benefits.

House Bill

New Section 1860D–9 would create a Medicare Prescription Drug Trust Fund. Requirements applicable to the Part B trust fund would apply in the same manner to the Drug Trust Fund as they apply to the Part B Trust Fund. The Managing Trustee would pay from the Fund, from time to time, low-income subsidy payments, subsidy payments, and payments for administrative expenses. The Managing Trustee would transfer, from time to time, to the Medicaid account amounts attributable to allowable increases in administrative costs associated with identifying and qualifying beneficiaries eligible for low-income subsidies. Amounts deposited into the Trust Fund would include the federal amount which would otherwise be payable by Medicaid except for the fact that Medicaid becomes the secondary payer of drug benefits for the dual eligibles. The provision would authorize appropriations to the Trust Fund an amount equal to the amount of payments from the Trust Fund reduced by the amount transferred to the Trust Fund.

The provision would specify that any provision of law relating to the solvency of the trust fund would take into account the Fund and the amounts received by, or payable from, the Fund.

Senate Bill

A separate account, known as the Prescription Drug Account, would be established within the Part B Trust Fund. Funds in this Account would be kept separate from other funds within the Trust Fund. Payments

would be made from the Account to eligible entities and Medicare Advantage plans and for low-income subsidies, reinsurance payments, and administrative expenses. Appropriations would be made to the Account equal to the amount of payments and transfers made from the Account.

Conference Agreement

The conference agreement establishes a Medicare Prescription Drug Account in the Part B Trust Fund. Funds in this Account will be kept separate from other funds within the Trust Fund. Payments will be made from the Account for low-income subsidies, subsidy payments, payments to qualified retiree prescription drug plans, and administrative expenses. Transfers would be made to the Medicaid account for increased administrative costs. States would make payments to the Account for dual eligibles as provided for under Section 1935(c). Appropriations would be made to the Account equal to the amount of payments and transfers from the Account. In order to ensure prompt payments in the early months of the program, there are appropriated such amounts the Secretary certified as necessary, not to exceed 10% of estimated expenditures for 2006.

Subpart 3—Application to Medicare Advantage Program and Treatment of Employer-Sponsored Programs and Other Prescription Drug Plans

Application to Medicare Advantage Program and Related Managed Care Programs (New Section 1860D–21 of Conference agreement; Section 101 of House bill; Sections 201 and 205 of Senate bill).

Present Law

No provision.

House Bill

Beginning January 1, 2006, at least one MA plan offered by an MA organization in an area would be required to: (1) offer qualified drug coverage under Part D; (2) meet the beneficiary protections outlined in the new Section 1860D–3, including requirements relating to information dissemination as well as grievance and appeals; and (3) provide the same information required from prescription drug plan sponsors when submitting a bid, unless waived by the Administrator. MA organizations providing qualified drug coverage would receive low-income subsidy payments and direct and reinsurance subsidies. A single premium would be established for drug and non-drug coverage.

There would be exceptions for the prescription drug coverage offered by private fee-for-service (PFFS) plans. PFFS plans would not be required to negotiate prices or discounts; however, to the extent a plan did so, it would be required to meet related Part D requirements.

Senate Bill

In addition to current law requirements, Medicare beneficiaries would also be required to be enrolled in the new Part D (prescription drug program) in order to enroll in MA (except for PFFS).

Beginning on January 1, 2006, MA plans, other than PFFS and MSA plans, would be required to offer each enrollee qualified prescription drug coverage that met the requirements for such coverage under the MA program and under Part D of Medicare. An MA plan could offer qualified prescription drug coverage that exceeded the coverage required under Part D, as long as it also offered an MA plan in the area that provided only the required coverage. This provision would also establish payments to each MA organization offering an MA plan that provided qualified prescription drug coverage, including a low-income drug subsidy.

Conference Agreement

Beginning January 1, 2006, an MA organization cannot offer an MA plan in an area unless either that plan (or another MA plan offered by the organization in the same service area) includes required prescription drug coverage, and could not offer prescription drug coverage (other than that required under parts A and B) to an enrollee under an MSA plan or under another MA plan unless such drug coverage was qualified prescription drug coverage and unless the requirements of this section, with respect to such coverage are met. Qualified coverage is basic coverage or qualified coverage that provides supplemental drug benefits so long as there is no MA monthly supplemental beneficiary premium under the plan.

An individual enrolled in a health benefits plan would not be considered to have been deemed to make an election into an MA–PD plan, unless the plan provides prescription drug coverage. An individual enrolled in an MA plan would not be considered to have been deemed to make an election into an MA–PD plan, unless: (1) for purposes of the January 1, 2006 election, the MA plan provided as of December 31, 2005 any prescription drug coverage; or (2) for periods after January 1, 2006, such MA plan was an MA–PD plan. An individual who discontinues enrollment in an MA–PD plan during his/her first year of eligibility could enroll in a prescription drug plan under part D at the time of their election of coverage under original Medicare fee-for-service program.

If an individual is enrolled in an MA plan (other than an MSA plan) that does not provide qualified prescription drug coverage, and the organization discontinues offering all MA plans without prescription drug coverage, then the individual would be deemed to have elected the original Medicare fee-for-service program, unless the individual affirmatively enrolls in an MA–PD plan. This disenrollment would be treated as an involuntary termination of the MA plan.

The provisions of this part would apply under Part C of Medicare with respect to prescription drug coverage provided under MA–PD plans in lieu of other Part C provisions that would apply to such coverage. The Secretary could waive these provisions to the extent that they duplicate provision under Part C or as may be necessary in order to improve coordination. The Secretary may also waive the pharmacy network requirements of section 1860D–4(b)(1)(C) in the case of an MA–PD plan that provides access (other than mail order) to qualified prescription drug coverage through pharmacies owned and operated by the MA organizations. The Secretary must determine the organization's pharmacy network is sufficient to provide comparable access for enrollees under the plan.

Private fee-for-service plans (PFFS) plans would not be required to negotiate prices or discounts; however, to the extent a plan did so, it would be required to meet related Part D requirements. If the PFFS plan provided coverage for drugs purchased from all pharmacies, without additional cost-sharing, requirements for pharmacy access and public disclosure of pharmaceutical prices for equivalent drugs would not apply. For PFFS plans, the drug utilization management program and the medication therapy management program would not be required. For PFFS plans, the Secretary would determine the amount of reinsurance payment using a methodology that bases such amount on the Secretary's estimate of the amount of such payment that would be payable if the plan were an MA–PD plan and that takes into account the average reinsurance payment made for a population of similar risk under MA–PD plans. The risk corridor provisions would not apply, and plans would be exempt from negotiations on bid terms.

If an organization provides benefits under a reasonable cost reimbursement contract and also elects to provide qualified prescription drug coverage, then the provisions of this section and related provisions in part C would apply in the same manner as applied to local MA–PD plans. Individuals, who were not enrolled in the reasonable cost plan, could not enroll in the prescription drug plan. The bid of the reasonable cost plan would not be taken into account in computing any standardized bid amount under this section.

In general, the provisions of Part D and related provisions of Part C apply to PACE programs in the same manner as they apply to MA–PD plans. The organization may not enroll persons not enrolled in PACE. Bids are not taken into account in computing the standardized bid amount.

Special Rules for Employer-Sponsored Programs (New Section 1860D–22 of Conference agreement; New section 1860D–8 of House bill; New Section 1860D–21 and 1860D–22 of Senate bill).

Present Law

No provision.

House Bill

Under New section 1860D–8, special subsidy payments would be made to a ''qualified retiree prescription drug plan.'' A qualified plan would be defined as employment-based retiree health coverage (including coverage offered pursuant to one or more collective bargaining agreements) meeting certain requirements. The Administrator would have to determine that coverage had at least the same actuarial value as standard coverage. The sponsor (and the plan) would be required to maintain and provide access to records needed to ensure the adequacy of coverage and the accuracy of payments made. Further, the sponsor would be required to provide certifications of coverage. Payment could not be made for an individual unless: the individual was covered under the retiree plan, entitled to enroll under a PDP or MA Rx or EFFS Rx plan but elected not to. Subsidy payments would equal 28% of allowable costs between $250, but not greater than $5,000, indexed annually by the percentage increase in Medicare per capita prescription drug costs. The provision would clarify that nothing in the section would be construed as precluding an individual covered under an employment-based retiree plan from enrolling in a PDP plan or MA or EFFs plan or having the employment based plan from paying the premium. Employment-based supplemental coverage would be considered the primary payer for purposes of the Medicare secondary payment provisions.

Senate Bill

New Section 1860D–21 of the Senate bill would authorize the Administrator to make direct payments to sponsors of qualified retiree prescription drug plans (as defined under New Section 1860D–20) for each beneficiary enrolled in the plan who was not enrolled in Part D. The amount of the payment would equal the direct subsidy percent of the monthly national average premium for the year, as adjusted by risk adjusters. The direct subsidy percent would be 100% minus the applicable percent as defined under the new Section 1860D–17. The applicable percentage for an area would be 30% divided by: 1) 100%, minus two) a percentage equal to total reinsurance payments that would be made in a year divided by such amount plus total payments that would be made to plans in the year for standard coverage.

The Administrator would establish payment methods, which could include interim payments. Payments would be made from the Prescription Drug Account.

New Section 1860D–22 would require the Administrator to make direct payments to

sponsors of qualified state pharmaceutical assistance programs for each beneficiary enrolled in the plan who was not enrolled in Part D. The amount of the payment would be calculated in the same way that such payments were calculated for retiree plans. Further, the Administrator would provide for additional payments in behalf of each person who would otherwise qualify for a low-income subsidy, if the individual were enrolled in Part D. The payment would equal the amount the Administrator estimates would have been paid under the subsidy provisions, but in no case more than the average payment made under the subsidy provisions for an individual in the same income group.

Conference agreement

New Section 1860D–22 of the conference agreement establishes special rules for employer-sponsored programs. Under certain conditions, the Secretary is required to make special subsidy payments to sponsors of qualified retiree prescription drug plans. These payments are to be made on behalf of an individual covered under the retiree plan, entitled to enroll under a PDP or MA–PD plan but elected not to. Subsidy payments will equal 28% of gross covered retiree plan-related prescription drug costs greater than $250 but not greater than $5,000, adjusted annually by the percentage increase in Medicare per capita prescription drug costs.

Qualified retiree prescription drug plans must be employment-based group health plans. Group health plans include welfare plans defined under the Employee Retirement Income Security Act, federal and state governmental plans, including such plans as the Federal Employee Health Benefits program and CalPERS, collectively bargained plans, and church plans. Conferees expect that in the case of interpretive matters with regard to plan sponsors of group health plans, CMS will coordinate with the Department of Labor and Treasury Department for guidance. The sponsor must provide the Secretary with an attestation that the actuarial value of prescription drug coverage under the plan is at least equivalent to the actuarial value of standard prescription drug coverage. The sponsor, or administrator designated by the sponsor, shall maintain and afford the Secretary access to necessary records for the purpose of audits and other oversight activities. The sponsor is required to provide disclosure of information in accordance with disclosure of information on creditable coverage.

Nothing in the section is to be construed as precluding an individual covered under an employment-based retiree plan from enrolling in a PDP plan or MA–PD plan or having the employment-based plan from paying the premium. The PDP or MAPD plan would constitute primary coverage, not the employer. Employment-based retiree coverage may provide coverage that is better than standard coverage to retirees under a qualified retiree prescription drug plan. Employment-based retiree health coverage may provide coverage that is supplemental to benefits provided under a prescription drug plan or MA–PD plan to enrollees in such plans. Nothing is to prevent employers from providing flexibility in benefit design and pharmacy access provisions for basic drug coverage so long as actuarial equivalence requirements are met.

About one-third of Medicare beneficiaries receive coverage for prescription drugs from their former employers. Retirees are generally happy with their coverage and want to keep it. But employer plans are under increasing pressure to drop or scale back coverage. In 1988, 66% of large employers provided health benefits. In 2002, that number slipped to just 34%. Costs for retiree health coverage rose 16.0% in 2002, while prescription drug expenditures increased by 11.8% last year, and most employers predict double-digit health inflation well into the future. Conferees believe the employer retiree subsidies included in the conference report will help employers retain and enhance their prescription drug coverage so that the current erosion in coverage would plateau or even improve. Absent this assistance, many more retirees will lose their employer sponsored coverage.

State Pharmaceutical Assistance Programs (New Section 1860D–23 of Conference agreement).

Present Law

A number of states currently have programs to provide low-income persons, not qualifying for Medicaid, with financial assistance in meeting their drug costs. The state programs differ substantially in both design and coverage.

House Bill

No provision.

Senate Bill

No provision.

Conference agreement

New Section 1860D–23 of the conference agreement requires the Secretary, by July 1, 2005, to establish requirements to ensure effective coordination between a Part D plan (both a prescription drug plan and MA–PD plan) and a state pharmaceutical assistance program (SPAP). The coordination requirements relate to payment of premiums and coverage and payment for supplemental drug benefits, and assistance with cost-sharing. Requirements must be included for enrollment file-sharing, claims processing, claims reconciliation reports, application of the catastrophic out-of-pocket protection, and other administrative procedures specified by the Secretary. Requirements are to be consistent with applicable law, to safeguard the privacy of any identifiable beneficiary information. The agreement provides that the requirements must include a method for the application by a Part D plan of specified funding amounts for enrolled beneficiaries for supplemental benefits. The Secretary is required, when developing the requirements, to consult with state programs, the PDP sponsors, MA organizations, States, pharmaceutical benefit managers, employers, data processing experts, pharmacists, pharmaceutical manufacturers, and other experts.

This legislation allows state pharmacy assistance programs to act as administrative intermediaries for the purpose of facilitating enrollment of SPAP members in prescription drug plans and in the discount card program.

A state pharmaceutical program that this provision applies to is one: (1) that provides financial assistance for the purchase or provision of supplemental prescription drug coverage on behalf of eligible individuals; and (2) which, in determining program eligibility and amount of payment, provides assistance to beneficiaries in all Part D plans and does not discriminate based on the Part D plan in which the individual is enrolled. A card used under Part D may also be used for benefits under the state program.

The agreement authorizes the Secretary, based on an approved application, to provide payments to state pharmaceutical assistance programs for the purpose of educating program beneficiaries about Part D coverage, providing technical assistance to facilitate selection and enrollment in plans, and other activities to promote effective coordination. The report provides $62.5 million in mandatory spending in each fiscal year 2005 and 2006 to help promote coordination between Medicare plans and SPAPs.

Coordination Requirements for Plans Providing Prescription Drug Coverage (New Section 1860D–24 of Conference agreement).

Present Law

No provision.

House Bill

No provision.

Senate Bill

No provision.

Conference Agreement

The New Section 1860D–24 of the conference agreement requires the Secretary to apply the coordination requirements established under the New Section 1860D–23 for state pharmaceutical assistance programs, to other prescription plans including Medicaid (including a plan operating under an 1115 waiver), group health plans, federal employees health benefits plan, military coverage (including TRICARE), and other coverage specified by the Secretary.

The coordination requirements include coordination of procedures to establish third-party reimbursement of out-of-pocket costs. The provision does not change the application of these procedures. The Secretary may impose user fees for the transmittal of information necessary for benefit coordination.

Medicare Prescription Drug Discount Card and Transitional Assistance Program (New Section 1860D–31 of Conference agreement; Section 105 of House bill; Section 111 of Senate Bill).

Present Law

On July 12, 2001, the President announced a new national drug discount card program for Medicare beneficiaries. Under this program, CMS would endorse drug card programs meeting certain requirements. This program was viewed as an interim step until a legislative reform package, including both a drug benefit and other Medicare reforms, was enacted. Implementation of the drug discount card program was suspended by court action.

House Bill

The provision would require the Secretary to establish a program to: (1) endorse prescription drug discount card programs meeting certain requirements; (2) provide for prescription drug accounts; and (3) make available information on such programs to beneficiaries. The Secretary would begin operation of the endorsement program within 90 days of enactment. The account part of the program would begin no later than September 2004. The Secretary would provide for an appropriate transition and termination of the program on January 1, 2006. The program would be voluntary.

Eligible beneficiaries would be defined as persons eligible under Part A or enrolled in Part B, but not enrolled in an MA plan offering qualified prescription drug coverage. The Secretary would establish a process through which an Part D eligible individual could make an election to enroll under the new Section 1807 with an endorsed program. The beneficiary would have to enroll for a year in order to receive the benefits for the year. An individual would, in general have only one opportunity for enrollment. This would occur during an initial, general enrollment period as soon as possible after enactment, and annually thereafter. The annual open enrollment periods would be coordinated with those for MA. An individual who enrolled in the new Section 1807, subsequently enrolled in an MA plan with drug coverage, and then discontinued such MA enrollment would be permitted to reenroll under Section 1807.

In general, eligible beneficiaries would not be permitted to enroll after their initial enrollment period (as defined under Part B). The Secretary would establish an open enrollment period for current beneficiaries.

The Secretary would establish a process through which an Part D eligible individual, enrolled under the new Section 1807, would

select an eligible entity to provide access to negotiated prices. The entity would be one, which had been awarded a contract and served the state in which the beneficiary resided. Eligible entities would be pharmaceutical benefit management companies, wholesale and retail pharmacy delivery systems, insurers, MA organizations, other entities, or any combination of these.

The enrollment process, established by the Secretary, would use rules similar to those established for MA. Individuals could not select more than one entity at a time and, except for unusual circumstances (including changing residential setting, such as nursing home placement.) change the selection once a year. The process would provide for selecting eligible entities for individuals who enrolled in the New Section 1807, but failed to select an entity. Entities would compete for beneficiaries on the basis of discounts, formularies, pharmacy networks, and other services.

The Secretary would broadly disseminate information to eligible beneficiaries regarding enrollment, selection of eligible entities, and the coverage made available by entities. The enrollment fee would be $30 with the 2004 fee including any portion of 2003 covered by the program. The fee would be collected in the same manner as Part B premiums are collected from social security payments, except the collection would be made only once a year. States could pay the fee for some or all low-income enrollees in the state. No federal matching payments would be available. The Secretary would make 2/3 of the fee collected available to the eligible entity.

Each eligible entity would be required to issue a card and an enrollment number to each enrolled beneficiary and to provide for electronic methods to coordinate with prescription drug accounts established under the New Section 1807A.

Beneficiary protections would be established including guaranteed issue and nondiscrimination provisions. If an eligible entity served a state, it would be required to serve the entire state. Entities would be required to disseminate, to each beneficiary who selected the entity, summary information on negotiated prices, access to such prices through pharmacy networks, and how the formulary functioned. Upon request, entities would be required to provide general coverage, utilization, and grievance information. In addition, entities would be required to have a mechanism for providing specific information upon request. The new Part D provisions relating to pharmacy access would apply to eligible entities. To the extent the Secretary determined they could be implemented on a timely basis, entities would be required to meet the new Part D provisions with respect to development and application of formularies and the requirements to have in place an effective cost and drug utilization management program, quality assurance measures and systems, and a program to control fraud, abuse and waste. Each entity would be required to have in place meaningful procedures for hearing and resolving grievances and for expedited determinations and reconsiderations of coverage determinations. Entities would be required to provide pharmaceutical support services. They would also be required to provide for confidentiality and accuracy of enrollee records and periodic reports to the Secretary.

Entities would be required to provide beneficiaries with access to negotiated prices (including applicable discounts). Such discounts would not be taken into account in establishing ''best price'' for purposes of Medicaid calculations. If the entity used a formulary, negotiated prices would only be available for formulary drugs. Negotiated prices could not be limited to mail order drugs. Entities and contracting pharmacies could not charge beneficiaries for any required services. Entities would be required to disclose to the Secretary the extent to which discounts, or rebates or other remuneration or price concessions made available by a manufacturer were passed through to enrollees; such information would be confidential. Entities would be required to notify enrollees at the time of purchase of the differential between any prescribed drug and the cost of the lowest cost available generic drug that was therapeutically equivalent and bioequivalent.

The Secretary would be required to establish a prescription drug account for each enrolled individual and deposit into the account the federal contribution amount. This amount would be $800 for an accountholder with income under 135% of poverty, $500 for an accountholder with income between 135% and 150% of poverty, and $100 for all other persons. Income would be determined under the state Medicaid program or by the Social Security Administration (SSA). Such sums as may be necessary would be authorized to be appropriated to the SSA. If the program was not in effect for all of 2004, the amounts would be prorated. Persons would not be eligible for a federal contribution if they were eligible for drug coverage under Medicaid, group health plan, Medigap, medical care for members of the uniformed services, Veterans' medical care, Federal Employees Health Benefits program, or the Indian Health Care Improvement Act. The provision would authorize appropriations to the Part B trust fund of an amount equal to the amount by which benefits and administrative costs exceeded the portion of enrollment fees retained by the Secretary.

The provision would establish a new Section 1807A, Prescription Drug Accounts, that would be established for each enrolled beneficiary. Contributions to the account would include federal contributions, any state contributions, private contributions (including employer and individual contributions) and spousal rollover contributions. If the accountholder was married at the time of death, the amount in the account attributable to public contributions would be credited to the account, if any, of the surviving spouse, or if the spouse was not an Part D eligible individual, into a reserve account to be held for when the spouse became an Part D eligible individual.

Costs of the voluntary prescription drug discount card program would not be considered in calculating the Part B premium.

By March 1, 2005, the Administrator would be required to submit a report to Congress on the progress made in implementing the new prescription drug benefit, including specific steps that had been taken, and need to be taken, to ensure timely start of the program on January 1, 2006.

Senate Bill

Section 111 would add a new Section 1807 to the Social Security Act, *Medicare Prescription Drug Discount Card Endorsement Program*. The Secretary would establish a program under which the Secretary would endorse card programs offered by prescription drug card sponsors meeting certain requirements and would make available information on such programs to beneficiaries. Eligible sponsors would be entities with demonstrated experience and expertise in operating a prescription drug discount card program or similar program that the Secretary determined to be appropriate to provide benefits to Medicare beneficiaries. Such entities would include pharmaceutical benefit management companies, wholesale or retail pharmacist delivery systems, insurers, other entities, or any combination of these.

Any individual entitled to Part A and enrolled in Part B would be eligible to enroll in an endorsed prescription drug card program. The Secretary would be required to establish procedures for identifying eligible beneficiaries. The Secretary would also be required to establish procedures under which beneficiaries could make an election to enroll and disenroll in an endorsed card program. A beneficiary could only be enrolled in one endorsed program at a time. Card sponsors could charge annual enrollment fees, not to exceed $25. The fee would be the same for all eligible Medicare beneficiaries enrolled in the program and would be collected by the card sponsor.

The Secretary would provide information, which compared the costs and benefits of various programs. This information dissemination, intended to promote informed choice, would be coordinated with the dissemination of other educational information on other Medicare options. Each card sponsor would make available to each beneficiary (through the Internet or otherwise) information that the Secretary identified as being necessary to provide for informed choice by beneficiaries among endorsed programs; this would include information on enrollment fees, negotiated prices, and services related to drugs offered under the program. The sponsor would have to provide information on how the formulary functioned. The Medicare toll-free number, 1–800–MEDICARE, would be used to receive and respond to inquiries and complaints.

Each endorsed drug card program would have to meet beneficiary protection requirements, including those relating to beneficiary appeals and marketing practices. They would also have to ensure that beneficiaries were not charged more than the lower of the negotiated retail price or the usual and customary price. Each card sponsor would secure the participation of a sufficient number of pharmacies that distributed drugs directly to patients to ensure convenient access (including adequate emergency access) for beneficiaries enrolled in the program. Convenient access would be determined by the Secretary and would take into account reasonable distances to pharmacy services in both urban and rural areas. Each card sponsor would be required to have in place procedures for assuring that quality service was provided to eligible beneficiaries enrolled in a prescription drug discount card program. They would also have to safeguard individually identifiable information in accordance with the Health Insurance Portability and Accountability Act (HIPAA). Sponsors would be prohibited from charging any fees, except for the annual enrollment fee. Card sponsors could not recommend switching an Part D eligible individual to a drug with a higher negotiated price, unless a licensed health professional recommended a switch based on a clinical indication. Negotiated prices could not change more than once every 60 days.

Card sponsors would provide enrolled beneficiaries with access to negotiated prices used by the sponsor for payment for prescription drugs, provided such drugs were not excluded under the program's formulary. The term negotiated price, would include all discounts, direct or indirect subsidies, rebates, price concessions, and direct or indirect remunerations. Medicaid negotiation rules, including rebate requirements, would not apply.

Each card program would be required to provide pharmaceutical support services such as education, counseling, and services to prevent adverse drug interactions. Each card sponsor would issue a discount card to program enrollees.

Sponsors seeking endorsement of a card program would submit required information

to the Secretary. The Secretary would review the information and determine whether to endorse the program. A program could not be approved unless it and the sponsor complied with the requirements of the new Section 1807.

Sponsors could use a formulary. Sponsors electing to use a formulary would be required to establish a pharmaceutical and therapeutic committee (that included at least one academic expert, at least one practicing physician and at least one practicing pharmacist) to develop and review the formulary. The committee would base clinical decisions on the strength of scientific evidence and standards of practice. The formulary would have to include drugs within each therapeutic category and class of covered drugs (as defined by the Secretary) although not necessarily for all drugs within such categories and classes. The committee would establish policies and procedures to educate and inform health care providers concerning the formulary. Drugs could not be removed from the formulary until after appropriate notice had been provided to beneficiaries, physicians, and pharmacies. The Secretary would provide appropriate oversight to ensure compliance of programs; including verification of the negotiated prices and services provided. Each program sponsor would be required to report to the Secretary on program performance, use of drugs by beneficiaries, financial information of the sponsor, and other information required by the Secretary. The Secretary could not disclose any proprietary data that was reported. The Secretary could use Parts A and B claims data for purposes of conducting a drug utilization review program.

Section 111 would add a new Section 1807A to the Social Security Act, *Transitional Prescription Drug Assistance Card Program for Eligible Low-Income Beneficiaries*. The Secretary would award contracts to prescription drug card sponsors, offering a program that was endorsed by the Secretary under the new Section 1807, to offer a prescription drug card assistance program to eligible low-income beneficiaries. The program would begin no later than January 1, 2004. The Secretary would provide for a transition and discontinuation of the drug card program and the low-income assistance card program when the new Part D program became effective. The transitional programs would continue to operate at least 6 months after the date benefits first became available under Part D.

All individuals meeting the definition of QMB, SLMB, or QI–1, or those with income below 135 percent of poverty who were not eligible to receive drug benefits under Medicaid, could receive assistance with their prescription drug costs, effective January 1, 2004. In addition, those determined to have income below 135 percent of poverty could receive assistance with their prescription drug costs. These persons would have access, through a drug discount card, to up to $600 per year. The entire $600 benefit would be available for the entire year; any balance left on the card in one year could be carried forward. Beneficiaries would be subject to cost-sharing requirements, which could not be less than 5% of the negotiated price for a drug, or 10% for a transitional assistance eligible individual. Cost-sharing charges would not count against the $600. At a minimum, card sponsors would provide low-income enrollees with a minimum of a 20% discount from the average wholesale price for each covered drug.

In general, the enrollment procedures established for the drug discount card program would apply for this program. Each sponsor offering an assistance card program would be required to enroll any low-income person wishing to enroll if the program served the geographic area where the beneficiary resides. An individual enrolling in an assistance card program would be simultaneously enrolled in a discount card program offered by the sponsor. Enrollment fees would be waived for these individuals and would instead be paid by the Secretary.

Eligible beneficiaries would have to be provided the information required for the discount card program. In addition, sponsors would be required to notify low-income enrollees, on a periodic basis, of the amount of coverage remaining and on the grievance and appeals process under the program.

Each card sponsor would secure the participation of a sufficient number of pharmacies that distributed drugs directly to patients to ensure convenient access for beneficiaries enrolled in the program. The Secretary would determine whether convenient access was provided; mail order pharmacies would not be included in the determination. Further, the Secretary could not make a determination that convenient access had been provided, unless an appropriate arrangement was in place for low-income persons in long-term care facilities.

The Secretary would be required to establish procedures under which benefits under the assistance card program were coordinated with coverage under a state pharmaceutical assistance program or Medicare+Choice plan.

Drug discount card managers could establish formularies. A low-income enrollee would have the right to appeal to obtain coverage for a drug not on the formulary if the prescribing physician determined that the formulary drug was not as effective for the individual or had adverse effects for the individual. If a plan offered tiered cost-sharing for covered drugs, an enrollee would have the right to request that a nonpreferred drug be treated on terms applicable for a preferred drug if the prescribing physician determined that the preferred drug was not as effective for the individual or had adverse effects for the individual.

Sponsors offering assistance card programs would be required to process claims negotiate with brand name and generic manufacturers and others for price concessions, track individual beneficiary expenditures, and perform other functions specified by the Secretary. Each sponsor would receive data exchanges in a format specified by the Secretary.

Entities would be required to assure that low-income beneficiaries were informed at the time of purchase of any difference between the price of the prescribed drug and the lowest cost generic drug that was therapeutically equivalent and bioequivalent and that was available at the pharmacy or other dispenser. Entities would also be required to have meaningful procedures for hearing and resolving grievances, comparable to those established for Medicare+Choice plans. In addition, eligible entities would be required to meet Medicare+Choice requirements relating to coverage determinations.

Sponsors seeking to offer an assistance program would be required to submit information to the Secretary, in the manner specified by the Secretary. The Secretary could not approve a program unless the sponsor and program met the requirements of the new Section 1807A. Further, the Secretary would have to determine that the entity was appropriate to provide benefits to low-income beneficiaries, was able to manage the monetary assistance provided under the program, agreed to submit to audits by the Secretary, and provided other assurances require by the Secretary. There would be no limit on the number of sponsors who could be awarded contracts. The contract would be for the lifetime of the program and cover the same service area served by the sponsor under the card program under Section 1807. The sponsor could submit an application for endorsement under both programs simultaneously.

The Secretary would pay sponsors the amount agreed to in the contract between the sponsor and the Secretary. Payments would be made from the Part B trust fund but would not be considered in the calculation of the Part B premium.

The Secretary would implement New Sections 1807 and 1807A to assure that discounts and benefits were available no later than January 1, 2004. The Secretary would provide for an appropriate transition and discontinuation of the programs; such transition would ensure that benefits continue to operate until the first Part D enrollment period ended.

Conference Agreement

a. Establishment of Program. The conference agreement adds a new Section 1860D–31 to the Social Security Act, Medicare Prescription Drug Discount Card and Transitional Assistance Program. The Section requires the Secretary to establish a program to endorse prescription drug discount card programs meeting certain requirements. Discount card eligible individuals would receive access to prescription drug discounts through card sponsors throughout the U.S. The program will also provide transitional assistance for low-income persons enrolled in endorsed programs. The program is voluntary for eligible individuals.

The agreement requires the Secretary to implement the program so that discount cards and transitional assistance are available no later than 6 months after enactment. The Secretary is required to promulgate regulations to carry out the program. They could be promulgated on an interim final basis which could be effective on the date of issuance. In the case interim final regulations are promulgated, a public comment period would be provided. The Secretary could change or revise the regulations after conclusion of the comment period.

The conference agreement specifies that the new program would not, except as provided for during an individual's transition period, apply to covered discount card drugs dispensed after December 31, 2005. However, any transitional assistance for low income persons would be available after that date to the extent the assistance was for drugs dispensed on or before that date.

Special rules may apply for an individual in a transition period who is also enrolled under a card program as of December 31, 2005. The transition period to the new Part D is the period beginning January 1, 2006 and ending on the effective date of the individual's coverage under Part D or at the close of the individual's initial enrollment period for Part D. During this period, discounts may continue to apply for drugs dispensed to the individual, no annual enrollment fee would be applicable, the individual could not change the endorsed plan in which they were enrolled, and the balance of any transitional assistance remaining on January 1, 2006 would remain available for drugs dispensed during this period.

b. Eligibility. The conference agreement specifies that persons eligible for the discount card are those entitled to or enrolled under Part A or enrolled under Part B. However individuals enrolled in Medicaid (or under any Section 1115 Medicaid waiver) who are entitled to any medical assistance for outpatient prescribed drugs would not be a discount card eligible individual.

An individual eligible for transitional assistance is a discount card eligible individual, residing in one of the 50 states or the

District of Columbia, whose income is not more than 135% of the official poverty line applicable to the family size involved. Certain persons would not be eligible for transitional assistance. These are persons who had coverage for, or assistance with, covered discount card drugs under: (1) a group health insurance plan or health insurance plan (other than coverage under a plan under Medicare Part C or coverage consisting only of excepted benefits as that term is defined under Section 2791 of the Public Health Service Act); (2) Chapter 55 of the United States Code relating to medical and dental care for members of the uniformed services; and (3) a plan under the Federal employees health benefits program.

Certain transitional eligible assistance eligible individuals may also qualify as special transitional assistance eligible individuals. These are persons with incomes below 100% of the official poverty line.

The Secretary is required to provide for appropriate rules for the treatment of medically needy persons as discount eligible individuals and as transitional assistance eligible individuals.

c. Enrollment. The conference agreement requires the Secretary to establish a process through which a discount card eligible individual is enrolled and disenrolled in a discount card program. An individual not enrolled in a card program may enroll in any card program, serving residents of the state at any time beginning on the initial enrollment date and before January 1, 2006. Completion of a standard enrollment form, specified by the Secretary, is required. Each program sponsor is required to transmit to the Secretary (in a form and manner specified by the Secretary) information on persons completing the enrollment forms. They are also required to provide certain information relating to the certification as a transitional assistance eligible individual.

The conference agreement specifies that a discount eligible individual may only be enrolled in one endorsed card program at a time. An individual enrolled in one program in 2004 could change the election for 2005. The Secretary will establish a process for making this change, which will be similar to, and coordinated with, that established for annual coordinated elections for Medicare+Choice plans under Part C. The agreement requires the Secretary to permit individuals to change programs in which they were enrolled if they changed residence outside the service area of the plan or under other exceptional circumstances. The Secretary is permitted to consider a change in residential setting (such as placement in a nursing facility) as an exceptional circumstance. Also meeting this criteria would be enrollment or disenrollment from a Medicare+Choice plan through which an individual was enrolled in an endorsed program.

An individual could voluntarily disenroll from an endorsed program at any time. Such individual could not enroll under another endorsed program except during the open enrollment period or under the exceptional circumstances specified by the Secretary. An individual, who was not a transitional assistance eligible individual, could be disenrolled by the program sponsor, if the individual failed to pay the annual enrollment fee.

A Medicare+Choice organization or organization operating under a reasonable cost contract that wishes to become a prescription drug card sponsor may elect to limit enrollment in its endorsed discount card program to eligible enrollees enrolled in the plan. If the organization elects this option, its enrollees can only enroll in the endorsed discount card program offered by that sponsor.

A card sponsor may charge an annual enrollment fee, not to exceed $30, for each enrollee. The fee for either 2004 or 2005 could not be prorated. The sponsor will ensure that the annual enrollment fee (if any) is the same for all enrollees residing in the state. The annual enrollment fee is to be collected by the program sponsor. The annual enrollment fee for a transitional assistance eligible individual is to be paid by the Secretary on the individual's behalf.

The Secretary will establish an arrangement under which a state could pay for some, or all, of the enrollment fee for some or all enrollees who are not transitional assistance eligible individuals. The payment would be paid directly by the state to the sponsor. No federal matching payments would be available.

The Secretary will establish special rules for individuals who change, during a year, the endorsed program in which they are enrolled.

Each card sponsor will issue, in a standard format specified by the Secretary, a discount card to each enrollee. The card will establish proof of enrollment. It may be used in a coordinated manner to identify the sponsor, program, and individual. The Secretary will specify the effective date that card enrollees will have access to negotiated prices and transitional assistance, if any.

d. Information. The conference agreement requires the Secretary to provide for activities that broadly disseminate information to discount card eligible individuals and prospective eligible individuals. These persons would receive information on enrollment in endorsed card programs and on the features of the drug discount card and transitional assistance program. In order to promote informed choice, the Secretary will provide for the dissemination of information, which compares the annual enrollment fee and other features of such programs, which could include comparative prices for covered drugs. To the extent practicable, this will be coordinated with the dissemination of educational material on other Medicare options. The required information will also include educational materials on the variability of discounts on covered drugs under an endorsed program. To the extent practicable, the Secretary will ensure the provision of required information at least 30 days prior to the initial enrollment date. The Secretary, through the use of 1–800–MEDICARE, will provide for the receipt and response to inquiries and complaints concerning the discount card program and endorsed programs.

The conference agreement requires each card sponsor to make available to discount card eligible individuals (through the Internet and otherwise) information the Secretary identifies as being necessary to promote informed choice. This includes information on enrollment fees and negotiated prices for covered drugs. Each sponsor is required to have a mechanism (including a toll free number) for providing, on request, specific information to individuals enrolled in the program. Specific information includes information on negotiated prices and the amount of transitional assistance remaining to the individual. The sponsor is required to inform transitional assistance eligible individuals of the availability of such toll-free numbers to provide information on the amount of available assistance to the individual. Information on the balance of transitional assistance available will have to be available at the point-of-sale, either electronically or by telephone.

The conference report requires sponsors to provide that each pharmacy that dispensed a covered discount drug to inform program enrollees of any difference between the price of the drug provided to the enrollee and the price of the lowest priced generic drug covered under the program that is therapeutically equivalent and bioequivalent and available at such pharmacy. The notice is to be provided at the time of purchase, or in the case of a mail order drug, at the time of delivery. The Secretary may waive this requirement under circumstances specified by the Secretary.

e. Discount Card Program. The conference agreement requires each card sponsor to provide each enrollee with access to negotiated prices. These negotiated prices would take into account negotiated price concessions such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations for covered drugs. Negotiated prices include any dispensing fees. Seniors currently benefit from prescription drug assistance programs offered by pharmaceutical companies. Conferees intend that these programs continue to be offered until the full implementation of the prescription drug benefit. Nothing in this conference report shall be interpreted as encouraging the discontinuation or diminution of these benefits.

Each prescription drug card sponsor must secure the participation of a sufficient number of pharmacies that dispense drugs directly to enrollees to ensure convenient access to covered drugs at negotiated prices. This requirement may only be met by entities dispensing drugs other than solely by mail order. Conferees intend for seniors to have access to a bricks and mortar pharmacy. The Secretary will establish convenient access rules that are no less favorable than standards for convenient access to pharmacies applicable under TRICARE. Applicable TRICARE standards are those specified in the statement of work solicitation (#MDA906–03–R–0002) as of March 13, 2003.

A prescription drug card sponsor (and any pharmacy contracting with the sponsor to provide covered discount card drugs) may not charge enrollees for any items and services required to be provided under the program. This prohibition would not apply to the annual enrollment fee for persons who are not transitional assistance eligible individuals or for the charge for the drug (consistent with the negotiated price) reduced by any transitional assistance.

The agreement further provides that negotiated prices will not be taken into account for purposes of making best price calculations under the Medicaid rebate program.

Each endorsed card program is required to implement a system to reduce the likelihood of medication errors and adverse drug interactions and to improve medication use.

f. Eligibility Procedures. The conference agreement requires the Secretary to establish procedures for eligibility determinations for endorsed programs and for those eligible as a transitional assistance eligible individual or a special transitional eligible individual. The Secretary is to define the terms income and family size and specify the methods and period for which they are determined. If such methods provide for use of information for prior time periods, the Secretary is required to permit an individual whose circumstances changed to have eligibility for transitional assistance determined for a more recent period. The Secretary may use a reconsideration process or other method.

An individual wishing to be treated as a transitional assistance eligible individual or special transitional eligible individual could self-certify through a simplified means as to their income, family size, and prescription drug coverage (if any). The certification could also be done by another qualified person, acting on the individual's behalf. The certification could be provided before, on or after the time of enrollment in an endorsed

program. The self-certification would be deemed as consent to have the information verified by the Secretary. A verified self-certification for as a transitional assistance or special transitional assistance eligible individual would be applicable for the entire period of enrollment in any endorsed program.

The Secretary is required to establish verification methods, which could include sampling and use of information on Medicaid eligibility provided by the states, financial information from the Commissioner of Social Security, and financial information from the Secretary of the Treasury. The Secretary could find that an individual met the income requirements for transitional assistance if the individual is within a category of discount card eligible individuals who are enrolled under Medicaid (such as qualified Medicare beneficiaries, specified low-income Medicare beneficiaries, and certain qualified individuals). States will be required, as a condition of Federal Medicaid assistance to provide, on a timely basis, information that allows the Secretary to identify persons eligible for drug coverage under Medicaid, or who are transitional assistance eligible individuals, or special transitional eligible individuals. The Secretary is required to establish a reconsideration process for persons determined not to be transitional eligible or special transitional assistance eligible individuals. The results are to be communicated to the individual and drug card sponsor involved. The Secretary may enter into contracts to perform the reconsideration function.

g. Transitional Assistance. The conference agreement provides special provisions for low-income persons. A transitional assistance eligible individual will be entitled to have his or her discount card enrollment fee paid. Those individuals with incomes below 100% of poverty (special transitional assistance eligible individuals) would be liable for coinsurance charges of 5% of incurred costs up to $600 in both 2004 and 2005. Other transitional assistance eligible individuals (those with incomes between 100% and 135% of poverty) would be liable for coinsurance charges of 10% of incurred costs up to $600 in both 2004 and 2005. Thus, the program will pay 95% of a special transitional eligible individual's incurred drug costs up to $600 in 2004 and 90% of other transitional eligible individual's incurred drug costs up to $600 in 2004. Similarly, payment would be made for 95% or 90%, whichever is appropriate, of the individual's incurred drug costs up to $600 in 2005. In addition, any balance left over from 2004 may be added to the amount available in 2005, except no rollover would be permitted if the individual voluntarily disenrolled from an endorsed plan. No funds will be available under this program for covered discount card drugs dispensed after December 31, 2005. The Secretary will provide a method for the reimbursement of card sponsors for transitional assistance.

The $600 annual amount is to be prorated in 2004, for persons not enrolling in an endorsed program and providing self-certification prior to the program's initial implementation date. For 2005, the amount is to be prorated for persons not enrolling in an endorsed program and providing self-certification prior to February 1, 2005.

The conference agreement permits a pharmacy to reduce the coinsurance otherwise applicable. It also permits states to pay some or all of the coinsurance for some or all transitional assistance eligible enrollees. The payment would be made directly by the state to the pharmacy. No federal matching payments would be available for these costs; further they could not be considered as Medicare cost-sharing for purposes of the qualified Medicare beneficiary program.

The conference agreement includes provisions to ensure access to transitional assistance for qualified residents of long-tem care facilities and American Indians. It requires the Secretary to establish procedures to ensure such access for qualified residents of long-term care facilities. The Secretary could waive requirements of the new Section 1860D–31, as necessary, to negotiate arrangements with sponsors to provide arrangements with pharmacies that support long-term care facilities. The Secretary is also required to establish procedures to ensure that pharmacies operated by the Indian Health Service, Indian tribes and tribal organizations, and urban Indian organizations have the opportunity to participate in the pharmacy networks of at least two endorsed programs in each of the 50 states and the District of Columbia where such a pharmacy operates. Where necessary, the Secretary could waive requirements of the new Section 1860D–31.

The availability of negotiated prices or transitional assistance could not be taken into account in determining an individual's eligibility for or benefits under any other Federal program. Any nonuniformity of benefits resulting from the implementation of the new Section 1807 (such as the waiver of an enrollment fee) would not be taken into account in calculations of any required additional benefits under Part C.

h. Qualifications for Card Sponsors. The conference agreement defines entities eligible to be card sponsors and establishes criteria that such entities would have to meet. The agreement specifies that a card sponsor could be any nongovernmental entity that the Secretary determines is appropriate to offer an endorsed discount card program. An entity which could qualify includes a pharmaceutical benefit management company, a wholesale or retail pharmacy delivery system, an insurer (including one that offered Medigap policies), an organization under Part C, or any combination of these. Each program would have to be operated directly, or through arrangements with an affiliated organization (or organizations), by one or more organizations with demonstrated experience and expertise in operating such a program. Further, the program would have to meet business stability and integrity requirements specified by the Secretary. The sponsor will be required to have arrangements, satisfactory to the Secretary, to account for transitional assistance provided to eligible individuals.

The conference agreement requires each sponsor seeking endorsement to submit an application to the Secretary. The Secretary would review the application and determine whether to endorse the program. The Secretary could not endorse the program unless the program and sponsor comply with the applicable requirements of the new Section 1860D–31 and the sponsor enters into a contract with the Secretary to carry out such requirements. An endorsement would be for the duration of the discount card and transitional assistance program. The Secretary could make an exception for cause.

The conference agreement requires the Secretary to ensure that at least 2 endorsed programs (each offered by a different sponsor) are available to each eligible individual. The

Secretary may limit (but not below 2) the number of sponsors in a state that were awarded contracts.

Card sponsors enrolling individuals in any part of a state would be required to permit eligible individuals in all parts of the state to enroll. An exception would apply in the case of a Medicare+Choice organization, which elects to limit enrollment in its endorsed discount card program to eligible enrollees enrolled in its Medicare+Choice plan.

Each prescription drug card sponsor will be required to pass on to discount eligible enrollees the negotiated prices for covered drugs, including discounts negotiated with pharmacies and manufacturers, to the extent such discounts are disclosed under required disclosure rules. Each card sponsor will be required to provide meaningful procedures for hearing and resolving grievances between the sponsor and enrollees in a manner similar to that required for Medicare+Choice. The operations of an endorsed card program are covered functions and a card sponsor is a covered entity for purposes of applying the administrative simplification provisions established in Part C of Title XI of the Social Security Act. Included are regulations promulgated under that Part including privacy regulations. The Secretary could waive the relevant portions of privacy regulations for an appropriate limited period of time in order to promote participation of sponsors.

The sponsor of an endorsed card program may not provide or market services under the program except if the product or service is directly related to a covered discount card drug or a discount price for a nonprescription drug. Sponsors will also be required to meet additional requirements as the Secretary identifies are needed to ensure that enrollees are not charged more than the lower of the negotiated price or the usual and customary price.

Special rules apply to Medicare+Choice organizations or organizations offering enrollment under a reasonable cost contract. An organization could elect to limit enrollment in its endorsed discount card program to eligible enrollees enrolled in its plan. In this case, special rules would apply. The sponsor could not enroll individuals not enrolled in the plan. The pharmacy access requirements applicable to card sponsors would be deemed to be met if access is made available through a pharmacy network (and not only through mail order) and the network is approved by the Secretary. The Secretary could waive requirements applicable to card sponsors to the extent he determined they were duplicative or conflicted with a Medicare+Choice or cost contract requirement or were necessary in order to improve coordination of the card program with Medicare+Choice or cost contract benefits.

Each card sponsor will be required to disclose to the Secretary information relating to: (1) program performance; (2) use of drugs by card program enrollees; (3) extent to which negotiated price concessions made available by the manufacturer are passed through to enrollees through pharmacies or otherwise; and (4) other information specified by the Secretary. The Medicaid provision providing for the confidentiality of drug information will apply to any drug pricing information (other than aggregate data) disclosed under these requirements.

The Secretary will provide appropriate oversight to ensure compliance of card programs and sponsors with the requirements of the new Section 1860D–31. The Secretary would have the right to audit and inspect any books and records of sponsors (and any affiliated organization) that pertain to the card program, including amounts payable to the sponsor. The Secretary could impose sanctions for abusive practices.

i. Territories. The conference agreement provides federal assistance to territories, which establish a plan to provide transitional assistance for covered discount drugs to some or all eligible persons residing in the state. Eligible persons are those entitled to benefits under Part A or enrolled in Part B with incomes below 135% of the poverty line. The total amount of available federal assistance is $35 million. The amount available for each territory would be determined using the

ratio of the total number of Medicare residents in the territory to Medicare residents in all the territories.

j. Funding. The conference agreement creates a separate Transitional Assistance Account in the Part B Trust Fund. Funds in this account are to be kept separate from other funds within the Trust fund. Payments are to be made from the Account in such amounts as the Secretary certifies are necessary to make payments for transitional assistance. Appropriations are to be made to the Account equal to the amount of payments from the Account. Such sums as are necessary would be authorized to be appropriated for the Secretary's administrative expenses. Payments could not be made to sponsors for administrative expenses, except for payment of the enrollment fee for transitional eligible individuals. Costs associated with the Medicare prescription drug card and the transitional assistance program would be excluded from the calculation of the Part B premium.

Definitions; Treatment of References to Provisions in Part C (New Section 1860D–41 of Conference agreement; *New Section 1860D–10 of House bill;* New Sections 1860D, 1860D–26 and Section 110 of Senate bill).

House Bill

New Section 1860D–10 would provide cross-references to other sections of the bill for definitions of covered outpatient drugs, initial coverage limit, Medicare Prescription Drug Trust Fund, PDP sponsor, qualified prescription drug coverage, and standard coverage. It would define a prescription drug plan as health benefits coverage that: (1) is offered under a policy, contract, or plan by a PDP sponsor pursuant to and in accordance with a contract between the Administrator and the sponsor; (2) provides qualified prescription drug coverage; and (3) meets the applicable beneficiary protection requirements. It would specify that the term ''insurance risk'' would, for a participating pharmacy, mean the type commonly assumed only by insurers licensed by a state and not payment variations designed to reflect performance-based measures of activities within control of the pharmacy, such as formulary compliance and generic drug substitution. The section would further provide that any reduction or waiver of cost-sharing would not be in violation of kickback and similar prohibitions.

MA and EFFS plans would be required to offer drug plans pursuant to the requirements of Sections 1851 and New Section 1860e–2(d). The provision would specify that Part C requirements relating to a drug plan or sponsor would be applied (unless otherwise specified) as if: (1) any reference to a MA or other plan included a reference to a prescription drug plan; (2) any reference to a provider-sponsored organization included a reference to a PDP sponsor; (3) any reference to a contract included a reference to a drug plan contract; and (4) any reference to Part C included a reference to Part D.

Senate Bill

New Section 1860 D would define a number of terms used in the bill. The ''Administrator'' would be defined as the Administrator of the new Center for Medicare Choices established under the bill.

A ''Part D eligible individual'' would be an individual entitled to, or enrolled for, benefits under Part A and enrolled in Part B. An ''eligible entity'' would be any risk bearing entity that the Administrator determined to be appropriate to provide eligible beneficiaries with benefits under a Medicare Prescription Drug Plan. Eligible entities would include pharmaceutical benefit management companies, wholesale or retail pharmacist delivery systems, insurers (including insurers that offered Medigap policies), other risk bearing entities, or any combination of these. This requirement would not preclude State pharmacy assistance programs from becoming a qualified entity if they meet the requirements.

A ''Medicare Prescription Drug Plan'' would offer prescription drug coverage under a policy, contract or plan by an eligible entity pursuant to and in accordance with a contract between the Administrator and the entity. The plan would have to be approved by the Administrator.

The provision would specify that Part C requirements relating to MedicareAdvantage would be applied (unless otherwise specified) as if: (1) any reference to a MedicareAdvantage plan included a reference to a Medicare Prescription Drug plan; (2) any reference to a provider-sponsored organization included a reference to an eligible entity; (3) any reference to a contract included a reference to a drug plan contract; and (4) any reference to Part C included a reference to Part D.

The provision would permit sponsors of employment-based retiree coverage that offer a prescription drug plan to restrict enrollment in the plan to eligible beneficiaries enrolled in such coverage. Sponsors could not offer enrollment in a Medicare Prescription Drug plan based on the health status of beneficiaries.

Entities offering a Medicare Prescription Drug plan or a MedicareAdvantage organization offering a MedicareAdvantage plan could enter into an agreement with a state pharmaceutical assistance program (including one established under a Section 115 waiver) to coordinate coverage.

Conference Agreement

New Section 1860D–41 provides cross references to other sections of the bill for definitions of basic prescription drug coverage, covered Part D drugs, creditable prescription drug coverage, Part D eligible individual, fallback prescription drug plan, initial coverage limit, MA plan, MA–PD plan, Medicare Prescription Drug Account, PDP approved bid, PDP region, qualified prescription drug coverage, standard prescription drug coverage, state pharmaceutical assistance program; and subsidy-Part D eligible individual. It defines the term ''insurance risk'' as meaning for a participating pharmacy, risk of the type commonly assumed only by insurers licensed by a state and does not include payment variations designed to reflect performance-based measures of activities within control of the pharmacy, such as formulary compliance and generic drug substitution. A PDP sponsor is defined as a non-governmental agency that is certified under Part D as meeting Part D requirements and standards. A prescription drug plan is defined as prescription drug coverage that: is offered (1) under a policy, contract, or plan that has been approved under Part D; and (2) by a PDP sponsor pursuant to and in accordance with a contract between the Secretary and the sponsor under Part D.

The provision specifies that Part C requirements are to be applied (unless otherwise specified) as if: (1) any reference to a MA plan included a reference to a prescription drug plan; (2) any reference to a provider-sponsored organization included a reference to a PDP sponsor; (3) any reference to a contract included a reference to a drug plan contract; (4) any reference to Part C included a reference to Part D; and (5) any reference to a Part C election period is a reference to a Part D enrollment period.

Miscellaneous Provisions (New Section 1860D–42 of conference agreement; New Section 1860D–16 of House bill; Section 1860D–26 of Senate bill).

Present Law

No provision.

House Bill

The Secretary would be required to submit a legislative proposal within six months of enactment containing necessary technical and conforming amendments. Not later than January 1, 2005, the Administrator would be required to submit a report containing recommendations for providing benefits under Part D for drugs currently paid for under Part B.

Senate Bill

New Section 1860D–26 would require the Secretary, within six months of enactment, to submit a legislative proposal for any necessary technical and conforming amendments.

Conference Agreement

The agreement includes miscellaneous provisions. It permits the Secretary to waive Part D requirements, including the requirement for two plans in an area, insofar as the Secretary determines it necessary to secure access to qualified drug coverage in the territories.

The agreement requires the Secretary to submit a legislative proposal within six months of enactment containing necessary technical and conforming amendments to titles I and II of the bill. Not later than January 1, 2005, the Secretary is required to submit a report to Congress containing recommendations for providing benefits under Part D for drugs currently paid for under Part B. By March 1, 2005, the Secretary is required to submit a report to Congress on the progress made in implementing the drug benefit. The report will include specific steps taken, and that need to be taken, to ensure a timely start on January 1, 2006. The report is to include recommendations regarding an appropriate transition form the discount card and transitional assistance program.

Medicare Advantage Conforming Amendments (Section 102 of Conference agreement; Section 231 of House bill; Sections 201 and 204 of Senate bill).

Present Law

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, P.L. 107–188, made temporary changes to reporting dates and deadlines. First, CMS moved its annual announcement of M+C payment rates from no later than March 1 to no later than the 2nd Monday in May, effective only in 2003 and 2004. It also temporarily moved the deadline for plans to submit information about ACRs, M+C premiums, cost sharing, and additional benefits (if any) from no later than July 1 to no later than the 2nd Monday in September in 2002, 2003, and 2004. It also changed the annual coordinated election period from the month of November to November 15th through December 31 in 2002, 2003, and 2004. Once the temporary provision expires, the reporting dates and deadlines would return to the pre-P.L. 107–188 dates.

In addition, P.L. 107–188 will continue to allow Medicare beneficiaries to make and change election to an M+C plan on an ongoing basis through 2004. Then beginning in 2005, individuals will only be able to make changes on the more limited basis, originally scheduled to be phased in beginning in 2002. Beneficiaries can make or change elections during the annual coordinated election period. Current Medicare beneficiaries may also change their election at any time during the first 6 months of 2005 (or first 3 months of any subsequent year). Additionally, there are special enrollment rules for newly eligible aged beneficiaries as well as special enrollment periods for all enrollees under limited situations, such as an enrollee who changes place of residence.

The Secretary must provide information to Medicare beneficiaries and prospective beneficiaries on the coverage options provided under the M+C program, including open season notification, a list of plans and other general information.

House Bill

The reporting deadline for ACRs and other information would permanently move to July 1 of each year. The annual coordinated election period would be permanently changed to November 15 through December 31. The announcement of payment rates, including rates for EFFS plans, would be permanently moved to no later than the second Monday in May.

In addition to the information dissemination required under current law, the Secretary would be required to provide beneficiaries with a list of plans that are or would be available in an area, to the extent the information was available at the time the materials were prepared for mailing.

Senate Bill

Each MA organization would be required to submit information by the second Monday in September, including: (1) notice of intent and information on the service area of the plan; (2) the plan type for each plan; (3) specific information for coordinated care and PFFS plans; (4) enrollment capacity; (5) the expected mix of enrollees, by health status; and (6) other information specified by the Secretary.

Medicare beneficiaries would retain their ability to make and change elections to a Medicare+Choice plan through 2005. The current law limitation on changing elections that begins in 2005, would be delayed until 2006. Further, the annual coordinated election period for 2003 through 2006 would begin on November 15 and end on December 31. Beginning in 2007, the annual coordinated election period would be during the month of November.

In addition to the information dissemination required under current law, the Secretary would be required to provide: (1) the MA monthly basic beneficiary premium; (2) the monthly beneficiary premium for any enhanced medical benefits; (3) the MA monthly beneficiary obligation for qualified prescription drug coverage; (4) the catastrophic coverage amount (including the maximum limitation on out-of-pocket expenses) and unified deductible for the plan; (5) the outpatient prescription drug coverage benefits; (6) any beneficiary cost-sharing, including information on the unified deductible; (7) comparative information relating to prescription drug coverage; (8) if applicable, any reduction in the Medicare Part B premium; (9) whether the MA monthly premium for enhanced benefits was optional or mandatory; and (10) quality and performance indicators for prescription drug coverage, including a comparison with FFS Medicare.

Additionally, the Secretary would conduct a special information campaign to inform MA eligible beneficiaries about plans. The campaign would begin on November 15, 2005 and ending on December 31, 2005.

Conference Agreement

The conference agreement allows Medicare beneficiaries to retain their ability to make and change elections to a Medicare+Choice plan through 2006. The current law limitation on changing elections that begins in 2005, is delayed until 2006. Further, the annual coordinated election period for 2004 and 2005 begins on November 15 and ends on December 31. For 2006, the annual coordinated election period begins on November 15 and ends on May 15, 2006. Beginning in 2007, the annual coordinated election period will begin on November 15 and end on December 31.

The Secretary is to provide for an education and publicity campaign to inform MA eligible individuals about the availability of MA plans, including MA–PD plans, offered in different areas and the election process for MA plans. If any portion of an individual's initial enrollment period for Part B occurs after the end of the annual coordinated election period, their initial enrollment period would be extended through the end of their Part B initial enrollment period.

The conference agreement will limit an individual's right to change MA plans, for plan years beginning on or after January 1, 2006. This limit will not affect an individual's opportunity to make changes during the annual coordinated election period, but it will limit changes during the continuous open enrollment and disenrollment periods in a year. Individuals enrolled in an MA plan that provides qualified prescription drug coverage, may only disenroll from their plan to get coverage through FFS Medicare or through another MA plan that does not provide qualified prescription drug coverage. They may not leave their plan to obtain coverage under an MA–PD plan or under a prescription drug plan under Part D. Conversely, individuals enrolled in an MA–PD plan, may only change to another MA–PD plan or they may get coverage under FFS Medicare with coverage under a drug plan under part D. They may not enroll in an MA plan if it does not provide qualified prescription drug coverage.

An MA–PD plan could provide for a separate or differential payment for a participating physician who prescribes covered part D drugs in accordance with an electronic prescription program meeting Part D requirements. Such payment could take into consideration the implementation costs for the physician and could also be increased for those participating physicians who significantly increased: (1) formulary compliance; (2) lower cost and therapeutically equivalent alternatives; (3) reductions in adverse drug interactions; and (4) efficiencies in filing prescriptions through reduced administrative costs. Additional or increased payment could be structured in the same manner as medication therapy management fees under section 1869(D)–4(c)(2)(E).

An MA eligible individual could elect qualified prescription drug coverage in accordance with Section 1860D–1.

Medicaid Amendments (Section 103 of Conference agreement; Section 103 of House bill; Section 104 of Senate Bill).

Present Law

Some low-income aged and disabled Medicare beneficiaries are also eligible for full or partial coverage under Medicaid. Within broad federal guidelines, each state sets its own eligibility criteria, including income eligibility standards. Persons meeting the state standards are entitled to full coverage under Medicaid. Persons entitled to full Medicaid protection generally have all of their health care expenses met by a combination of Medicare and Medicaid. For these ''dual eligibles'' Medicare pays first for services both programs cover. Medicaid picks up Medicare cost-sharing charges and provides protection against the costs of services generally not covered by Medicare, including prescription drugs. State Medicaid programs have the option to include prescription drugs in their Medicaid benefit packages. All states include drugs for at least some of their Medicaid beneficiaries and many offer it to all program recipients entitled to full Medicaid benefits.

As noted earlier, Federal law specifies several population groups that are entitled to more limited Medicaid protection. These are qualified Medicare beneficiaries (QMBs), specified low income beneficiaries (SLIMBs), and certain qualified individuals (QI–1s). Assistance under the QI–1 program, originally available for the period January 1, 1998 to December 31, 2002, has been extended to March 31, 2004.

States make eligibility determinations for their Medicaid populations. Federal matching payments for Medicaid services in the territories is subject to an annual cap.

Current Medicaid law requires manufacturers to pay state Medicaid programs a basic rebate for single source and innovator multiple source drugs. Basic rebates are calculated by comparing the average manufacturer price for a drug (the average price paid by wholesalers) to the ''best price,'' which is the lowest price offered by the manufacturer in the same period to any wholesaler, retailer, nonprofit, or public agency. For purposes of determining Medicaid rebates, prices paid by a number of federal and state entities are excluded from the definition of ''best price.''

House Bill

Section 103 would add a new Section 1935 to the Social Security Act entitled ''Special Provisions Relating to Medicare Prescription Drug Benefit.'' The provision would require states, as a condition of receiving federal Medicaid assistance, to make eligibility determinations for low-income premium and cost-sharing subsidies, inform the Administrator of cases where eligibility has been established, and otherwise provide the Administrator with information that may be needed to carry out Part D. The provision would provide for the phased-in federal assumption of associated administrative costs. In 2005, the federal matching rate would be increased by 6⅔ percent and in 2006 by 13⅓ percent. In each subsequent year, the percent would be increased by 6⅔ percentage points (but in no case could the rate exceed 100 percent). Beginning in 2019, the federal matching rate would be 100 percent. The state would be required to provide the Administrator with the appropriate information needed to properly allocate administrative expenditures that could be made for similar eligibility determinations.

The provision would provide for the federal phase-in of the costs of premiums and cost-sharing subsidies for dual eligibles (i.e. persons eligible for Medicare and full Medicaid benefits, including drugs). Over the 2006–2020 period, the federal matching rate for these costs would be increased to cover 100% of what would otherwise be state costs. States would be required to maintain Medicaid benefits as a wrap around to Medicare benefits for dual eligibles; states could require that these persons elect Part D drug coverage.

Residents of territories would not be eligible for regular low-income subsidies. However, territories would be able to get additional Medicaid funds, beginning at $25 million in 2006 and increasing in subsequent years by the annual percentage increase in prescription drug costs for Medicare beneficiaries. In order to obtain these funds, territories would be required to formulate a plan on how they would dedicate the funds to assist low-income Medicare beneficiaries in obtaining covered outpatient prescription drugs. The Administrator would be required to report to Congress on the application of the law in the territories.

Senate Bill

Section 104 would add a new Section 1935 to the Social Security Act entitled ''Special Provisions Relating to Medicare Prescription Drug Benefit.'' The provision would require states to make low-income eligibility determinations for low income subsidies. States would be required, for purposes of the transitional prescription drug card assistance program, to establish eligibility standards consistent with that program; establish

procedures for providing presumptive eligibility determinations (similar to that which currently apply for low-income pregnant women and children); make eligibility determinations for the card program; and communicate to the Secretary information on eligibility determinations or discontinuations. For purposes of the low-income subsidies for the new Part D program, states would be required, beginning November 2005, to make eligibility determinations; inform the Administrator of cases where eligibility was established, and otherwise provide the Administrator with any information required to carry out Part D. States would be required to enter agreements with the Commissioner of Social Security to use all social security field offices in the state as information and enrollment sites for making eligibility determinations. As part of the eligibility determination process, states would also be required to screen for eligibility for Medicare cost-sharing assistance under the QMB, SLIMB, and QI–1 programs.

The federal government would pay an enhanced matching rate for administrative costs associated with making eligibility determinations. The rate would be 75% for the period January 1, 2004–September 30, 2005, 70% for fiscal year 2006, 65% for FY 2007, and 60% beginning in FY 2008. Beginning November 1, 2005, the rate would be 100% for purposes of making eligibility determinations for low-income subsidies.

In addition, states would be entitled to enhanced matching for the costs associated with designing, developing, acquiring and installing improved eligibility determination systems, including hardware and software, for low-income subsidy programs. The enhanced rate would be 90% for fiscal years 2004, 2005, and 2006. The systems would be required to comply with any standards established by the Secretary for improved eligibility systems. Further, the systems would have to be compatible with the standards established under the administrative simplification provisions of Title XI of the Social Security Act.

Medicaid beneficiaries who were eligible for drug benefits under their state Medicaid program would remain in Medicaid. Beginning January 1, 2006, states agreeing to provide a drug benefit to their dual eligible population that was at least equivalent to minimum standards would be relieved of their responsibility to pay Medicare Part B premiums for persons with incomes between the level established for the supplemental security income program and 100% of the federal poverty level. The minimum standards would be defined as follows. A state would be required to meet all current law coverage standards for dual eligibles under Medicaid, including nominal cost-sharing requirements. States would have to provide beneficiary protections equivalent to those provided under Part D. States could not place a limit on the number of prescriptions for dual eligibles. States would be permitted to cover smoking cessation drugs for this population group.

If on the date of enactment, a state provided medical assistance to aged and disabled persons up to 100% of poverty, it would be entitled to have the federal government assume the costs for Medicare Part A cost-sharing. The Part A costs would be assumed so long as the state maintained the expanded coverage. The provision would apply effective January 1, 2006.

Residents of Puerto Rico and the territories would not be eligible for low-income subsidies. Instead, if they chose to provide assistance to their low-income residents they would receive an increase in amounts otherwise paid to them under Medicaid. The aggregate amount available would be $37.5 million for the last 3 quarters of FY2006, and $50 million for FY2007. In subsequent fiscal years, the aggregate amount would be the amount available the previous year, increased by the percentage increase in prescription drug spending.

The provision would extend the QI–1 program through December 2008 with total annual allocations of $400 million through fiscal year 2008 and $100 million for the first quarter of fiscal 2009.

The provision would expand outreach requirements for the Commissioner of Social Security to include outreach activities for low-income subsidy individuals. By January 1, 2005, the Secretary would submit a report to Congress to recommend a voluntary option for dual eligibles to enroll in Part D drug plans.

The provision would exempt negotiated prices by any qualified plan offering Medicare drug coverage from the calculation of Medicaid ''best price.''

Conference Agreement

The conference agreement would add a new Section 1935 to the Social Security Act entitled ''Special Provisions Relating to Medicare Prescription Drug Benefit.'' The provision establishes certain requirements, as a condition of receiving federal Medicaid assistance. States are required to provide the Secretary with Medicaid eligibility information necessary to carry out transitional prescription drug assistance verification. They are required to make eligibility determinations for low-income premium and cost-sharing subsidies, inform the Secretary of cases where eligibility has been established, and otherwise provide the Secretary with information that may be needed to carry out Part D. Further, as part of the eligibility determination process, states are required to make determinations for Medicare cost-sharing assistance. Regular federal matching applies to these activities.

The agreement provides for the federal phase-in of the costs of premiums and cost-sharing subsidies for dual eligibles (i.e., persons eligible for Medicare and full Medicaid benefits, including drugs). The agreement provides for a phased-down state contribution. For each month beginning in 2006, each state is required to provide for payment to the Secretary equal to the product of: (1) 1/12 of the product of the base year state Medicaid per capita expenditures for full-benefit dual eligibles and the state matching rate, and updated to the year involved by the applicable growth factor; (2) the total number of dual eligibles for such state for the month; and (3) the factor for the month. The base year is defined as the weighted average of gross Medicaid expenditures (including dispensing fees) for prescription drugs in 2003 and the estimated actuarial value of prescription drug benefits provided under a capitated care plan for full benefit dual eligibles in that year. The applicable growth factor in 2004, 2005, and 2006 is the average annual percent change in the per capita amount of prescription drug expenditures as determined based on the most recent National Health Expenditure projections. In subsequent years, the growth factor is the annual percentage increase average per capita expenditures under Part D. The factor under #3 is 90% in 2006, phasing down to 75% over 10 years. The Secretary is required to notify each state by October 15 of the amount computed under the formula for the following year, beginning in 2006. A state's failure to make required payments would result in interest charges and in an offset to amounts otherwise payable under Medicaid.

The agreement requires the Secretary when determining gross expenditures for 2003 to: (1) use data from the Medicaid Statistical Information System (MSIS) and other available data; (2) exclude expenditures for drugs that are not covered Part D drugs, and (3) reduce the portion of expenditures not attributable to dispensing fees by an adjustment ratio applied to such portion. The adjustment ratio for a state is equal to 1 minus the ratio in 2003 of aggregate payments under rebate agreements under section 1927 to gross expenditures under Medicaid for covered outpatient drugs.

The agreement specifies that Medicare is the primary payer for covered drugs for dual eligibles. Medicaid coverage is not available for such drugs or any cost-sharing for such drugs. States may provide coverage for drugs, other than Part D covered drugs in the manner otherwise provided for non-full benefit dual eligibles or through an arrangement with the prescription drug plan of MA–PD plan.

Residents of territories would not be eligible for regular low-income subsidies. However, territories would be able to apply for additional Medicaid funds. The total amount available is $28.125 million beginning in the last 3 quarters of 2006, $37.5 million in 2007 and increasing in subsequent years by the annual percentage increase in prescription drug costs for Medicare beneficiaries. In order to obtain these funds, territories would be required to provide assurances that additional funds would be used covered drugs and administrative costs (with no more than 10 percent of the total used for administrative expenses.) The Secretary is required to report to Congress on the application of the provision in the territories.

The agreement exempts prices negotiated from manufacturers for discount card drugs under an endorsement card program and prices negotiated by a prescription drug plan under Part D, a MA–PD plan or a qualified retiree prescription plan from the calculation of Medicaid ''best price.''

The agreement extends the QI–1 program through September 30, 2004. It expands outreach requirements for the Commissioner of Social Security to include outreach activities for transitional assistance and low-income subsidy individuals.

Medigap Amendments (Section 104 of Conference agreement; Section 104 of House bill; Section 103 of Senate bill).

Present Law

Most beneficiaries have some health insurance coverage in addition to basic Medicare benefits. Some individuals obtain private supplementary coverage through an individually-purchased policy, commonly referred to as a ''Medigap'' policy. Beneficiaries with Medigap insurance typically have coverage for Medicare's deductibles and coinsurance; they may also have coverage for some items and services not covered by Medicare. Individuals generally select from one of 10 standardized plans, though not all 10 plans are offered in all states. The 10 plans are known as Plans A through Plan J. Plan A covers a basic package of benefits. Each of the other nine plans includes the basic benefits plus a different combination of additional benefits. Plan J is the most comprehensive. Plans H, I, and J offer some drug coverage.

The law provided for the development by the National Association of Insurance Commissioners (NAIC) of standardized benefit packages. It also provides for modifications of such packages when Medicare benefit changes are enacted.

All insurers offering Medigap policies are required to offer open enrollment for 6 months from the date a person first enrolls in Medicare Part B (generally when the enrollee turns 65). The law also guarantees issuance of specified Medigap policies for certain persons whose previous supplementary coverage was terminated. Guaranteed issue also applies to certain persons who

elect to try out a managed care option under the Medicare+Choice plan program.

Medicare beneficiaries buy supplemental coverage to help pay for health care costs not covered by Medicare. Almost one-quarter (24 percent) of Medicare beneficiaries purchase this coverage as individuals through the private insurance ''Medigap'' market. In 1990, Congress mandated the creation of 10 standardized Medigap policies through the National Association of Insurance Commissioners (NAIC). All 10 plans are required to cover beneficiaries' coinsurance—some of the costs of Medicare services for which beneficiaries are responsible, such as 20 percent of the costs of a physician visit. Nine out of 10 of those policies, which comprise more than 90 percent of the Medigap market, are required to cover the Part A inpatient hospital deductible, and the most popular Medigap policy covers both the Part A hospital deductible and the $100 Part B deductible for physician services. Insulating beneficiaries from this cost sharing incentives over utilization of health services.

Numerous studies have demonstrated that covering deductibles and coinsurance has led to higher Medicare spending because beneficiaries become insensitive to costs. Beneficiaries with Medigap consume $1,400 more in Medicare services than beneficiaries without supplemental coverage, and $500 more than beneficiaries with employer-sponsored insurance. This higher utilization drives up costs for everyone—premiums of Medicare beneficiaries without Medigap coverage and costs to taxpayers.

In addition, only the three most expensive Medigap plans cover prescription drugs, and that coverage is limited. Yet, 8 of the 10 plans are required to cover foreign travel insurance, while most beneficiaries never leave their home country.

And despite standardization, premiums continue to increase and vary widely. From 1998 to 2000, average premiums rose 16 percent for plans without drug coverage, and more than twice as fast, 37 percent, for plans with drug coverage. In addition, premiums vary dramatically for identical plans in the same location. Weiss Ratings, Inc. analyzed Medigap premiums in 2001. A 65-year old man living in Ft. Myers, Florida would pay about $3,600 for Plan J from Physicians Mutual Insurance Company, but only $2,700 with United Healthcare Insurance Company through AARP. The same gentleman living in Las Vegas would spend about $1,500 for Plan C with United American Insurance Company, but about half that amount—$778 B with the USAA Life Insurance Company for the same policy.

All of these factors lead conferees to believe Medigap policies should be restructured in light of changes to the marketplace since standardization. Conferees encourage the National Association of Insurance Commissioners (NAIC) to modernize the Medigap market by reforming first dollar coverage requirements that drive over utilization of services and premiums. Conferees believe that in developing the two new policies included in the conference report, NAIC should consider much broader changes to the Medigap market that will effectuate reduced premiums and more rational coverage policies that create incentives for appropriate utilization of services.

House Bill

The provision would prohibit, effective January 1, 2006, the issuance of new Medigap policies with prescription drug coverage. The prohibition would not apply to policies replacing another policy with drug coverage. Beneficiaries could keep their existing policies. Further, it would not apply to policies meeting new standards, as outlined below.

The provision would guarantee issuance of a substitute Medigap policy for persons, enrolling in Part D, who at the time of such enrollment were enrolled in and terminated enrollment in a Medigap policy H, I, or J. The guaranteed enrollment would be for any of the Plans A through Plan G. The guarantee would apply for enrollments occurring in the new Medigap plan within 63 days of termination of enrollment in a Medigap drug Plan H, I, or J. The insurer could not impose an exclusion based on a pre-existing condition for such individuals. Further, the insurer would be prohibited from discriminating in the pricing of such policy on the basis of the individual's health status, claims experience, receipt of health care or medical condition.

The provision would provide for the development by the NAIC of two new standardized Medigap plans and would outline the standards for these policies. The first new policy would have the following benefits (notwithstanding other provisions of law relating to core benefits): (1) coverage of 50% of the cost-sharing otherwise applicable (except coverage of 100% cost-sharing applicable for preventive benefits); (2) no coverage of the Part B deductible; (3) coverage of all hospital coinsurance for long stays (as in current core package); and (4) a limitation on annual out-of-pocket costs of $4,000 in 2006 (increased in future years by an appropriate inflation adjustment as specified by the Secretary). The second new policy would have the same benefit structure as the first new policy, except that: (1) coverage would be provided for 75%, rather than 50%, of cost-sharing otherwise applicable; and (2) the limitation on out-of-pocket costs would be $2,000, rather than $4,000. Both policies could provide for coverage of Part D cost-sharing; however, neither policy could cover the Part D deductible.

Senate Bill

Effective January 1, 2006, Medigap drug policies could not be sold, issued or renewed for Part D enrollees. Persons who had such policies could obtain Medigap coverage without drug benefits. Beneficiaries who sought to enroll during the Part D open enrollment period established for current beneficiaries would be guaranteed issuance of such non-drug policies (without an exclusion based on preexisting conditions). Medigap issuers would be required to notify individuals of these changes 60 days prior to the Part D open enrollment period.

Medigap insurers could not be required to participate as an eligible entity under the new Part D.

Conference agreement

The agreement prohibits, effective January 1, 2006, the selling, issuance, or renewal of existing Medigap policies with prescription drug coverage for Part D enrollees. The prohibition would not apply to renewal of Medigap prescription policies for persons who are not Part D enrollees. Persons enrolling under Part D during the initial enrollment period could enroll in a plan without drug coverage, or continue their previous policy as modified to exclude drugs. H, I, and J policies, modified to exclude drugs, could continue to be offered to new enrollees. Medigap issuers would be required to notify individuals of these changes 60 days prior to the initial Part D enrollment period.

The provision guarantees issuance of a substitute Medigap policy for persons, enrolling in Part D, who at the time of such enrollment were enrolled in and terminated enrollment in a Medigap policy H, I, or J or a pre-standard policy that included drug coverage. Evidence of enrollment and termination would be required. The guaranteed enrollment is for any of the Plans A, B, C, and F within the same carrier of issue. The guarantee applies for enrollments occurring in the new Medigap plan within 63 days of termination of enrollment in a Medigap drug Plan H, I, or J. The insurer may not impose an exclusion based on a pre-existing condition for such individuals. Further, the insurer is prohibited from discriminating in the pricing of such policy on the basis of the individual's health status, claims experience, receipt of health care or medical condition. The conferees intend that these provisions be administered in such a manner as to avoid a break in coverage.

The conference agreement requires the Secretary to request the National Association of Insurance Commissioners to review and revise standards for benefit packages taking into account the changes in benefits resulting form the enactment of this Act and to otherwise update standards to reflect other changes in law included in the Act. To the extent practicable, the revision will provide for implementation of revised standards as of January 1, 2006.

The revision is to include 2 new benefit packages. The first new package will have the following benefits (notwithstanding other provisions of law relating to core benefits): (1) coverage of 50% of the cost-sharing otherwise applicable (except coverage of 100% cost-sharing applicable for preventive benefits); (2) no coverage of the Part B deductible; (3) coverage of all hospital coinsurance for long stays and 365 extra lifetime days of coverage (as in current core package); and (4) a limitation on annual out-of-pocket costs of $4,000 in 2006 (increased in future years by an appropriate inflation adjustment as specified by the Secretary). The second new benefit package will have the same benefit structure as the first new package except that: (1) coverage would be provided for 75%, rather than 50%, of cost-sharing otherwise applicable; and (2) the limitation on out-of-pocket costs would be $2,000, rather than $4,000.

Medigap issuers could not be required to participate as a PDP sponsor under the new Part D, nor could a State make such a requirement.

Additional Provisions Relating to Medicare Prescription Drug Discount Card and Transitional Assistance Program (Section 105 of Conference agreement).

Present Law

No provision.

House Bill

No provision.

Senate Bill

No provision.

Conference Agreement

The conference agreement includes additional provisions relating to the implementation of the Medicare prescription drug discount card and transitional assistance program. It excludes program costs from the calculation of the Part B premium. It applies Medicaid confidentiality provisions to drug pricing data reported by manufacturers under the program.

The conference agreement includes additional administrative provisions. It specifies that the following sections of law would not apply to the card program: New Section 1871(a)(3) of the Social Security Act relating to time line for publication of final rules; Chapter 35 of Title 44 of the U.S. Code relating to coordination of federal information policy; Section 553(d) of Title 5 of the U.S. Code requiring at least 30 days between issuance and effective date of a substantive rule; and Section 801(a)(3)(A) of title 5 of the U.S. Code providing 60 days for congressional review of a major rule.

The contracting authority extended to the Secretary under Medicare+Choice also applies to the Secretary with respect to the

discount card program. There could be no judicial review of a determination not to endorse or enter into a contract with a card sponsor. Further, an order to enjoin any provision of the new section 1807 would not affect any other provision of the section and all provisions are to be treated as severable.

The Secretary of the Treasury, upon written request from the Secretary of HHS, is required to disclose to officers and employees of HHS certain information with respect to a taxpayer for the most recent taxable year for which information is available in the Internal Revenue Service's taxpayer data information system, or if no return was filed for that year, the year before that. Required information would consist of whether the adjusted gross income (as modified by HHS regulations) of the taxpayer, and if applicable the taxpayer's spouse, exceeds amounts that are 100 percent and 135 percent of the official poverty line. Such information may only be used to determine eligibility for the transitional low-income assistance program.

State Pharmaceutical Assistance Transition Commission (Section 106 of Conference agreement; Section 107 of House bill).

Present Law

A number of states currently have programs to provide low-income persons, not qualifying for Medicaid, with financial assistance in meeting their drug costs. The state programs differ substantially in both design and coverage.

House Bill

The provision would establish a State Pharmaceutical Assistance Transition Commission to develop a proposal for dealing with the transitional issues facing state programs and participants due to implementation of the new Part D prescription drug program. The Commission, to be established on the first day of the third month following enactment, would include: (1) a representative of each governor from each state with a program that the Secretary identified as having a benefit package comparable to or more generous than the new Part D; (2) representatives from other states that had pharmaceutical assistance programs, as appointed by the Secretary; (3) representatives (not exceeding the total under #1 and #2) of organizations that represented interests of participants, appointed by the Secretary; (4) representatives of MA organizations; and (5) the Secretary or the Secretary's designee and other members specified by the Secretary. The Commission would develop the proposal in accordance with specified principles, namely: (1) protection of the interests of program participants in the least disruptive manner; (2) protection of the financial and flexibility interests of states so they are not financially worse off; and (3) principles of Medicare modernization outlined in Title II of the Act.

The Commission would report to the President and Congress by January 1, 2005. The report would contain specific proposals including specific legislative or administrative recommendations, if any. The Commission would terminate 30 days later.

Senate Bill

No provision.

Conference agreement

The agreement establishes a State Pharmaceutical Assistance Transition Commission to develop a proposal for dealing with the transitional issues facing State programs and participants due to implementation of the new Part D prescription drug program. The Commission, to be established as of the first day of the third month following enactment, will include: (1) a representative of each governor from each state with a program that the Secretary identifies as having a benefit package comparable to or more generous than the low-income assistance under the new Section 1860D–14; (2) representatives from other states that have pharmaceutical assistance programs, as appointed by the Secretary; (3) representatives (not exceeding the total under #1 and #2) of organizations that have an inherent interest in the participants or the program itself; appointed by the Secretary; (4) representatives of MA organizations, Pharmacy Benefit Managers and other private insurance plans; and (5) the Secretary or the Secretary's designee and other members specified by the Secretary. The Commission is to develop the proposal in accordance with specified principles, namely: (1) protection of the interests of program participants in the least disruptive manner; (2) protection of the financial and flexibility interests of states so they are not financially worse off; and (3) principles of Medicare modernization outlined in Title II of the Act.

The Commission will report to the President and Congress by January 1, 2005, including specific legislative or administrative recommendations, if any. The Commission will terminate 30 days later. The Conferees intend the Commission to play an integral role in identifying potential problems and proposing creative solutions to ensure a seamless transition for States and beneficiaries in coordinating and interacting with the new Medicare plans.

Studies and Reports (Section 107 of Conference agreement; New Section 1860D–10 of House bill; Section 102, Section 106 and Section 110 of Senate bill).

House Bill

Under the new Section 1860D–10, the Secretary, within six months of enactment, would be required to review the current standards of practice for pharmacy services provided to patients in nursing facilities. Specifically, the Secretary would assess: (1) the current standards of practice, clinical services, and other service requirements generally utilized for such pharmacy services; (2) evaluate the impact of those standards with respect to patient safety, reduction of medication errors, and quality of care; and (3) recommend necessary actions. The Secretary would submit a report to the Congress on the findings and recommendations.

Senate Bill

Section 110 would require the Secretary to conduct a thorough review of the standards of practice for pharmacy services provided to patients in nursing facilities. The Secretary would assess the current standards, clinical services and other service requirements generally used in long-tern settings and evaluate the impact of these standards with respect to patient safety, reduction of medication errors, and quality of care. Within 18 months of enactment, the Secretary would be required to submit a report to Congress on the study containing: (1) a detailed description of the Secretary's plans to implement the Act in a manner consistent with applicable state and federal laws designed to protect the safety and quality of care of nursing facility patients; and (2) recommendations regarding necessary actions and appropriate reimbursement to ensure the provision of care in such manner.

Section 102 would require the Administrator to conduct a study, and report to Congress by January 1, 2005, on allowing persons not entitled to Part A, but enrolled in Part B, to enroll in Part D.

Section 106 requires the Secretary, on an ongoing basis, would study variations in spending and drug utilization under Part D to determine the impact on premiums. The Secretary would examine the impact of geographic adjustments of the monthly national average premium on the maximization of competition and the ability of eligible entities to contain costs. The Secretary would submit an annual report to Congress beginning in 2007.

Conference Agreement

The agreement requires the Secretary to study variations in per capita spending for covered Part D drugs among PDP regions to determine the amount of such variation that is attributable to price variations and the differences in per capita utilization that is not taken into account in the health status risk adjustment made to PDP bids. The Secretary is required to submit a report to Congress on the study including information on the extent of geographic variation in per capita utilization, an analysis of the impact of direct subsidies and whether such subsidies should be adjusted to take into account such variation, and recommendations regarding the appropriateness of applying an additional geographic adjustment factor to bids.

The conference agreement requires the Secretary, within six months of enactment, to review the current standards of practice for pharmacy services provided to patients in nursing facilities. Specifically, the Secretary is to assess: (1) the current standards of practice, clinical services, and other service requirements generally utilized for such pharmacy services; and (2) evaluate the impact of those standards with respect to patient safety, reduction of medication errors, and quality of care. The report is to contain a description of the Secretary's plans to implement this Act in a manner consistent with applicable state and federal laws designed to protect the safety and quality of care of nursing facility patients. The report must also include recommendations regarding necessary actions.

The conference agreement requires the Secretary to enter into a contract with the Institute of Medicine to carry out a comprehensive study of drug safety and quality issues in order to provide a blueprint for system-wide change. The objectives of the study are to: (1) develop a full understanding of drug safety and quality issues through an evidence-based review of the literature, case studies, and analysis; (2) attempt to develop credible estimates of the incidence, severity and costs of medication errors; (3) evaluate alterative approaches to reducing medication errors; (4) provide guidance on high-priority strategies to achieve drug safety goals; (5) assess opportunities and key impediments to broad nationwide implementation of medication error reductions; and (6) develop an applied research agenda to evaluate the health and cost impacts of alternative interventions. The study is to be completed within an 18-month period. Such sums as may be necessary are authorized.

The agreement requires the Secretary to provide a study on the feasibility and advisability of providing multi-year contracts with PDP sponsors and MA organizations.

The agreement requires the GAO to conduct a study to determine the extent to which utilization and access to covered Part D drugs for low-income subsidy eligible individuals differs from that for persons who would qualify as subsidy eligible individuals except for application of the assets test. The report is due to Congress by September 30, 2007.

Grants to Physicians to Implement Electronic Prescription Programs (Section 108 of Conference agreement; Section 121 of Senate bill).

Present Law

No provision.

House Bill

No provision.

Senate Bill

The Secretary would be authorized to award grants to health care providers to implement electronic prescription programs. There would be authorized to be appropriated such sums as may be necessary for each of fiscal years 2006, 2007, and 2008.

Conference Agreement

The agreement authorizes the Secretary to make grants to physicians for the purpose of assisting them to implement electronic prescription programs in complying with the standards under the new Section 1860D–(4)(e). The Secretary, in awarding the grant shall give special consideration to physicians who serve a disproportionate number of Medicare patients and give preference to physicians who serve a rural or underserved area. Grant funds may be used for purchasing, leasing, and installing hardware and software; making upgrades and other improvements; and providing education and training to eligible physician staff on the use of technology. Grant applicants are required to provide the secretary with information necessary to evaluate the project and to ensure that funding is expended only for the purposes for which it is made. The applicant must agree to make available non-Federal contributions totaling at least 50 percent of the costs. $50 million is authorized for FY 2007, and such sums as may be necessary for FY 2008 and FY 2009.

Expanding the Work of Medicare Quality Improvement Organizations to Include Parts C and D (New section 109 of the Conference agreement).

Present Law

Quality improvement organizations (QIOs) review medical necessity and quality of services provided under Medicare.

House Bill

No provision.

Senate Bill

No provision.

Conference agreement

The conference agreement expands the work of quality improvement organizations (QIOs) to include Part C and Part D. It is required to offer providers, practitioners, MA organizations, and PDP sponsors quality improvement assistance pertaining to prescription drug therapy. The secretary is to request the Institute of Medicine of the National Academy of Sciences to conduct a study of the QIO program including an evaluation of the program and the extent to which other entities could perform similar quality improvement functions as well as or better than QI0s. The Secretary will report to Congress on such study by June 1, 2006. If the Secretary finds, based on the study, that other entities could improve quality as well as or better than QI0s, the Secretary shall provide increased competition through such entities.

Conflict of Interest Study (Section 110 of Conference agreement).

Present Law

No provision.

House Bill

No provision.

Senate Bill

No provision.

Conference Agreement

The conference agreement requires the Federal Trade Commission to conduct a study of differences in payment amounts for pharmacy services provided to enrollees in group health plans that utilize pharmacy benefit managers (PBMs). The study is to include an assessment of the differences in costs incurred by such enrollees and plans for drugs dispensed by mail order pharmacies owned by PBMs compared to those not owned by PBMs, and community pharmacies. The study is to examine whether such plans are acting in a manner that maximizes competition and results in lower prescription drug prices for enrollees. The report is due to Congress within 18 months of enactment. It is to include recommendations regarding any legislation to insure the fiscal integrity of the Part D program. Conferees note the Secretary has the authority to accept or reject bids, based, among other factors, costs associated with delivering drug benefits.

The intent of the conferees in including this assessment by the FTC is to assess whether Medicare spending is likely to be adversely affected because of the use of mail order pharmacies that are owned and operated by a PBM under contract to a prescription drug plan or MA–PD plan. Therefore, this study should evaluate to what extent prescription drug spending is likely to be affected if a PDP or MA–PD plan approves the dispensation of covered drugs from a mail-order pharmacy owned directly or indirectly by a PBM compared to drug utilization and costs if the mail-order pharmacy were independently owned. Such assessment shall take into account the following:

(1) whether mail order pharmacies that are owned by PBMs (or entities that own PBMs) dispense fewer generic drugs compared to single source drugs within the same therapeutic class when compared to mail order pharmacies that are not owned by PBMs,

(2) whether mail order pharmacies that are owned by PBMs (or entities that own PBMs) routinely switch patients from lower priced drugs to higher priced drugs (in the absence of a clinical indication) when compared to mail order pharmacies that are not owned by PBMs,

(3) whether mail order pharmacies owned by PBMs (or entities that own PBMs) sell a higher proportion of repackaged drugs than mail order pharmacies that are not owned by PBMs,

(4) whether mail order pharmacies owned by PBMs (or entities owned by PBMs) sell repackaged drugs at prices above the manufacturer's average wholesale price,

(5) Other factors deemed relevant by the FTC.

In conducting this study, the FTC shall consider whether competition or drug pricing behavior by PBMs would be affected if PBMs were to bear financial risk for drug spending. The FTC shall issue a written report within 18 months of the date of enactment.

Disclosure of Return Information for Purposes of Carrying Out Medicare Catastrophic Prescription Drug Program. (Section 106 of House Bill).

Present Law

Current law authorizes, under specified circumstances, the disclosure by the Secretary of the Treasury of returns and return information for purposes other than tax administration.

House Bill

The provision would permit the Secretary of the Treasury, upon written request from the Secretary of the Department of Health and Human Services (HHS) to disclose to officers and employees of HHS specific information with respect to a specified taxpayer for a specific tax year. The information that could be disclosed is taxpayer identity information and the adjusted gross income for the taxpayer or, if less, the income threshold limit specified under the new Part D ($200,000 in 2006). A specified taxpayer would be either: (1) an individual who had adjusted gross income for the year in question in excess of the income threshold specified in the new Part D ($60,000); or (2) an individual who elected to use more recent income information as permitted under Part D. Individuals filing joint returns would each be treated separately with each person considered to have an adjusted gross income equal to one-half of the total.

Return information disclosed, could be used by officers and employees of HHS only for administering the prescription drug benefit. They could disclose the annual out-of-pocket threshold applicable to an individual to the entity offering the individual prescription drug coverage. The sponsor could use such information only for the purposes of administering the benefit.

Senate Bill

No provision.

Conference Agreement

No provision.

Limitation on Prescription Drug Benefits of Members of Congress (Section 107 of Senate Bill).

Present Law

Members of Congress are entitled to receive health benefits through the Federal Employees Health Benefits (FEHB) program.

House Bill

No provision.

Senate Bill

During calendar year 2004, the actuarial value of the drug benefit of any Member of Congress enrolled in a FEHBP plan could not exceed the actuarial value of any prescription drug benefit under Title XVIII of the Social Security Act passed by the first session of the 108th Congress and enacted into law. The Office of Personnel Management would promulgate necessary regulations.

Conference Agreement

No provision.

Protecting Seniors With Cancer (Section 108 of Senate Bill).

Present Law

Medicaid pays Part B premiums for QMBs, SLIMBs and QI–1s. It pays Medicare cost-sharing charges for QMBs.

House Bill

No provision.

Senate Bill

The cost-sharing specified under the low-income subsidy provisions would be modified for persons diagnosed with cancer. The cost-sharing specified under New Section 1860D–19 would apply except for the following changes. The QMB population would have a full premium subsidy for at least one drug plan available in the area where the beneficiary resided. For the SLIMB and QI–1 population, there would be no premium for any plan whose premium was at or below the monthly national average premium. For other persons below 160% of poverty, only a percentage of the premium otherwise applicable. Persons with incomes above 160% of the poverty line would have, in 2006, the same cost-sharing otherwise specified under the bill.

Conference Agreement

No provision.

Protecting Seniors With Cardiovascular Disease, Cancer, or Alzheimer's Disease (Section 109 of Senate Bill).

Present Law

Medicaid pays Part B premiums for QMBs, SLIMBs and QI–1s. It pays Medicare cost-sharing charges for QMBs.

House Bill

No provision.

Senate Bill

The cost-sharing specified under the low-income subsidy provisions would be modified

for persons diagnosed with cardiovascular disease, cancer, diabetes or Alzheimer's disease. The cost-sharing specified under New Section 1860D–19 would apply except for the following changes. The QMB population would have a full premium subsidy for at least one drug plan available in the area where the beneficiary resided. For the SLIMB and QI–1 population, there would be no premium for any plan whose premium was at or below the monthly national average premium. For other persons below 160% of poverty, only a percentage of the premium otherwise applicable. Persons with incomes above 160% of the poverty line would have, in 2006, the same cost-sharing otherwise specified under the bill.

Conference Agreement

No provision.

Medication Therapy Management Assessment Program (Section 110A of Senate Bill).

Present Law

No provision.

House Bill

No provision.

Senate Bill

The Secretary would be required to establish a 1-year assessment program to contract with qualified pharmacists to provide medication therapy management services to fee-for-service beneficiaries. The Secretary would designate 6 geographic areas (at least 2 rural), each containing not less than 3 sites. The program would be implemented between October 1, 2004 and January 1, 2005. Beneficiaries in an area could participate if they identified a qualified pharmacist to furnish medication therapy management services. The Secretary would enter into contracts with qualified pharmacists to provide such services. The fee established under the contract would be designed to test various payment methodologies including one that applied a relative value scale and fee schedule. Payments would be made from the Part B trust fund and be budget neutral. The Secretary would be required to make data on the program available and report to Congress within 6 months of completion of the program.

Conference Agreement

No provision.

Section 133. Pharmacy Benefit Managers Transparency Requirements (Section 133 of Senate Bill).

Present Law

No provision.

House Bill

No provision.

Senate Bill

An eligible entity offering a Medicare prescription drug plan under Part D or a MedicareAdvantage organization offering a MedicareAdvantage plan under Part C could not enter a contract with a pharmacy benefit manager (PBM) owned by a pharmaceutical manufacturing company. PBMs would be required to provide the following information, on an annual basis, to the Assistant Attorney General for Antitrust of the Department of Justice and the Inspector General for the Department of Health and Human Services: (1) aggregate amount of any and all rebates, discounts, administrative fees, promotional allowances, and other payments received or recovered from each pharmaceutical manufacturer; (2) the amount of payments received or recovered from each pharmaceutical manufacturer for each of the top 50 drugs (as measured by volume); and (3) the percentage differential between the price PBMs pay pharmacies and the price the PBM charges the PDP or MA organization. Failure to disclose could result in civil penalties; further, the U.S. district court could order compliance. No disclosed information would be made public, except as might be relevant to any judicial action or proceeding. Nothing in the provision would be intended to prevent disclosure to either body of Congress or any duly authorized committee or subcommittee.

Conference Agreement

No provision.

Office of the Medicare Beneficiary Advocate (Section 134 of Senate Bill).

Present Law

No provision.

House Bill

No provision.

Senate Bill

Within 1 year of enactment, the Secretary would be required to establish an Office of the Medicare Beneficiary Advocate within the Department of Health and Human Services. The Office would establish a toll-free number for beneficiaries to obtain information on the Medicare program, particularly with respect to Part D. It would establish a website with easily accessible information on PDPs and MA plans. From amounts appropriated to the Secretary's administrative account, $2 million could be used to establish the Office and such funds as may be necessary would be used to operate the Office.

Conference Agreement

No provision.

TITLE II—MEDICARE ADVANTAGE

Subtitle A—Implementation of Medicare Advantage Program

Sec. 201. Implementation of Medicare Advantage program

Present Law

Health maintenance organizations (HMOs) and other types of managed care plans have long participated in the Medicare program, beginning with private health plan contracts in the 1970s and the Medicare risk contract program in the 1980s. In 1997, Congress passed the Balanced Budget Act of 1997 (BBA 1997, P.L. 105–33), which replaced the risk contract program with the Medicare+Choice (M+C) program. M+C plans include coordinated care plans (HMOs, preferred provider organizations or PPOs, and provider-sponsored organizations or PSOs), private fee for service (PFFS) plans, and, on a temporary basis, medical savings accounts (MSAs).

House Bill

Section 200. Title II would establish the Medicare Enhanced Fee-for-Service (EFFS) program, under which Medicare beneficiaries would be provided access to a range of regional EFFS plans that could include preferred provider networks, beginning in 2006. It would establish the Medicare Advantage (MA) program, upon enactment, to replace the M+C program, which would continue to offer coordinated care and other plans on a county-wide basis as under current law. It would also use competitive bidding, beginning in 2010, in the same style as the Federal Employees Health Benefits program (FEHBP) for certain EFFS plans and MA plans, to promote greater efficiency and responsiveness to Medicare beneficiaries.

Senate Bill

Title II would establish the Medicare Advantage (MA) program, which would replace the M+C program, beginning in 2006. The MA program would continue to offer coordinated care and other plans on a county-wide basis as under current law. It would also establish regional PPOs, to be offered in regions. Beginning in 2008, it would establish a limited competition program, in areas designated as ''highly competitive.''

Conference Agreement

Section 201. The conference agreement establishes the Medicare Advantage (MA) program under Part C of Medicare. Any reference under Part C of Medicare to the ''Medicare+Choice'' program is deemed to be a reference to ''Medicare Advantage'' and ''MA''.

This title modernizes and revitalizes private plans under Medicare. The Balanced Budget Act (BBA) of 1997 altered payments for private plans and expanded the types of plans that could be offered under Medicare. Since payment rate changes were implemented, enrollment in private plans has fallen from 6.2 million beneficiaries in 1998 to 4.6 million beneficiaries in November 2003, and the number of plans has decreased from 346 risk plans in 1998 to 155 (151 coordinated care plans and 4 private FFS plans) in November 2003. This disruption has been due, in part, to unpredictable and insufficient payments. BBA 97 fundamentally de-linked payments to plans from FFS payment growth.

To increase beneficiary choice, Title II reforms the payment system in 2004. All plans would be paid at a rate at least as high as the rate for traditional FFS Medicare, as recommended by the Medicare Payment Advisory Commission (MedPAC). After 2004, private plans' capitation rates would grow at the same rate as FFS Medicare. To increase beneficiary choice in more rural areas, Title II would establish regional plans, which would encourage private plans to serve Medicare beneficiaries in larger regions, beginning in 2006. Both local and regional MA private plans would bid competitively against a benchmark beginning in 2006.

Once private plans became established, and enrollment in private plans increased, a demonstration of comparative cost adjustment in selected sites would begin in 2010. Plan bids from private plans and rates for traditional FFS Medicare would be averaged to create a benchmark for competitive bidding. The competitive program would encourage beneficiaries to enroll in the most efficient plan, producing savings for both beneficiaries, through reduced premiums, and for taxpayers, through relatively lower Medicare costs.

Subtitle B—Immediate Improvements

Section 211. Immediate improvements

Present Law

Under current law, Medicare+Choice (M+C) plans are paid an administered monthly payment, called the M+C payment rate, for each enrollee. The per capita rate for a payment area is set at the highest of three amounts: (1) a minimum payment (or floor) rate, (2) a rate calculated as a blend of an area-specific (local) rate and a national rate, or (3) a rate reflecting a minimum increase from the previous year's rate (currently 2%).

A budget neutrality adjustment is made so that estimated total M+C payments in a given year will be equal to the total payments that would be made if payments were based solely on area-specific rates. The budget neutrality adjustment may only be applied to the blended rates because rates cannot be reduced below the floor or minimum increase amounts. The blend payment is also adjusted to remove the direct and indirect costs of graduate medical education. The blend payment amount is based on a weighted average of local and national rates for all Medicare beneficiaries.

Each year, the three payment amounts are updated by formulas set in statute. Both the floor and the blend are updated each year by a measure of growth in program spending, the national growth percentage. The minimum increase provides for an increase of at least 2% over the previous year's amount.

If an individual is in a short-term general hospital at the time he or she elected to enroll in an M+C plan or change from one M+C

plan to another, payment for such services would be made through FFS or the original plan. Conversely, if an individual terminates enrollment in an M+C plan, that organization would be responsible for payment for such services until the date of the individual's discharge.

House Bill

Section 212(a). For 2004, a 4th payment mechanism would be added and plans would receive the highest of the four payment calculations (the floor, blend, minimum percentage increase, or the new amount). The new payment amount would be 100% of fee-for-service (FFS) costs. The FFS payment would be based on the adjusted average per capita cost for the year, for an MA payment area, for services covered under Parts A and B for beneficiaries entitled to benefits under Part A, enrolled in Part B and not enrolled in an MA plan. This payment would be adjusted to remove payments for direct medical education costs and to include the additional payments that would have been made if Medicare beneficiaries entitled to benefits from facilities of the Department of Veteran Affairs (VA) and the Department of Defense (DOD) had not used those services (VA/DOD adjustment).

Section 212(b). In 2004, no adjustment would be made for budget neutrality, which would fund the blend for that year.

Section 212(c). The calculation of the minimum percentage increase would also be revised. For 2004 and beyond, the minimum percentage increase would be the greater of: (1) a 2% increase over the previous year's payment rate (as under current law), or (2) the previous year's payment increased by the national per capita MA growth percentage. For purposes of calculating the minimum percentage increase, there would be no adjustment to the national growth percentage for prior years' errors before 2004. Beginning in 2005 and each subsequent year, the payments to a plan would be based on its prior year rate increased by the revised minimum percentage increase.

Section 212(d). The area-specific MA capitation rate (the local component of the blend) would be adjusted to include the VA/DOD adjustment, beginning in 2004.

Section 212(e). Beginning January 1, 2004, the payment rule for beneficiaries in a short-term general hospital at the time they either elected to enroll in or to terminate their enrollment in an M+C plan, would be extended to a beneficiary in an inpatient rehabilitation facility.

Section 212(f). No later than 18 months after enactment of this Act, the Medicare Payment Advisory Commission would report to Congress providing an assessment of the method used for determining the adjusted average per capita cost (AAPCC). The report would examine the variation in costs between different areas, including differences in input prices, utilization and practice patterns; the appropriate geographic area for payment; and the accuracy of the risk adjustment methods in reflecting differences in the cost of providing care to different groups of beneficiaries.

Section 212(g). No later than July 1, 2006, the Administrator would submit a report to Congress that described the impact of additional financing provided under this Act and other Acts, (including the Balanced Budget Refinement Act of 1999—BBRA and the Benefits Improvement and Protection Act of 2000—BIPA) on the availability of MA plans in different areas and the impact on lowering premiums and increasing benefits under such plans.

Section 212(h). The Secretary would calculate and announce the new MA capitation rates within 6 weeks of enactment of this legislation.

Senate Bill

Section 203. [§1853(c)]. For payments before 2006, the payment would be calculated in the same manner as under current law—the highest of the blend, minimum payment (floor) rate, or minimum percentage increase. However the calculation of the minimum percentage increase would change for 2005. The minimum percentage increase for 2005 would be a 3% increase over the rate for the area for 2003. For 2006 and subsequent years, it would be a 2% increase over the previous year (but calculated as though the increase in 2005 was 2%.) Additionally, beginning in 2014, the minimum amount (floor) would be increased by the percentage increase in the CPI for all consumers, for the 12-month period ending in June of the previous year.

Section 204(b). The Secretary would conduct a study to determine the extent to which M+C cost-sharing discourages access to covered services or discriminates based on the health status of M+C eligible beneficiaries. The Secretary would submit a report to Congress, providing recommendations for legislation and administrative action, no later than December 31, 2004.

Section 210. The costs of DOD and VA military facility services would be included in the area specific M+C payment and the local fee for service rates beginning in 2006.

Conference Agreement

Section 211(a). The conference agreement makes several changes to the payments for MA plans. In some MA payment areas, the MA payment rate is lower than the costs of providing FFS care to enrollees in traditional Medicare in some parts of the country. Many private plans have seen their Medicare payment rates rise much less rapidly than the costs of FFS Medicare, as they have been held to increases of two percent annually every year since 1998, except for 2001 when a three percent increase was paid due to the BIPA. Health costs in general are running much higher than the two percent payment increases that most plans are receiving in the areas where most of the beneficiaries are enrolled in Medicare+Choice. Plans find it difficult—if not impossible—to contract with providers if FFS Medicare can reimburse providers at higher rates than private plans may offer, given their Medicare payments. If paid less than FFS Medicare, private plans may be forced to increase enrollee premiums or cost-sharing, or decrease supplemental benefits, such as prescription drug coverage. Since 1998, the number of plans participating in M+C has declined from 346 to 155.

To encourage plan entry, all private plans would be paid at a minimum of the FFS rate. In addition, private plan rates would increase at the same rate as growth in FFS Medicare. The goal is to increase beneficiary choice, by increasing private plan participation in Medicare.

For 2004, a 4th payment mechanism will be added and plans will receive the highest of the four payment calculations (the floor, blend, minimum percentage increase, or the new amount). The new payment amount is 100% of fee-for-service (FFS) costs. The FFS payment is based on the adjusted average per capita cost for the year, for an MA payment area, for services covered under Parts A and B for beneficiaries entitled to benefits under Part A, enrolled in Part B and not enrolled in an MA plan. The 4th payment mechanism, 100% fee-for-service, will be rebased no less than once every 3 years. This payment will be adjusted to: (1) remove payments for direct medical education costs, and (2) include the additional payments that would have been made if Medicare beneficiaries entitled to benefits from facilities of the Department of Veteran Affairs (VA) and the Department of Defense (DOD) had not used those services (VA/DOD adjustment).

Section 211(b). In 2004, no adjustment will be made for budget neutrality, in order to fund the blend for that year.

Section 211(c). The calculation of the minimum percentage increase will also be revised. For 2004 and beyond, the minimum percentage increase will be the greater of: (1) a 2% increase over the previous year's payment rate (as under current law); or (2) the previous year's payment increased by the national per capita MA growth percentage. For purposes of calculating the minimum percentage increase, there will be no adjustment to the national growth percentage for prior years' errors before 2004. Beginning in 2005 and each subsequent year, the payments to a plan will be based on its prior year rate increased by the revised minimum percentage increase.

Section 211(d). The area-specific MA capitation rate (the local component of the blend) will be adjusted to include the VA/DOD adjustment, beginning in 2004.

Section 211(e). Beginning January 1, 2004, the payment rule for beneficiaries in a short-term general hospital at the time they either elected to enroll in or to terminate their enrollment in an MA plan, will be extended to a beneficiary in an rehabilitation hospital, a distinct part rehabilitation unit, or a long-term care hospital. For beneficiaries leaving their MA plan while receiving these inpatient hospital services, this provision will expand the rule that disallows payment for such services under fee-for-service payments for inpatient hospitals. Under the expansion, payments will be prohibited from any type of payment provision under Medicare for inpatient services, for the type of facility, hospital, or unit involved.

Section 211(f). No later than 18 months after enactment of this Act, the Medicare Payment Advisory Commission (MedPAC) will submit a report to Congress providing an assessment of the method used for determining the adjusted average per capita cost (AAPCC). The report will examine the variation in costs between different areas, including differences in input prices, utilization and practice patterns; the appropriate geographic area for payment of local MA plans; and the accuracy of the risk adjustment methods in reflecting differences in the cost of providing care to different groups of beneficiaries.

Section 211(g). No later than July 1, 2006, the Secretary will submit a report to Congress that describes the impact of additional financing provided under this Act and other Acts, (including the Balanced Budget Refinement Act of 1999—BBRA and the Benefits Improvement and Protection Act of 2000—BIPA) on the availability of MA plans in different areas and the impact on lowering premiums and increasing benefits under such plans.

Section 211(h). The Medicare Payment Advisory Commission (MedPAC) will conduct a study to determine the extent to which MA cost-sharing affects access to covered services or selects enrollees based on the health status of MA eligible beneficiaries. MedPAC will submit a report to Congress, providing recommendations for legislation and administrative action, no later than December 31, 2004.

Section 211(i). Within 6 weeks after enactment, the Secretary will determine and announce the revised MA capitation rates. The revised payment rates will be subject to the same transition rules that applied to revised payments after the passage of the Benefits Improvement and Protection Act of 2000 (BIPA, P.L. 106–554), including the requirement that plans that previously announced

their intention to terminate their contract or reduce their service area could rescind their notice, among other transition rules. Also for 2004, any changes to payments made under this Act will be effective beginning in March 2004, and would be adjusted to include any additional amounts plans would have received if the new payment system had been effective January 1. If a plan revises its submission of information to the Secretary, and it includes changes in beneficiary premiums, beneficiary cost-sharing, or benefits under the plan, then the plan is required to notify each enrollee in writing, within 3 weeks after the date that the Secretary approves the changes. There will be no administrative or judicial review of any determination made by the Secretary for application of this section or payment rates.

In order to clarify current law, if a private fee-for-service plan has contacts and agreements with a sufficient number and range of providers within a category of health care professionals and providers, it may charge higher beneficiary copayments to providers in that category who do not have such contracts or agreements (other than deemed contracts or agreements).

Subtitle C—Offering Medicare Advantage (MA) Regional Plan; Medicare Advantage Competition

Section 221. Establishment of MA regional plans

Present Law

M+C plans include coordinated care plans (HMOs, preferred provider organizations or PPOs, and provider-sponsored organizations or PSOs), private fee for service (PFFS) plans, and, on a temporary basis, medical savings accounts (MSAs).

Enrollment in any individual M+C plan is open only to those beneficiaries living in a specific service area. An M+C payment area is defined as a county, or equivalent area as specified by the Secretary. Plans define a service area as a set of counties and county parts, identified at the zip code level. At a state's option, the service area could be defined as the entire state; however, to date, no state has done so.

House Bill

Section 201(a). [§1860E–1(a)] Beginning January 1, 2006, the Administrator would establish the EFFS program for EFFS eligible individuals in EFFS regions. Plans would be offered on a regional basis, in at least 10 regions established by the Administrator. Before establishing the regions, the Administrator would conduct a market survey and analysis, including an examination of current insurance markets, to determine how the regions should be established. Regions would be established to take into consideration maximizing full access for all EFFS-eligible individuals, especially those residing in rural areas. [§1860E–1(b)]. EFFS plans would be required to provide either fee-for-service (FFS) or preferred provider coverage. Under FFS coverage, plans would: (1) reimburse hospitals, physicians and other providers at a rate determined by the plan on a FFS basis, without placing providers at risk, (2) not vary rates based on the provider's utilization, and (3) not restrict the selection of providers from among those who were lawfully authorized to provide covered services and agreed to accept the plan's terms and conditions. Under preferred provider coverage, plans would: (1) have a network of providers who agreed to a contractually-specified reimbursement for covered benefits with the organization, and (2) provide for reimbursement for all covered benefits regardless of whether they were provided within the network.

[§1860E–1(c)]. EFFS plans would have to comply with existing eligibility, election, and enrollment provisions (under §1851) including guaranteed issue and renewal, but could offer cash rebates, reduced premiums, or supplemental benefits to beneficiaries if plan bids were below a specified benchmark.

[§1860E–3(a)]. The Administrator may enter into contracts with up to three EFFS organizations in any region.

Senate Bill

Section 211. [§1858(a)]. Beginning January 1, 2006, a preferred provider organization (PPO) plan would be offered to MA eligible individuals in preferred provider regions. A PPO would be an entity with a contract that met other requirements of this Act. A PPO would have a network of providers that agreed to contractually specified reimbursements for covered benefits under Parts A and B. The PPO would pay for all covered services an enrollee received, whether provided in or out of network.

[§1858(a)(3)]. There would be at least 10 regions. Each region would have to include at least one state, and could be the entire United States. The Secretary could not divide states so that portions of the state were in different regions. To the extent possible, the Secretary would include multi-state metropolitan statistical areas (MSAs) in a single region, except that he or she could divide an MSA where necessary to establish a region of such size and geography to maximize the participation of PPOs. The Secretary could use the same regions established for the prescription drug program, under Part D. The service area of a PPO would be the region.

Each plan would be offered to any MA eligible individual residing in the service area.

Section 211. [§1858(b)]. PPOs would be required to establish a sufficient number and range of health care professionals and providers willing to provide services under the plan's terms. The Secretary would consider this requirement to be met if the organization had a sufficient number of contracts and agreements with a sufficient number and range of providers. These arrangements would not restrict enrollee access to other providers for covered services. Additionally, if the plan was in a state where 25% or more of the population resided in a health professional shortage area, these arrangements would also not restrict the categories of licensed health professionals or providers from whom the enrollee could obtain covered benefits. The Secretary could disapprove any PPO believed to attract a population that is healthier than the average population of the region serviced by the plan.

Section 211. [§1858(d)]. If there were bids for more than three plans in a preferred provider region, the Secretary would limit the number of plans to the three lowest-cost credible plans that met or exceeded the quality or minimum standards.

Conference Agreement

The conference agreement establishes a new regional plan program beginning in 2006. The Secretary will establish between 10 and 50 regions across the nation. Plans wishing to participate in this program will be required to serve an entire region. By requiring plans to serve larger service areas that bring together both urban and rural areas, the program will bring greater health plan choices to areas not previously served by the Medicare+Choice program, particularly rural areas.

In establishing Medicare Advantage regions (MA regions), the Secretary will conduct a market study to determine how regions should best be constructed to maximize plan participation and availability of plans to beneficiaries. The conference agreement includes a number of provisions to provide incentives for plans to participate in the regional program. These provisions include risk corridors for plans during the first 2 years of the program, 2006 and 2007; a stabilization fund to encourage plan entry and limit plan withdrawals; a blended benchmark that will provide greater responsiveness to the market by allowing plan bids to influence the benchmark amount; and a network adequacy fund to assist plans in forming adequate networks, particularly in rural areas. While private plans have experience in serving Medicare beneficiaries at a local level, such plans have not previously operated on a region-wide basis. These provisions will assist plans as they enter this new line of business and learn the market dynamics of serving beneficiaries across larger regions.

Section 221(a). This provision establishes a 2-year moratorium on new local preferred provider organizations in order to encourage PPOs to operate at the regional level. PPOs that are in operation as of December 31, 2005, including demonstration projects, will be allowed to continue operations and expand enrollment in their existing service areas during this period; however they will not be allowed to expand their service areas. PPOs will be able to enter new or expanded service areas again beginning January 1, 2008.

Section 221(b). The conference agreement allows MA regional coordinated care plans under the MA program. An MA regional plan: (1) has a network of providers who agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan, (2) provides for reimbursement for all covered benefits regardless of whether such benefits are provided within such network of providers, and (3) has a service area of one or more MA regions. A local MA plan is an MA plan that is not an MA regional plan, and local MA areas are defined, as under current law, as a county or equivalent area specified by the Secretary. MSA and PFFS plans are defined as local plans, although nothing prevents an MSA plan or an MA PFFS plan from serving one or more regions, or the entire Nation.

Section 221(c). [§1858(a)(1)]. The service area for an MA regional plan will consist of an entire MA region and may not be segmented.

[§1858(a)(2)]. No later than January 1, 2005 the Secretary will establish and publish a list of MA regions. There will be between 10 and 50 regions within the 50 states and the District of Columbia. Before establishing the MA regions, the Secretary will conduct a market survey and analysis, including an examination of current insurance markets. The regions should maximize the availability of MA regional plans to all MA eligible individuals without regard to health status, especially beneficiaries residing in rural areas. To the extent possible, each region should include at least one State, should not divide States across regions, and should include multi-State Metropolitan Statistical Areas in a single region. The Secretary may periodically review MA regions and, based on the review, revise the regions to be more appropriate. An MA regional plan may be offered in more than one region including all regions.

Single Deductible and Catastrophic Limit

Present Law

Medicare does not have a catastrophic limit on beneficiary out-of-pocket expenses, although some M+C plans offer an out-of-pocket limit as an added benefit. The original Medicare FFS program includes a Part B deductible and a separate Part A deductible for hospital stays.

House Bill

Section 201(a). [§1860E–2(b and c)]. EFFS plans could only be offered in a region if the plan, among other requirements, included a

single deductible for benefits under Parts A and B, and a catastrophic limit on out-of-pocket expenses.

Senate Bill

Section 202. [§1852(a)]. Each MA plan would have to offer a maximum limitation on out-of-pocket expenses and a unified deductible.

Conference Agreement

Section 221(c). [§1858(b)]. In order to ensure that MA regional plans are structured more like existing private market plans for the under-65 population, the conference agreement requires MA regional plans to include a single deductible for benefits under Parts A and B. The single deductible may be applied differentially for in-network services and may be waived for preventive or other items and services. MA regional plans will also be required to include two catastrophic limits—one for out-of-pocket expenditures for in-network Part A and B benefits and one for out-of-pocket expenditures for all Part A and B benefits. Payment rates to these plans are not increased to provide this coverage.

Risk Corridors

Present Law

No provision.

House Bill

No provision.

Senate Bill

Section 211. [§1858(e)]. The PPO would notify the Secretary of the total amount of costs incurred during 2007 and 2008 in providing covered benefits under Part A and B of Medicare, except that certain expenses would not be included (administrative expenses over the amount determined appropriate by the Administrator and amounts expended for enhanced medical benefits).

The Secretary would be required to establish risk corridors for the regional PPO plans for 2006 and 2007. Medicare would share risk with PPO organizations after costs fell above or below a risk corridor of 5% as follows: (1) Medicare would share 50% of the losses or profits between 105% and 110% of a target which consists of Medicare's MA payment plus the beneficiaries' contributions; and (2) Medicare would share 90% of the losses or profits above 110% of the target. PPOs would be at full risk for all enhanced medical benefits. A beneficiary's liability would not be affected by these risk corridors in the given years.

Conference Agreement

Section 221(c). [§1858(c)]. In order to encourage plans to enter the regional market and to provide assistance to these plans during the start-up phase of their business, Medicare will share risk with MA regional plans if costs fall above or below a specific risk corridor. These risk corridors will be available to plans during 2006 and 2007. The conference agreement provides that MA regional plans notify the Secretary of: (1) the total costs of providing Part A and B benefits and the portion attributable to allowable administrative expenses, and (2) the costs of providing rebatable integrated benefits and the portion of these costs attributable to allowable administrative expenses. Allowable cost is defined, with respect to an MA regional plan for a year, as the total amount of costs incurred in providing benefits under the original Medicare FFS program, and rebatable integrated benefits, reduced by administrative expenses. Rebatable integrated benefits are defined as non-drug supplemental benefits provided by a plan, as part of its required rebate to beneficiaries, that are integrated with the benefits under the original Medicare fee-for-service program. The Secretary will have discretion to evaluate whether certain rebatable benefits should be included in allowable costs for risk corridor calculations.

[§1854(c)(2)(D)]. The target amount is defined as an amount equal to the sum of: (1) the total monthly payments made to the organization for enrollees in the plan for the year that are attributable to benefits under the original Medicare FFS program; (2) the total of the MA monthly basic beneficiary premium, collectable for the enrollees for the year; and (3) the total amount of rebatable integrated benefits that the Secretary determines are appropriate for inclusion in the risk corridor calculation. The target amount does not include the cost of administrative expenses for FFS benefits or for rebatable supplemental benefits.

[§1854(c)(2)]. There will be no payment adjustment if the allowable costs for the plan are at least 97 percent, but do not exceed 103 percent of the target amount for the plan. If allowable costs for the plan are more than 103 percent but less than 108 percent of the target amount for the plan for the year, the Secretary will increase the total monthly payments made to the organization by 50 percent of the difference between 103 percent and allowable costs. If allowable costs for the plan are greater than 108 percent of the target amount, the Secretary will increase the total monthly payments to the plan by an amount equal to the sum of: (1) 2.5 percent of the target amount; and (2) 80 percent of the difference between allowable costs and 108 percent of the target. Conversely, if the allowable costs for the plan are less than 97 percent, but greater than or equal to 92 percent of the target amount, the Secretary will reduce the total monthly payment to the plan by 50 percent of the difference between 97 percent of the target amount and the allowable cost. If the allowable costs for the plan are below 92 percent of the target, the Secretary will reduce the total monthly payments to the organization by the sum of: (1) 2.5 percent of the target amount, and (2) 80 percent of the difference between 92 percent of the target and the allowable cost.

[§1854(c)(3)]. Each contract under the MA program will provide the information the Secretary deems necessary to carry out this subsection. While the Secretary has the right to inspect and audit all books and records pertaining to information provided under this section, the information disclosed or obtained may only be used to carry out this section.

Organizational and Financial Requirements

[§1854(d)]. In order to facilitate the offering of MA plans in regions that may encompass multiple states, the conference agreement establishes rules for applying licensing requirements across states. If an MA organization offering an MA regional plan is organized and licensed under State law in a state in the region but does not meet the requirements in other states in the region, the Secretary may waive such requirement for an appropriate period of time. Such a waiver can only be granted if the organization demonstrates to the Secretary's satisfaction that it has filed the necessary application to meet the other state's requirements. If an MA organization is organized and licensed under more than one state in the region, and the organization does not meet the requirements of each state, the organization may select the rules of one State and apply those rules to the entire service area until such time as the organization meets a state's requirements, in a manner specified by the Secretary.

Stabilization Fund

Present Law

No provision.

House Bill

No provision.

Senate Bill

Section 231. If an area was designated as highly competitive, benchmarks would not apply. Instead, a plan would bid the total payment it was willing to accept (not taking into account risk adjustment) for providing required Parts A and B benefits to plan enrollees residing in the service area. The Secretary would substitute the second lowest bid for the benchmark. If there were fewer than three bids, the Secretary would be required to substitute the lowest bid for the benchmark. Total funding for this provision is limited to $6 billion over 2009 through 2013.

Conference Agreement

Section 221(c). [§1858(e)]. During the past several years a number of plans have pulled out of the Medicare+Choice program due to changing market conditions and an inflexible payment formula. Plans were held to 2 percent annual payment increases while costs in the fee-for-service program were rising at a much faster rate. Under current law, the Secretary had no ability to respond quickly to these market changes, resulting in plan withdrawals which have affected millions of beneficiaries. In order to promote greater stability in the regional program and provide the Secretary with a tool to respond to market fluctuations, the conference agreement establishes an MA Regional Plan Stabilization Fund. The Fund can be used to provide incentives for plan entry in each region and plan retention in MA regions with below- average MA penetration. Initially, $10 billion will be available for expenditures from the Fund beginning on January 1, 2007 and these start-up funds will only be available until December 31, 2013. Funds will be drawn from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund in a proportion that reflects the relative weight that the benefits under Parts A and B represent of the actuarial value of the total benefit. Additional funds will be available in an amount equal to 12.5% of average per capita monthly savings from regional plans that bid below the benchmark. The additional funds will be deposited on a monthly basis into a special account in the Treasury.

The Fund is designed to allow the Secretary to respond to market conditions on a temporary basis. If the Fund is used for either plan entry or retention for 2 consecutive years, the Secretary must report to Congress on the underlying market conditions in the regions. These reports will give Congress time to respond to the market conditions through changes to the regions or the underlying payment system.

[§1858(e)(2)]. The funds will be available in advance of appropriations to MA regional plans in accordance with specified funding limitations. [§1854(e)(5)]. The total amount projected to be expended from the Fund in any year may not exceed the amount available in the Fund as of the first day of that year. If the use of the stabilization fund results in increased expenditures under this title, the increased expenditures shall be counted as expenditures from the Fund. The Secretary will only obligate funds if the Secretary, the Chief Actuary of CMS, and the appropriate budget officer certifies that there are sufficient funds at the beginning of the year to cover all such obligations for that year. The Secretary will take steps to ensure that sufficient funds are available to make such payments for the entire year, which may include computing additional payment amounts or limitations on enrollment in MA regional plans receiving such payments. [§1858(e)(2)(D)]. Expenditures from the Fund will first be made from amounts made available from the initial funding.

[§1858(e)(3)]. Plan entry incentives are available for either a one-year national bonus payment or multi-year adjustments in regional payments; however in no case can

there be a regional payment adjustment if there is a national bonus for that year. In order to encourage the offering of plans in all regions, the national bonus payment will be available to an MA organization that elects to offer a regional plan in each MA region in a year, but only if one of the regions did not have a plan available in the previous year. Funding is only available for a single year, but more than one organization can receive the incentive in the same year. The national bonus payment will: (1) be available to an organization only if it offers plans in every MA region; (2) be available to all MA regional plans of the organization regardless of whether any other MA regional plan is offered in any region; and (3) be equal to 3 percent of the benchmark amount otherwise applicable for each MA regional plan offered by the organization, subject to funding limitations.

[§1858(e)(3)]. If a national bonus payment is not made, a regional payment adjustment can be made. The regional payment adjustment is an increased payment for an MA regional plan offered in an MA region that did not have any MA regional plans offered in the previous year. The Secretary will determine the adjusted payment amount based solely on plans' bids in the region, and the adjusted payment amount will be available to all plans offered in the region. The amount can be based on the mean, mode, median or other measure of such bids and may vary from region to region, but the payment amount cannot be determined through a method that limits the number of plans or bids in the region. Such a payment adjustment will be treated as a change to the benchmark amount in that region for purposes of calculating individual plan payments and beneficiary rebates.

[§1858(e)(3)(C)(ii)]. Subject to funding limitations, the Secretary will determine the period of time that funds are available for regional payment changes to encourage plan entry. If funding will be provided for a second consecutive year under this provision, the Secretary is required to submit a report to Congress describing the underlying market dynamics in the region and recommending changes to the payment methodology. Multi-year funding may be made available to all MA plans offered in a region. If this multi-year increased amount is made available to MA plans in a region, funding will not be available for plan retention in the region in the following year. Regional payment adjustments will not be taken into account when computing the underlying benchmark for the subsequent year.

[§1858(e)(4)]. In addition to using the Fund to encourage plans to enter regions that might otherwise go unserved, the Secretary may also use the fund to encourage plans to remain in regions if market conditions are causing plan withdrawals. Incentives for plan retention could take the form of an increased payment to plans in regions that meet specific requirements. The requirements are: (1) one or more plans inform the Secretary that they will discontinue service in the region in the succeeding year; (2) the Secretary determines that if those plans were not offered, fewer than 2 MA regional plans, each offered by a different organization, would be offered in the region in the year; (3) for the previous year, the Secretary determines that the proportion of beneficiaries enrolled in MA regional plans in the region is less than national average of MA regional plan enrollment; (4) funds have not already been awarded for 2 consecutive years. Any additional payment amount will be treated as if it were an addition to the benchmark amount otherwise applicable, but will not be taken into account in the computation of the benchmark for any subsequent year. If plans receive funding under this part for a second year, the Secretary will submit a report to Congress that describes the underlying market dynamics in the region and includes recommendations concerning changes in the payment methodology otherwise provided for MA regional plans under this part.

[§1858(e)(4)]. The incentive for plan retention payment will be an amount determined by the Secretary, that does not exceed the greater of: (1) 3 percent of the benchmark amount applicable in the region; or (2) an amount that, when added to the benchmark, results in a ratio such that the additional amount plus the benchmark for the region divided by the adjusted average per capita cost (AAPCC) equals the weighted average of benchmarks for all regions divided by the AAPCC for the United States.

[§1858(e)(6)]. Not later than April 1 of each year beginning in 2008, the Secretary will submit a report to Congress and the Comptroller General of the United States that includes: (1) a detailed description of the total amount expended as a result of the Stabilization Fund in the previous year (and the projections for the current year) compared to the total amount that would have been expended under this title in each year if this subsection had not been enacted; (2) amounts remaining within the funding limitations; and (3) the steps the Secretary will take to ensure that the expenditures from the Stabilization Fund will not exceed the amount available. The report will include certification from the Chief Actuary of CMS that estimates are reasonable, accurate and based on generally accepted actuarial principles and methodologies.

[§1858(e)(7)]. Not later than January 1 of 2009, 2011, 2013 and 2015, the Comptroller General of the United States will submit a report to the Secretary and Congress on the application of payments from the Stabilization Fund. The reports will include an evaluation of: (1) the quality of care provided to individuals for which additional payments were made from the Stabilization Fund; (2) beneficiary satisfaction; (3) the cost of Stabilization Fund payments to the Medicare program; and (4) any improvements in service delivery. The report will also include a comparative analysis of the performance of MA regional plans receiving payments to MA regional plans not receiving Stabilization Fund payments, and recommendations for legislation or administrative action as the Comptroller General determines would be appropriate.

Regional Blended Benchmark

Present Law

Under current law, Medicare+Choice (M+C) plans are paid an administered monthly payment, called the M+C payment rate, for each enrollee. The per capita rate for a payment area is set at the highest of three amounts: (1) a minimum payment (or floor) rate, (2) a rate calculated as a blend of an area-specific (local) rate and a national rate, or (3) a rate reflecting a minimum increase from the previous year's rate (currently 2%). In general, the Secretary makes monthly payments for each M+C enrollee reduced by any Part B premium reduction, and adjusted for risk.

House Bill

Section 201. [§1860E–3(b)]. The EFFS region-specific non-drug monthly benchmark amount means an amount equal to 1/12 of the average (weighted by the number of EFFS eligible individuals in each local payment area in the region) of the annual MA payment rate for payment areas within the region.

Senate Bill

Section 211. [§1858(c)(2)]. Beginning in 2006, the Secretary would calculate a benchmark amount for required services for each region equal to the average of each benchmark amount for each MA payment area within the region, weighted by the number of MA eligible individuals residing in the payment area for the year. Each year, beginning in 2005, the Secretary would publish (at the time of publication of the risk adjustors under Part D—no later than April 15) the benchmark amount for each region, factors to be used for adjusting payments under the comprehensive risk adjustment methodology and methodology used for adjustments for geographic variations within a region.

Conference Agreement

Section 221(c). [§1854(f)]. Beginning in 2006, the Secretary will compute a ''blended benchmark'' amount for each MA region. The blended benchmark is designed to be responsive to market conditions in the region by allowing plan bids to influence the final benchmark amount. The MA region-specific non-drug monthly benchmark amount is defined as the sum of a statutory component and a plan-bid component for the year. The statutory component is the product of the statutory region-specific non-drug amount for the region and the year, and the statutory national market share percentage. The statutory region-specific non-drug amount, the first part of the statutory component, is an amount equal to the sum, (for each local MA area within the region) of the product of the MA area-specific non-drug monthly benchmark amount for the area and the year, and the number of MA eligible individuals residing in the local area, divided by the total number of MA eligible individuals residing in the region. The statutory national market share percentage, the second part of the statutory component, is equal to the proportion of MA eligible individuals nationally who were not enrolled in an MA plan during the most recent month during the previous year for which data are available.

The plan-bid component is the product of the weighted average of MA plan bids for the region and the year and the non-statutory market share percentage. The weighted average of plan bids for an MA region is calculated as the sum across MA regional plans, of (for each plan) the products of the unadjusted MA statutory non-drug monthly bid for the plan, and the plan's share of MA enrollment in the region. Or, in the first year in which any regional plan is offered in a region, if more than one MA regional plan is offered in that year, the plan's share of MA enrollment in the region is replaced in the formula either by (1) one divided by the number of plans in the region, or (2) a share estimated by the Secretary. The non-statutory market share percentage is one minus the statutory national market share percentage.

Uniform Coverage Determination

Present Law

An M+C organization may elect to have a single local coverage policy apply to its plan when the plan's service area includes more than one local coverage policy area. The Secretary will identify the local coverage policy that is most beneficial to M+C enrollees.

House Bill

No provision.

Senate Bill

No provision.

Conference Agreement

Section 221(c). [§1854(g)]. The organization offering an MA regional plan may elect to have a local coverage determination for the entire MA plan based on the local coverage determination applied for any part of the region, as selected by the organization. These local coverage determination are may be appealed under the applicable provisions of section 1869(f) (BIPA, sec. 522).

Assurance of Network Adequacy

Present Law

An M+C organization may select the providers in its network, so long as: (1) the organization makes the benefits available and accessible to each individual within the service area with reasonable promptness and in a manner which assures continuity in the provision of benefits; (2) when medically necessary, the organization makes benefits available and accessible 24 hours a day and 7 days a week; and (3) the plan provides reimbursement for services provided outside of the network when services are medically necessary and immediately required, when the services are renal dialysis and the beneficiary is temporarily out of the plan's service area, or when the services are maintenance care or post-stabilization. The organization must provide access to appropriate providers including credentialed specialists, and must provide emergency services without regard to prior authorization.

House Bill

No provision.

Senate Bill

No provision.

Conference Agreement

Section 221(c). [§1854(h)]. All current law network adequacy requirements will remain in place under the new regional program. However, because regions may encompass areas served by a single hospital, plans may have difficulty meeting their network adequacy requirements if they are unable to reach an agreement with such a hospital. In order to facilitate the meeting of these network adequacy requirements across large regions, the conference agreement allows the Secretary to provide payment to an essential hospital that provides services to enrollees in an area, in cases in which the MA organization offering the plan was unable to reach an agreement with the hospital regarding provision of services to plan enrollees. The Secretary will make the plan payment available only if the organization makes satisfactory assurances to the Secretary that it will pay the hospital an amount not less than the Medicare Part A payment for such services, and, with respect to specific services provided to an enrollee, the hospital demonstrates that its costs exceed the Medicare Part A payment. The agreement makes $25 million available in 2006, increased each year by the growth in the market basket percentage. Subject to that limit, the payment, if any, would be the amount by which the payment for inpatient hospital services if the hospital were a critical access hospital exceeds the payment for the same service that the hospital would otherwise receive. An essential hospital would be defined as a general acute care hospital that demonstrates to the Secretary that its costs exceed the Medicare Part A payment and is determined by the Secretary to be necessary for the plan to meet its network adequacy requirements.

Section 222. Competition program beginning in 2006

Submission of bidding and rebate information

Present Law

Under current law, Medicare+Choice (M+C) plans are paid an administered monthly payment, called the M+C payment rate, for each enrollee. The per capita rate for a payment area is set at the highest of three amounts: (1) a minimum payment (or floor) rate, (2) a rate calculated as a blend of an area-specific (local) rate and a national rate, or (3) a rate reflecting a minimum increase from the previous year's rate (currently 2%). In general, the Secretary makes monthly payments for each M+C enrollee, reduced by any Part B premium reduction, and adjusted for risk.

Each year a coordinated care plan of an M+C organization submits an adjusted community rate (ACR) proposal, estimating its proposed cost to serve Medicare beneficiaries for the following contract year and comparing such costs to the estimated costs of providing Medicare services to a commercial population. To the extent that a plan's ACR is below the administered payment amount, the plan must provide additional benefits to its enrollees or reductions in the Part B premium. In submitting its proposal, the organization must include information on: (1) the ACR; (2) the M+C monthly basic beneficiary premium; (3) a description of the deductible, coinsurance and copayments under the plan (including the actuarial value of each); and (4) a description of any required additional benefits. For supplemental benefits, the organization must also include: (1) the ACR, (2) the M+C monthly supplemental beneficiary premium, and (3) a description of the deductible, coinsurance and copayments, including the actuarial value of each.

House Bill

Section 221(a). Beginning in 2006, an MA organization would be required to provide the following information: (1) the monthly bid amount for the provision of all required items and services, based on average costs for a typical enrollee residing in the area and the actuarial bases for determining such amount; (2) the proportion of the bid attributed to the provision of statutory non-drug benefits (the ''unadjusted MA statutory non-drug monthly bid'' amount), statutory prescription drug benefits, and non-statutory benefits (including the actuarial basis for determining these proportions); and (3) additional information as the Administrator may require.

Senate Bill

Section 204. [§1854(a)]. Each MA organization would be required to submit information by the second Monday in September, including: (1) notice of intent and information on the service area of the plan; (2) the plan type for each plan; (3) specific information for coordinated care and PFFS plans; (4) enrollment capacity; (5) the expected mix of enrollees, by health status; and (6) other information specified by the Secretary. For coordinated care plans and PFFS plans, the plans would also be required to submit the plan bid (the total amount that the plan was willing to accept for required Parts A and B benefits not taking into account the application of comprehensive risk adjustment), the assumptions used in preparing the bid with respect to the number of enrollees in each payment area and the mix by health status, and any required information for prescription drug coverage. The plan bid would also have to be based on actuarial equivalence.

For any enhanced medical benefit package a plan chooses to offer, it would be required to provide the following information: (1) the ACR, (2) the portion of the actuarial value of such benefits package, if any, that would be applied toward satisfying the requirement for additional benefits, (3) the MA monthly beneficiary premium for enhanced benefits, (4) cost-sharing requirements, (5) the description of whether the unified deductible had been lowered or if the maximum out-of-pocket limitation had been decreased, and (6) other information required by the Secretary.

[§1854(a)(5)]. Each plan bid would be required to reasonably and equitably reflect the cost of benefits provided under that plan.

Conference Agreement

Section 222(a). Under the current Medicare+Choice system, plans are paid a fixed administrative amount regardless of their efficiency or their actual costs of providing services to the Medicare population. Beginning in 2006, an MA organization (other than an MSA) will be required to submit a bid to provide services to Medicare beneficiaries on either a local or a regional level. In submitting its bid, the plan will provide the following information: (1) the monthly aggregate bid amount for the provision of all required items and services, based on average revenue requirements (as applied under Title XIII of the Public Health Service Act for Health Maintenance Organizations) in the payment area for an enrollee with a national average risk profile (including demographic risk factors and health status); (2) the proportion of the bid attributable to the provision of benefits under the original Medicare fee-for-service program, basic prescription drug coverage, and supplemental health care benefits; (3) the actuarial basis for determining the amounts and proportions, and additional information as the Secretary may require to verify such actuarial basis; (4) a description of deductibles, coinsurance and copayments applicable under the plan and their actuarial value; and (5) for qualified prescription drug coverage, the information required under Title I of this Act. In order to facilitate regional plans being offered in more than one MA region, the Secretary will establish procedures to reduce paperwork for bids in multiple regions. Use of the term ''required revenue'' is intended to make clear that the bids of health plans incorporate all their revenue needs, both the medical costs of providing benefits and associated administrative costs (including profits or retained earnings).

The changes made in the bidding process under Part C do not apply to PACE programs, which operate outside of Part C. However, if they wish to offer qualified prescription drug coverage, they will be treated as a MA–PD local plan and must submit a bid for drug coverage.

Plan bids for supplemental benefits, for which plans charge a premium may include reductions in the cost sharing that would otherwise apply under the plan for Part A and B services. Benefits in each of the three areas (A/B benefits, prescription drug benefits, and supplemental benefits) will be integrated together in a way that is seamless to the beneficiary and paid for through a single premium.

Acceptance and Negotiation of Bid Amounts

Present Law

The Secretary reviews the information submitted by plans and approves or disapproves the premiums, cost-sharing amounts, and benefits. The Secretary does not have the authority to review the premiums for either MSA plans or PFFS plans.

House Bill

Section 221(a)(3)(C). The Administrator would have the same authority to negotiate bid amounts that the Director of the Office of Personnel Management has with respect to the Federal Employee Health Benefits Plan. The Administrator could negotiate the bid amount and could also reject a bid amount or proportion of the bid, if it was not supported by the actuarial basis. PFFS plans would be exempt from this negotiation.

Senate Bill

Section 204(a)(5). Each bid amount would have to reasonable and equitably reflect the cost of benefits provided by the plan.

Conference Agreement

Section 222(a). The conference agreement provides the Secretary with the authority to negotiate the monthly bid amount and the proportions, including supplemental benefits. The Secretary has similar authority to negotiate bid amounts to that of the Director of the Office of Personnel Management with respect to the Federal Employees

Health Benefits Program. The Secretary may only accept such a bid amount and proportion if they are supported by the actuarial bases, and reasonably and equitably reflect the revenue requirement (as applied under Title XIII of the Public Health Service Act for Health Maintenance Organizations) of benefits provided under the plan. As under current law, the Secretary does not have the authority to review the bid amounts for PFFS plans.

The Secretary may not require: (1) any MA organization to contract with a particular hospital, physician, or other entity or individual to furnish items and services under this title; or (2) a particular price structure for payment under such a contract to the extent consistent with the Secretary's authority.

Benefits under the original Medicare fee-for-service program option

Present Law

M+C plans are required to include all Medicare-covered services (Parts A and B benefits) except hospice care. In some circumstances, plans may also be required to offer additional benefits or reduced cost-sharing to their beneficiaries. The basic benefit package includes all of the required Medicare-covered benefits (except hospice services) as well as the additional benefits, as determined by a formula which is set in law. The adjusted community rate (ACR) mechanism is the process through which health plans determine the minimum amount of additional benefits, if any, they are required to provide to Medicare enrollees and the cost-sharing they are permitted to charge for those benefits. Medicare does not have a catastrophic limit on beneficiary out-of-pocket expenses although some M+C plans offer an out-of-pocket limit as an added benefit. The original Medicare FFS program includes a Part B deductible and a separate Part A deductible for inpatient hospital stays.

House Bill

MA organizations, other than PFFS plans, will be required to offer at least one plan in their service area that provides drug coverage as outlined in Title I. However, if an organization offers one such plan with drug coverage, they may offer alternative plans without such drug coverage. MA plans would be required to pay rebates to beneficiaries—in the form of additional benefits, reduced premiums, or cash payments—to the extent that program payments to MA plans exceeded bid amounts. MA plans would also be able to offer supplemental benefits for additional premiums.

Senate Bill

Section 202. [§1852(a)]. In addition to offering Medicare Parts A and B benefits (except hospice) and any additional required benefits, each MA plan (except MSAs, and in the case of prescription drug coverage, PFFS plans) would be required to offer: (1) qualified prescription drug coverage under Part D to beneficiaries residing in the area, and (2) a maximum limitation on out-of-pocket expenses and a unified deductible.

[§1852(a)(7)]. The unified deductible would be defined as an annual deductible amount applied in lieu of the inpatient hospital deductible and the Part B deductible. This would not prevent an MA organization from requiring coinsurance or a copayment for inpatient hospital services, after the unified deductible was satisfied, subject to statutory limitations.

[§1852(a)(2)(D)]. A PFFS plan could choose not to offer qualified prescription drug coverage under part D. Beneficiaries enrolling in such a PFFS plan could choose to enroll in an eligible entity under part D to receive their prescription drug coverage. [§1852(d)(4)]. A PFFS plan entirely meeting the access requirement for a category of providers through contracts or agreements (other than deemed contracts) could require higher beneficiary co-payments for providers who did not have such contracts or agreements.

Conference Agreement

Section 222(a). Beginning in 2006, plan bids will be compared to a benchmark amount. For MA local plans, the benchmark amount will be the MA payment rates. For MA regional plans, the benchmark amount will be the regional blended benchmark. Plans that submit bids below the benchmark will be paid their bids, plus 75 percent of the difference between the benchmark and the bid, which must be returned to beneficiaries in the form of additional benefits or reduced premiums. For plans that bid above the benchmark the government will pay the benchmark amount, and the beneficiary will pay the difference between the benchmark and the bid amount as a premium. When for an MA regional plan, in determining the actuarially equivalent level of cost-sharing for required benefits, only expenses for in-network providers will be taken into account for the application of the catastrophic limit. Supplemental benefits can include reductions in cost-sharing for A and B benefits below the actuarial value of the deductible, coinsurance and copayments that would be applicable, on average, to individuals in the original fee-for-service program.

MA organizations, other than PFFS plans, will be required to offer at least one plan in their service area that provides drug coverage as outlined in Title I. However, if an organization offers one such plan with drug coverage, it may offer alternative plans without such drug coverage.

Beneficiary Savings

Present Law

To the extent that a plan's ACR is below the administered payment amount, plans must provide reduced cost-sharing, additional benefits, or reduced Part B premiums to their Medicare enrollees. Such benefits must be valued at 100 percent of the difference between the projected cost of providing Medicare-covered services to its commercial population and the expected revenue for Medicare enrollees. Plans can choose which additional benefits to offer, however, the total cost of these benefits must at least equal the ''savings'' from Medicare-covered services. Plans may also place the additional funds in a stabilization fund or return funds to the Treasury.

House Bill

Section 221(b). An MA plan would be required to provide an enrollee a monthly rebate that equaled 75 percent of any average per capita savings (the amount by which the risk-adjusted benchmark exceeded the risk-adjusted bid). The rebate could be: (1) credited toward the MA monthly supplemental beneficiary premium or the prescription drug premium; (2) paid directly to the beneficiary; (3) provided by another means approved by the Administrator; (4) or any combination of the above. The remaining 25 percent of the average per capita savings would be retained by the federal government.

Benchmarks would equal one-twelfth of the annual MA capitation rate for an enrollee in that area, and would be calculated by updating the previous year's capitation rate by the annual increase in the minimum percentage increase.

Senate Bill

[§1854(c)]. If the weighted service area benchmark exceeded the plan bid, the Secretary would require the plan to provide additional benefits, and if the plan bid exceeded the weighted service area benchmark, the plan could charge an MA monthly basic beneficiary premium equal to the amount the bid exceeded the benchmark.

Section 204. [§1854(g)]. If the plan bid was lower than the weighted service area benchmark, the plan could, in addition to benefits allowed under current law, also lower the amount of the unified deductible and decrease the maximum limitation on out-of-pocket expenses. However, plans would be restricted from specifying any additional benefits that provided for the coverage of any prescription drug, other than that relating to covered drugs under Part D.

Conference Agreement

Section 222(b). The conference agreement requires an MA plan to provide an enrollee with a monthly rebate equal to 75 percent of any average per capita savings (the amount by which the risk-adjusted benchmark exceeds the risk-adjusted bid). In calculating such savings, and in order to ensure that savings are uniform for all enrollees in a plan, the benchmark and the bid will be risk adjusted according to a statewide (for local plans) or region-wide (for regional plans) risk adjuster. Alternatively, the Secretary has the discretion to risk adjust the benchmark and bid on a plan-specific basis for the purpose of calculating such savings. The beneficiary rebate can be credited toward the provision of supplemental health care benefits (including a reduction in cost-sharing, additional benefits or a credit toward any MA monthly supplemental beneficiary premium), the prescription drug premium, or the Part B premium. The plan will inform the Secretary about the form and amount of the rebate, or the actuarial value, in the case of supplemental health care benefits. The remaining 25 percent of the average per capita savings will be retained by the federal government.

Revision of Premium Terminology

Present Law

The M+C monthly basic beneficiary premium is the amount authorized to be charged for the plan based on the application of the ''limitation on enrollee liability''. The ''limitation on enrollee liability'' requires that the actuarial value of the premium, deductibles, coinsurance, and copayments applicable on average to enrollees in an M+C plan for required services does not exceed the actuarial value of deductibles, coinsurance, and copayments on average for beneficiaries in traditional Medicare. However, this average may be achieved by having higher copayments for some M+C services and lower copayments for other services. The supplemental beneficiary premium is amount authorized to be charged for the plan, such that the actuarial value of supplemental beneficiary premium, deductibles, coinsurance, and copayments for such benefits does not exceed the ACR for such benefits. These requirements do not apply to PFFS plans.

House Bill

Section 221 (d). For plans with a bid amount below the benchmark, the basic premium would be zero. For plans with bids above the benchmark, the basic premium would be equal to the amount by which the bid exceeded the benchmark.

Senate Bill

Section 204. If the weighted service area benchmark exceeded the plan bid, the plan would have to provide additional benefits. If the bid exceeded the weighted service area benchmark, the amount of the excess would be the MA monthly basic beneficiary premium.

Conference Agreement

Section 222(b). For plans providing rebates (plans that bid below the benchmark), the MA monthly basic beneficiary premium will be zero. For plans with bids above the applicable benchmark, the MA monthly basic beneficiary premium will equal the amount by which the bid exceeds the benchmark. The MA monthly prescription drug beneficiary premium is the portion of the aggregate monthly bid amount that is attributable to the provision of prescription drug benefits under Title I of this Act, less the amount of any rebate. The MA monthly supplemental beneficiary premium is the portion of the aggregate monthly bid amount that is attributable to the provision of supplemental health care benefits, less the amount of any rebate. The unadjusted MA statutory non-drug monthly bid is the portion of the bid submitted by a plan attributable to the provision of required benefits under Medicare fee-for-service.

Collection of Premiums

Present Law

Medicare beneficiaries may have their Part B premiums deducted directly from their Social Security benefits.

House Bill

Section 221(b). Enrollees would be permitted to have their MA premiums deducted directly from their Social Security benefits or through an electronic funds transfer. The Administrator would be required to provide a mechanism whereby a beneficiary who joined an MA plan and elected Part D coverage through the plan would be able to pay one consolidated premium amount.

Senate Bill

No provision.

Conference Agreement

Section 222(c). The conference agreement allows enrollees to have their MA premiums deducted directly from their Social Security benefits, through an electronic funds transfer, or such other mean as specified by the Secretary, including payment by an employer or under employment-based retiree coverage on behalf of an employee, a former employee, or a dependent. All premium payments deducted from Social Security benefits will be credited to the appropriate Trust Fund as specified by the Secretary (in consultation with the Commissioner of Social Security and the Secretary of the Treasury) and shall be paid to the MA organization involved. The MA plan may not impose a charge for individuals electing to pay their premiums through a deduction from their Social Security payments.

For individuals electing to have premiums deducted directly from Social Security benefits, the Secretary will transmit to the Commissioner of Social Security, by the beginning of each year, the name, social security account number, consolidated monthly beneficiary premium owed by the enrollee for each month during the year, and other information determined appropriate by the Secretary. Information will be periodically updated throughout the year. The Secretary will be required to provide a mechanism for the consolidation of any MA monthly basic beneficiary premium, any MA monthly supplemental beneficiary premium, and any MA monthly prescription drug beneficiary premium.

Computation of MA Benchmark and Payments of Plans Based on Bid Amounts

Present Law

Under current law, Medicare+Choice (M+C) plans are paid an administered monthly payment, called the M+C payment rate, for each enrollee. The per capita rate for a payment area is set at the highest of three amounts: (1) a minimum payment (or floor) rate, (2) a rate calculated as a blend of an area-specific (local) rate and a national rate, or (3) a rate reflecting a minimum increase from the previous year's rate (currently 2%). In general, the Secretary makes monthly payments for each M+C enrollee, reduced by any Part B premium reduction, and adjusted for risk.

House Bill

Section 221(c). For payments before 2006, the monthly payment amount would equal 1/12 of the annual MA capitation rate, for an enrollee for that area, reduced by any Part B premium reduction and adjusted for risk factors such as age, disability status, gender, institutional status and other factors the Administrator determines to be appropriate, including an adjustment for health status.

Beginning in 2006, MA payment rates would be determined by the Administrator by comparing plan bids to the benchmark. Non-drug benefits: Beginning in 2006, for plans with bids below the benchmark, the payment would equal the unadjusted MA statutory non-drug monthly bid amount, with adjustments for demographic factors (including age, disability, and gender) and health status and the monthly rebate. Conversely, for plans with bids at or above the benchmark, the payment amount would equal the MA area-specific non-drug monthly benchmark amount, with the demographic and health status adjustments. Drug benefits: Additionally, for an MA enrollee who enrolled in Part D and elected prescription drug coverage through the plan, the plan's payment would include a direct and a reinsurance subsidy payment and reimbursement for premiums and cost-sharing reductions for certain low-income beneficiaries, as outlined in Title I of this bill.

Senate Bill

Section 203. [§1853(a)]. Each MA organization would receive a separate monthly payment for: (1) benefits under FFS Medicare Parts A and B, and (2) benefits under the prescription drug program, Part D. The Secretary would ensure that payments for each enrollee would equal the MA benchmark amount for the payment area, as adjusted. The adjustments would include both a risk adjustment and an adjustment based on the ratio of the payment amount to the weighted service area benchmark.

Section 203. [§1853(c&d)]. Beginning in 2006, payments to MA plans would be determined differently, based on a comparison between plan bids and the weighted service area benchmark. The Secretary would however, continue to calculate the annual M+C capitation rates.

Plans would submit bids to the Secretary by the second Monday in September.

The Secretary would calculate the benchmark amounts as the greater of the minimum amount (floor) or the local FFS rate for the area. The local FFS rate would be calculated similarly to the adjusted average per capita cost (AAPCC), adjusted to remove the costs of indirect and direct graduate medical education.

The Secretary would calculate the weighted service area benchmark amount equal to the weighted average of the benchmark amounts for required services for the payment areas included in the service area of the plan.

The Secretary would determine the difference between each plan's bid and the weighted service area benchmark amount. For plan bids that equal or exceed the weighted service area benchmark, the MA organization would be paid the weighted service area benchmark amount. For plan bids below the weighted service area benchmark, the plan would be paid the weighted service area benchmark reduced by the amount of any premium reduction elected by the plan. The Secretary would adjust payments using the comprehensive risk adjustment methodology.

Section 205. This provision would establish the additional payments that would be made to the MA plans for the prescription drug coverage under Part D.

Conference Agreement

Section 222(d). The conference agreement defines the term MA area-specific non-drug monthly benchmark amount, for a month in a year, for a service area that is entirely within an MA local area, as an amount equal to 1/12 of the annual MA capitation rate for the area. For a service area within more than one MA local area, the amount is equal to the average of the local amounts, weighted by the projected number of enrollees in the plan residing in the respective local area. For an MA region, the MA region-specific benchmark amount for the region for the year is defined as the sum of the statutory component and the plan-bid component. The statutory component is a weighted average of the local MA benchmarks in the region.

Section 222(e). For payments before 2006, the conference agreement sets the monthly payment amount to equal 1/12 of the annual MA capitation rate, for an enrollee for that area, reduced by any Part B premium reduction and adjusted for demographic factors such as age, disability status, gender, institutional status and other factors the Secretary determines to be appropriate, including an adjustment for health status.

Beginning in 2006, MA payment rates will be determined by the Secretary by comparing plan bids to the benchmark. Non-drug benefits: Beginning in 2006, for plans with bids below the benchmark, the payment will equal the unadjusted MA statutory non-drug monthly bid amount, with adjustments for demographic factors (including age, disability, and gender) and health status, adjustments for intra-regional variation (if applicable), adjustments relating to risk adjustment, and the monthly rebate. To adjust for intra-regional variation, the Secretary will adjust the amounts to take into account variation in MA local payment rates among the different MA local areas included in a region. For adjustments relating to risk, the Secretary will adjust payments to MA plans to ensure that the sum of the monthly payment and any basic beneficiary premium equals the unadjusted MA statutory non-drug monthly bid amount, with demographic adjustments, and for an MA regional plan, adjustments for intra-regional variations. For plans with bids at or above the benchmark, the payment amount will equal the MA area-specific non-drug monthly benchmark amount, with the demographic and health status adjustments, adjustments for intra-regional variation (if applicable), and adjustments relating to risk adjustment. The use of a risk adjustment methodology that uses demographic factors and health status factors will continue as under current law, and the Secretary will continue to have the flexibility to develop and implement new risk adjustment methodologies. Drug benefits: Additionally, for an MA enrollee in an MA–PD plan, the plan's payment will include a subsidy payment and reimbursement for premiums and cost-sharing reductions for certain low-income beneficiaries, as outlined in Title I of this bill.

In the case of an MSA plan, the payment equals the MA area-specific non-drug monthly benchmark amount, adjusted for demographics and health status.

Annual Announcement Process

Present Law

The Secretary annually determines and announces, no later than May 1 for 2003 and

2004 and March 1, thereafter (for the following year), the annual M+C capitation rate for each M+C payment area and the risk and other factors to be used in adjusting these rates.

House Bill

Section 221(e). For years before 2006, for the calendar year concerned, the Secretary would announce the annual MA capitation rate for each MA payment area for the year and the risk and other factors to be used to adjust these rates. Beginning in 2006, the Secretary would announce yearly the MA area-specific non-drug benchmark and the adjustment factors relating to demographics, end stage renal disease (ESRD), and health status in each MA plan in the area.

Senate Bill

Section 203. [§1853(a)]. Beginning April 15, 2005 (at the same time as risk adjusters for prescription drug coverage were announced), the Secretary would annually announce the benchmark for each MA payment area and the risk adjustment factors.

Conference Agreement

Section 222(f). For payments in 2005, the conference agreement requires the Secretary to determine and announce the MA capitation rates for each MA payment area for 2005, and the risk and other adjustment factors, by the 2nd Monday in May of 2004. For 2006 and subsequent years, the Secretary will determine and announce, not later than the 1st Monday in April before the calendar year concerned, the MA capitation rate for each payment area, and the risk and other factors to be used in adjusting such rates. The Secretary will determine and announce, on a timely basis before the calendar year concerned, for each MA region and MA regional plan for which a bid is submitted, the MA region-specific non-drug monthly benchmark amount.

Protection Against Beneficiary Selection

Present Law

The M+C monthly basic and supplemental beneficiary premium cannot vary among individuals enrolled in a the same plan.

House Bill

Section 221(d). The MA monthly bid amount, the MA monthly basic, prescription drug, and the supplemental beneficiary premium would not vary among enrollees in the plan. Additionally, the MA monthly MSA premium would not vary within an MSA plan.

Senate Bill

Section 204. The provision would establish the requirement that the MA monthly basic beneficiary premium, the MA monthly beneficiary obligation for qualified prescription drug coverage, and the MA monthly beneficiary premium for enhanced medical benefits could not vary among beneficiaries enrolled in the plan. Also, the MA MSA premium would not vary among beneficiaries enrolled in the MSA plan.

Conference Agreement

Section 222 (g). Except as permitted to facilitate the offering of MA plans under contracts between MA organizations and employers, labor organizations or the trustees to a fund established by one or more employers or labor organizations (as currently allowed under sec. 1857(i)), the MA monthly bid amount, the MA monthly basic, prescription drug, and the supplemental beneficiary premium may not vary among enrollees in the plan.

Adjusted Community Rates

Present Law

Each year an M+C organization submits an ACR proposal, estimating their proposed cost of serving Medicare beneficiaries for the following contract year as compared to the estimated cost of providing the same services to a commercial population. The ACR process is a mechanism through which health plans determine the minimum amount of additional benefits they are required to provide to Medicare enrollees and the cost-sharing they are permitted to charge for those benefits.

House Bill

Plan bids would replace ACRs beginning in 2006.

Senate Bill

No provision.

Conference Agreement

Plan bids will replace ACRs beginning in 2006.

Plan Incentives

Present Law

A M+C organization may not operate a physician incentive plan unless it meets the following requirements: (1) no specific payment is made directly or indirectly under the plan to a physician or physician group as an inducement to reduce or limit medically necessary services provided to an enrollee; or (2) if the plan places a physician or group at substantial financial risk, it must provide stop-loss protection and conduct periodic surveys of current and former enrollees to determine the degree of access and satisfaction with the quality of services. The organization must provide the Secretary with sufficient information regarding the plan, to determine whether or not the plan is in compliance with these requirements.

House Bill

No provision.

Senate Bill

No provision.

Conference Agreement

Section 222 (h). An MA organization may not operate a physician incentive plan unless it provides assurances satisfactory to the Secretary. Requirements that the organization: (1) conduct periodic surveys, and (2) provide the Secretary with sufficient information regarding the plan, to determine whether or not the plan is in compliance with these requirements are replaced. Instead, the plan must provide such information as the Secretary requires on any physician incentive plan.

Continuation of treatment of enrollees with End-Stage Renal Disease

Present Law

The Secretary established a separate rate of payment to an M+C organization for individuals with ESRD who are enrolled in an M+C plan.

House Bill

No provision.

Senate Bill

No provision.

Conference Agreement

Section 222 (i). The conference agreement requires payment rates to be actuarially equivalent to rates that would have been paid with respect to other enrollees in the MA payment area (or such other area as specified by the Secretary) under the provision of this section in effect before the enactment of this Act. The Secretary may apply the competitive bidding methodology of this section, with appropriate adjustments to account for the risk adjustment methodology applied to ESRD payments.

Facilitating employer participation

Present Law

Employers may sponsor an M+C plan or pay premiums for retirees who enroll in an M+C plan. If an M+C plan contracts with an employer group health plan (EGHP) that covers enrollees in an M+C plan, the enrollees must be provided the same benefits as all other enrollees in the M+C plan, with the EGHP benefits supplementing the M+C plan benefits. The Secretary may waive or modify requirements that hinder the ability of employer or union group health plans to offer an M+C plan option.

House Bill

No provision.

Senate Bill

Section 206. The Administrator could permit an MA plan to establish a separate premium amount for enrollees in an employer or other group health plan that provides employment-based retiree health coverage. This provision would also apply the current law requirements to regional PPOs.

Conference Agreement

Section 222(j). The conference agreement allows the Secretary to waive or modify requirements that hinder the design of, offering of, or enrollment in an MA plan offered by employers, labor organizations, or the trustees of a fund established by one or more employers or labor organizations (to furnish benefits to any combination of current or former employees, or current or former members of the labor organization.) The MA plan may restrict enrollment to individuals who are beneficiaries and participants in such a plan.

Expansion of Medicare Beneficiary Education and Information Campaign

Present Law

The Secretary is authorized to collect a user fee from each M+C organization for use in carrying out enrollment information dissemination activities for the program as well as the health insurance and counseling assistance program. The fee is based on the ratio of the organization's number of Medicare enrollees to the total number of Medicare beneficiaries. There are authorized to be appropriated $1 million each year, reduced by any fees collected by the Secretary, to carry out these activities.

House Bill

No provision.

Senate Bill

No provision.

Conference Agreement

Section 222(k). The conference agreement allows the Secretary to also charge a PDP sponsor under Part D for its share of fees related to enrollment information dissemination activities. The authorization for appropriated amounts will be increased to $2 million each year, beginning in 2006.

Protection against Beneficiary Selection

Present Law

No provision.

House Bill

Section 221(d). The Administrator would not approve a plan if benefits were designed to substantially discourage enrollment by certain MA eligible individuals.

Senate Bill

Section 204. [§1854(a)]. The Secretary could disapprove a plan bid if he or she determined that the deductibles, coinsurance or copayments discouraged access to covered services or were likely to result in favorable selection of MA eligible beneficiaries.

Conference Agreement

Section 222(l). The Secretary may not approve a plan if the design of the plan and its benefits are likely to substantially discourage enrollment by certain MA eligible individuals.

Section 223. Effective date.

Present Law

No provision.

House Bill

Section 211(e). The MA program would be effective January 1, 2004. Section 21(g). The competition program would be effective January 1, 2006.

Senate Bill

Section 209. Generally effective January 1, 2006. However, the Secretary would apply payment and other rules for MSA plans, as if this title had not been enacted.

Conference Agreement

The conference agreement makes the amendments of Title II effective for plan years beginning on or after January 1, 2006, unless otherwise provided. The Secretary shall revise previously promulgated regulations for the changes due to the provisions of this Act, to carry out Part C of Medicare.

Subtitle D—Additional Reforms

Section 231. Specialized MA plans for special needs beneficiaries

Present Law

One model for providing a specialized M+C plan, EverCare, operates as a demonstration program. EverCare is designed to study the effectiveness of managing acute-care needs of nursing home residents by pairing physicians and geriatric nurse practitioners. EverCare receives a fixed capitated payment, based on a percentage of the AAPCC, for all nursing home resident Medicare enrollees.

House Bill

Section 233. A new MA option would be established—specialized MA plans for special needs beneficiaries (such as the EverCare demonstration). Special needs beneficiaries are defined as those MA eligible beneficiaries who were institutionalized, entitled to Medicaid, or met requirements determined by the Administrator. Enrollment in specialized MA plans could be limited to special needs beneficiaries until January 1, 2007. Interim final regulations would be required within 6 months of enactment. The Secretary would be permitted to offer specialized MA plans for plans that disproportionately serve beneficiaries with special needs who are the frail elderly. No later than December 31, 2005, the Administrator would be required to submit a report to Congress that assessed the impact of specialized MA plans for special needs beneficiaries on the cost and quality of services provided to enrollees.

Senate Bill

Section 222. A new M+C option would be established—specialized M+C plans for special needs beneficiaries (such as the EverCare demonstration). Special needs beneficiaries are defined as those M+C eligible beneficiaries who were institutionalized, entitled to Medicaid, or met requirements determined by the Secretary. Enrollment in specialized M+C plans could be limited to special needs beneficiaries until January 1, 2008. No later than December 31, 2006, the Secretary would be required to submit a report to Congress that assessed the impact of specialized M+C plans for special needs beneficiaries on the cost and quality of services provided to enrollees. No later than 1 year after enactment of this Act, the Secretary would be required to issue final regulations to establish requirements for special needs beneficiaries.

Conference Agreement

Section 231. The establishment of a specialized plan designation provides health plans the authority and incentives to develop targeted clinical programs to more effectively care for high-risk beneficiaries who have multiple chronic conditions or have complex medical problems. This provision designates two specific segments of the Medicare population as special needs beneficiaries, but also provides the Secretary the authority to designate other chronically ill or disabled beneficiaries as ''special needs beneficiaries'' to allow plans to serve additional high risk groups who would benefit from enrollment in plans that offer targeted geriatric approaches and innovations in chronic illness care. The Secretary should consider Medicare demonstrations for guidance regarding other potential special needs beneficiary designations.

The provision would establish a new Medicare Advantage option—Specialized Medicare Advantage plans for Special Needs Beneficiaries. Specialized Medicare Advantage plans are plans that exclusively serve special needs beneficiaries such as the Evercare and Wisconsin Partnership demonstrations and, at the discretion of the Secretary, those that serve a disproportionate number of such beneficiaries. Special needs beneficiaries are defined as Medicare Advantage enrollees who are institutionalized, or entitled to Medicaid, or individuals with severe and disabling conditions that the Secretary deems would benefit from a specialized plan. Specialized Medicare Advantage plans can limit enrollment to special needs beneficiaries until January 1, 2009. No later than 1 year after enactment of this act, the Secretary is required to issue final regulations to establish requirements for special needs beneficiaries. No later than December 31, 2007, the Secretary is required to submit a report to Congress that assesses the impact of Specialized Medicare Advantage plans on the cost and quality of care. The provision does not change current Medicare+Choice quality, oversight or payment rules.

The legislation also allows the Secretary to define as Specialized Medicare Advantage plans those that ''disproportionately'' serve special needs beneficiaries. Since there is no existing standard for measuring ''disproportionate,'' the provision gives the Secretary discretion in promulgating this part of the regulation with a view toward establishing quantitative criteria for defining ''disproportionate.'' The Secretary may identify such means of measuring ''disproportionate'' as are feasible to capture appropriate risk levels for designation as a ''Specialized Medicare Advantage Plan for Special Needs Beneficiaries.'' The Secretary may wish to require further validation that ''disproportionate'' plans are 'specialized'' by requiring evidence of processes or clinical programs designed to address the unique needs of the special needs beneficiaries served.

Section 232. Avoiding duplicative State regulation

Present Law

Medicare law currently preempts state law or regulation from applying to M+C plans to the extent they are inconsistent with federal requirements imposed on M+C plans, and specifically, relating to benefit requirements, the inclusion or treatment of providers, and coverage determinations (including related appeals and grievance processes).

House Bill

Section 232. Federal standards established by this legislation would supersede any state law or regulation (other than state licensure laws and state laws relating to plan solvency), with respect to MA plans offered by MA organizations.

Senate Bill

No provision.

Conference Agreement

Section 232. The conference agreement clarifies that the MA program is a federal program operated under Federal rules. State laws, do not, and should not apply, with the exception of state licensing laws or state laws related to plan solvency. There has been some confusion in recent court cases. This provision would apply prospectively; thus, it would not affect previous and ongoing litigation.

Additionally, no state may impose a premium, or similar, tax on premiums paid to MA organizations under this bill.

Section 233. Medicare Medical Savings Accounts (MSAs)

Present Law

BBA1997 authorized a demonstration for M+C MSAs. The M+C option combined a high-deductible health insurance plan with an M+C MSA. New enrollment was not allowed after January 1, 2003 or after the number of enrollees reached 390,000. No private plans have established an M+C MSA for Medicare beneficiaries. M+C plans (including MSAs) must have an ongoing quality assurance program for health care services provided to Medicare beneficiaries. The required elements of the program are specified in statute.

House Bill

Section 234. The requirement that MSAs report on enrollee encounters for an ongoing quality assurance program would be eliminated because MSAs are not plans but bank accounts. The Medicare MSA demonstration would be made a permanent option, the capacity limit would be removed and the deadline for enrollment would be eliminated. Non-contract providers furnishing services to enrollees of MSAs will be subject to the same balanced billing limitations as non-contract providers furnishing services to enrollees of coordinated care plans.

Senate Bill

Section 201. The deadline for enrollment in an MSA would be extended until December 31, 2003.

Conference Agreement

Section 233. Medicare MSAs are not being offered in the Medicare program today, despite the legislative authority granted in 1997 and despite the fact that non-Medicare MSAs are being offered. The Medicare MSA demonstration will be made a permanent option, the capacity limit will be removed and the deadline for enrollment will be eliminated. The requirement that MSAs report on enrollee encounters for an ongoing quality assurance program would be eliminated because MSAs are not plans but bank accounts. Non-contract providers furnishing services to enrollees of MSAs will be subject to the same balanced billing limitations as non-contract providers furnishing services to enrollees of coordinated care plans. The Conferees hope to encourage this additional choice for seniors through these changes.

Section 234. Extension of reasonable cost contracts

Present Law

Cost-based plans are those plans that are reimbursed by Medicare for the actual cost of furnishing covered services to Medicare beneficiaries, less the estimated value of beneficiary cost-sharing. The Secretary cannot extend or renew a reasonable cost reimbursement contract for any period beyond December 31, 2004.

House Bill

Section 235. Reasonable cost contracts could be extended or renewed indefinitely, with an exception that would begin in 2008. Beginning January 1, 2008, cost contracts could not be continued if during the entire previous year, the service area had two or more coordinated care MA plans or two or more EFFS plans, each of which met the following minimum enrollment requirements:

(1) at least 5,000 enrollees for the portion of the area that is within a metropolitan statistical area having more than 250,000 people and counties contiguous to such an area, and (2) at least 1,500 enrollees for any other portion of such area.

Senate Bill

Section 221. Reasonable cost contracts could be extended or renewed until December 31, 2009. Beginning in 2004, these plans would have to comply with certain requirements of the M+C program (and beginning in 2006 the MA program), including ongoing quality assurance programs, physician incentive plan limitations, uniform premium amount requirements, premium tax restrictions, federal preemption, authority of an organization to include supplemental health care benefits, benefit filling deadlines, contract renewals and beneficiary notifications, and proposed cost-sharing subject to the Secretary's review.

The Secretary would be required to approve a new application for a group practice HMO to enter into a reasonable cost contract if the group met certain requirements of the Public Health Service Act. The requirements would be that the group practice HMO, as of January 1, 2004, provided at least 85% of the services of a physician (which are provided as basic health services) through a medical group (or groups), and met other requirements for such entities specified in statute.

Conference Agreement

Section 234. The conference agreement ends the uncertainty about the continuation of cost contracts, allowing these plans to operate indefinitely, unless two other plans of the same type (i.e., either 2 local or 2 regional plans) enter the cost contract's service area. These other plans must meet the following minimum enrollment requirements: (1) at least 5,000 enrollees for the portion of the area that is within a metropolitan statistical area having more than 250,000 people and counties contiguous to such an area, and (2) at least 1,500 enrollees for any other portion of such area. The Conferees believe that if other private plans are willing to enter the cost contract's service area, then the cost contract should be required to operate under the same provisions as these other private plans.

Section 235. 2-year extension of Municipal Health Service demonstration projects

Present Law

The Municipal Health Services Demonstration Project operates in four cities. These cities use their existing public health programs as the nucleus of a coordinated system to provide community-based health care for the underserved urban poor. The project provides comprehensive health services, including a prescription drug benefit and dental services.

BBA 97 extended the program through 2000. The BBRA extended it through 2002, and the BIPA extended it through December 31, 2004.

House Bill

Section 236. Demonstration projects would be extended through December 31, 2009, for beneficiaries who reside in the city in which the project is operated.

Senate Bill

Section 618. Demonstration projects would be extended through December 31, 2006, for beneficiaries who reside in the city in which the project is operated.

Conference Agreement

Section 235. The conference agreement extends demonstration projects through December 31, 2006, for beneficiaries who reside in the city in which the project is operated.

Section 236. Payment by Program of All-Inclusive Care for the Elderly (PACE) providers for Medicare and Medicaid services furnished by non-contract providers

Present Law

PACE was created as a demonstration project in the Omnibus Budget Reconciliation Act (OBRA 86). The Secretary was required to grant waivers of certain Medicare and Medicaid requirements to a maximum of 10 (expanded to 15 in OBRA90) community-based organizations to provide health and long-term care services on a capitated basis to frail elderly persons at risk of being institutionalized. The Balanced Budget Act 97 (BBA97) made PACE a permanent part of Medicare and a state option for the Medicaid program.

House Bill

No provision.

Senate Bill

Section 223. For the Medicare program, protections against balance billing to PACE providers and beneficiaries enrolled with such PACE providers would apply in the same manner as applies to M+C. For the Medicaid program, with respect to services covered under the State plan (but not under Medicare) that were furnished to a beneficiary enrolled in a PACE program, the PACE program would not be required to pay a provider an amount greater than required under the state plan.

Conference Agreement

Section 236. For the Medicare program, protections against balance billing to PACE providers and beneficiaries enrolled with such PACE providers apply in the same manner as applies to M+C (MA). For the Medicaid program, with respect to services covered under the State plan (but not under Medicare) that are furnished to a beneficiary enrolled in a PACE program, the PACE program is not required to pay a provider an amount greater than required under the state plan.

Section 237. Reimbursement for Federally Qualified Health Centers (FQHCs) providing services under MA plans

Present Law

Services provided by FQHCs to Medicare enrollees are reimbursed at no more than 80% of the reasonable costs of providing such services less any beneficiary cost sharing amounts collected.

People who knowingly and willfully offer or pay a kickback, a bribe, or rebate to directly or indirectly induce referrals or the provision of services under a Federal program may be subject to financial penalties and imprisonment. Certain exceptions or safe harbors that are not considered violations of the anti-kickback statute have been established.

House Bill

No provision.

Senate Bill

Section 615. FQHCs would receive a wrap-around payment for the reasonable costs of care provided to Medicare managed care patients served at such centers. The provision would raise reimbursements to FQHCs, so that when they are combined with M+C payments and cost-sharing payments from beneficiaries, they would equal 100% of the reasonable costs of providing such services.

This provision would extend the safe harbor to include any remuneration between a FQHC (or entity control by and FQHC) and an MA organization.

Conference Agreement

Section 237. FQHCs will receive a wrap-around payment for the reasonable costs of care provided to Medicare managed care patients served at such centers. The provision raises reimbursements to FQHCs, so that when they are combined with MA payments and cost-sharing payments from beneficiaries, they equal 100% of the reasonable costs of providing such services.

This provision extends the safe harbor to include any remuneration between a FQHC (or entity control by an FQHC) and an MA organization.

Section 238. Study of performance-based payment systems

Present Law

No provision.

House Bill

Section 237. The Secretary would request that the IOM conduct a study to review and evaluate public and private sector experiences in: (1) establishing performance measures and payment incentives under the Medicare program, and (2) linking performance to payment. The Secretary would also request that no later than 18 months after enactment, the Institute submit a report to the Secretary and the Congress that included a review and evaluation of incentives to encourage quality performance, as specified in the statute. The study would also examine how these measures and incentives might be applied in the Medicare MA, EFFS, and FFS programs. The report would include recommendations regarding appropriate performance measures for use in assessing and paying for quality and would identify options for updating performance measures.

Senate Bill

Section 224. Within 2 months of enactment, the Secretary would be required to enter into an arrangement with IOM to evaluate leading health care performance measures and options to implement policies that align performance with payment under the Medicare program. The information that would be catalogued, reviewed and evaluated by IOM would be specified in statute. A report would be due to the Secretary and the congressional committees of jurisdiction within 18 months of enactment. There would be $1 million authorized to be appropriated to conduct the evaluation and prepare the report.

Conference Agreement

Section 238. The conference agreement requires that within 2 months of enactment, the Secretary shall enter into an arrangement with IOM to evaluate leading health care performance measures in the public and private sectors and options to implement policies that align performance with payment under the Medicare program. The information examined by IOM includes the validity of leading health care performance measures, the success and utility of alternative performance incentive programs, and options to implement policy that aligns performance with payments. The Institute shall consult with MedPAC. A report is be due to the Secretary and the congressional committees of jurisdiction within 18 months of enactment. There will be authorized to be appropriated such sums as may be necessary to conduct the evaluation and prepare the report.

Subtitle E—Demonstration of Comparative Cost Adjustment

Establishment of Demonstration

Present Law

No provision.

House Bill

Section 241. Beginning in 2010, FEHBP-style competition would begin nationwide in competitive areas. Competitive areas would be defined as areas in which Medicare beneficiaries have access to two private plans—either two MA or two EFFS plans—along

with traditional FFS Medicare; and private plan enrollment in the area that is at least as great as private plan enrollment nationwide, or 20 percent, whichever is lower. Competitive MA (CMA) areas would be limited to metropolitan statistical areas, or areas with substantial numbers of MA enrollees. To be considered a competitive area, the two private plans must be offered during the open season by different organizations, each meeting minimum enrollment requirements as of March of the previous year.

In competitive areas, private plans would submit bids and traditional FFS would calculate FFS amounts, based on the adjusted average per capita cost (AAPCC) in the area or region. The AAPCC would be adjusted to remove costs associated with direct graduate medical education, and to include costs of services provided to Medicare beneficiaries by the VA and DoD military facilities. In addition, payments would be adjusted for health status and other demographic factors.

The competitive benchmark would be set at the weighted average of the private plan bids and the FFS amount in the competitive area. In order to provide traditional FFS disproportionate influence in competitive areas, the weight of the benchmark for FFS would equal the nationwide proportion of Medicare beneficiaries enrolled in FFS, or the competitive area's proportion, if higher. The weights for all other private plans would equal the national proportion of beneficiaries enrolled in private plans, or the regional proportion if lower.

The competitive benchmark would be blended with the older, pre-2010 benchmark for the area over a 5-year period to allow for transition to a more competitive system.

Beneficiaries enrolling in plans with bids or FFS amounts below the competitive benchmark would receive 75 percent of the difference between the benchmark and bid/FFS amount, and the government would receive 25 percent of the difference. Beneficiaries enrolling in plans with bids/FFS amounts above the benchmark would pay the excess. Premium adjustments would be moderated over a 5-year period for beneficiaries remaining in traditional FFS in competitive areas. The traditional FFS beneficiary premium would be unaffected in non-competitive areas or regions.

Beginning in 2010, the MBA Administrator would announce the MA area-specific non-drug benchmark yearly. If applicable, the MBA Administrator would also announce, for the year and CMA area: the competitive MA non-drug benchmark; the national FFS market share percentage; the demographic, end-stage renal disease, and health status adjustment factors; the MA area-wide non-drug benchmark amount; the FFS area-specific non-drug amount; and MA enrollment.

To carry out this section, the MBA Administrator would transmit the name, social security number, and adjustment amount to the Commissioner of SSA at the beginning of each year and at periodic times throughout the year.

Senate Bill

No provision.

Conference Agreement

Section 241 [§1860 C–1]. In order to test whether direct competition between private plans and the original Medicare FFS program will enhance competition in Medicare, improve health care delivery for all Medicare beneficiaries, and provide for greater beneficiary savings and reductions in government costs, the conference agreement requires the Secretary to establish a demonstration for the application of comparative cost adjustment (CCA). The 6-year demonstration will begin on January 1, 2010. The first 4 years include a phase-in. Upon completion of the demonstration, the Secretary will submit a report to Congress that includes an evaluation of: (1) the financial impact on Medicare, (2) changes in access to physicians and other health care providers, and (3) beneficiary satisfaction under the demonstration and original Medicare fee-for-service. Based upon the results of the evaluation, the Secretary will provide recommendations for any extension or expansion of the demonstration. The demonstration cannot be extended unless there is a reauthorization from Congress.

Allowing for competition for enrollees, between private plans and original FFS Medicare, will level the playing field between all options available to Medicare beneficiaries. If traditional FFS Medicare is able to provide benefits at a lower cost than some or all private plans in a competitive area, then beneficiaries remaining in traditional FFS will see their premiums decline. In this case, beneficiaries enrolling in higher-cost private plans will be required to pay the extra price stemming from that decision. Likewise, if a private plan is able to offer Medicare beneficiaries coverage at a lower cost, then beneficiaries will be encouraged to enroll in the private plan by lowering the beneficiaries' costs of coverage under the private plan. In any case, beneficiaries will be entitled to the same defined benefit package and payments to plans will be fully adjusted for health and other demographic factors.

Without this stage of competition, private plans will have an incentive to shadow price their benchmarks. A floating benchmark rewards more efficient plans, and it allows these more efficient plans to lower the benchmark in future years, as their market share rises.

Several features were added in the Chairman's amendment in the nature of a substitute to allow for a smooth transition to a more competitive system in 2010 in competitive areas/regions, and to prevent shock to the current system. The competitive benchmark, based on private plan bids and traditional FFS rates, would be calculated based on the relative enrollment in FFS versus private plans nationwide (or the area/region if FFS enrollment is a larger proportion in the area/region). This feature ensures that the competitive benchmark is closer to the traditional FFS rate than would otherwise occur. Premium changes for beneficiaries remaining in traditional FFS in competitive areas would be phased-in over five years to prevent oscillations. In addition, the competitive benchmark would be phased-in over a 5-year period for private plans. This would allow for a more gradual change from the benchmarks under the pre-2010 system to the new competitive benchmark in competitive areas.

The Secretary will select CCA demonstration areas from among qualifying Metropolitan Statistical Areas (MSAs). To qualify, an MSA must have: (1) at least 25 percent of eligible Medicare beneficiaries enrolled in a local coordinated care MA plan; and (2) at least 2 coordinated MA local plans offered by different organizations, both of which meet minimum enrollment criteria. The total number of CCA areas may not exceed 6, or 25% of the total number of qualifying MSAs, whichever is lower.

To maximize the opportunity for a successful demonstration, the Secretary will select CCA demonstration areas to provide for geographic diversity and not seek to maximize the number of beneficiaries affected by the demonstration. At least one of the selected MSAs must be chosen from the 4 largest that qualify (based on the eligible MA population). At least one selected MSA must be chosen from among the 4 with the lowest population density. At least one must include a multi-State area. No more than 2 CCA areas may be located within the same geographic region. In addition, the Secretary will also grant priority to qualifying MSAs that have not had a Medicare preferred provider organization (PPO) plan demonstration.

In order to ensure that all beneficiaries residing in a CCA demonstration area have sufficient choice, a county within the MSA will be included only if it has at least 2 MA local coordinated care plans, each of which is offered by a different MA organization. An area will continue to be included as long as there is at least one MA local plan offered in the local area.

To minimize any possible disruption, the demonstration will be phased in over a four-year period between 2010 and 2013. Both the benchmark and changes to the Part B premiums under the original FFS program will be phased-in over this 4-year period.

In CCA areas, private plans would submit bids and traditional FFS would calculate FFS amounts, based on the adjusted average per capita cost (AAPCC) in the area or region. The AAPCC would be adjusted to remove costs associated with direct graduate medical education, and to include costs of services provided to Medicare beneficiaries by the VA and DoD military facilities. In addition, payments would be adjusted for health status and other demographic factors.

The CCA competitive benchmark would be set at the weighted average of the private plan bids and the FFS amount in the CCA area. In order to provide traditional FFS disproportionate influence in CCA areas, the weight of the benchmark for FFS would equal the nationwide proportion of Medicare beneficiaries enrolled in FFS, or the CCA area's proportion, if higher. The weights for all other private plans would equal the national proportion of beneficiaries enrolled in private plans, or the CCA proportion if lower.

The CCA competitive benchmark would be blended with the older, pre-2010 benchmark for the area over a 4-year period to allow for transition to a more competitive system.

Beneficiaries enrolling in plans with bids or FFS amounts below the CCA competitive benchmark would receive 75 percent of the difference between the benchmark and bid/FFS amount, and the government would receive 25 percent of the difference. Beneficiaries enrolling in plans with bids/FFS amounts above the benchmark would pay the excess. Premium adjustments would be moderated over a 4-year period for beneficiaries remaining in traditional FFS in CCA areas.

In order to test whether application of the CCA benchmark to the traditional FFS program will improve efficiency of the program, an individual residing in a CCA demonstration area who is enrolled in Part B of Medicare, but not enrolled in an MA plan, can have an adjustment to their Part B premium, either as an increase or a decrease. No premium adjustment would be made for individuals, for a month that they were eligible for a prescription drug subsidy, as defined in Title I of this Act. That is, individual with incomes below 150 percent of poverty and who also meet the assets requirements would continue to pay the Part B premium amount.

The Part B premium adjustment for FFS beneficiaries in CCA demonstration areas would be made as follows: (1) if the FFS area-specific non-drug amount for the month does not exceed the CCA non-drug benchmark, the Part B premium is reduced by 75% of the difference; and (2) if the FFS area-specific non-drug amount for the month exceeds the CCA non-drug benchmark, the Part B premium is increased by the full amount of the difference. This adjustment will be phased-in over 4 years. There is also a 5%

limit to the adjustment, irrespective of whether it is an increase or a decrease.

The premium adjustment will not affect any late enrollment penalties or income-related adjustments to the Part B premiums as established under Title VIII of this Act. The Secretary will transmit to the Commissioner of Social Security at the beginning of each year, the name, social security account number and the amount the any adjustment for each individual, and periodically through the year, update the information.

Nothing in the demonstration project in any way changes the entitlement to defined benefits under Parts A and B of the Medicare program. Throughout the demonstration, beneficiaries will have complete freedom to choose either a private plan or the traditional Medicare fee-for-service program.

Other Provisions

Expanding the work of Medicare Quality Improvement Organizations (QIOs) to include parts C and D

Present Law

QIOs, formerly known as Peer Review Organizations (PROs), are responsible for working with consumers, physicians, hospitals, and other care-givers to refine care delivery.

House Bill

No provision.

Senate Bill

Section 225. The responsibilities of the QIOs would be expanded to include M+C and MA organizations, prescription drug card sponsors, and eligible entities beginning January 1, 2004. Quality improvement assistance relating to prescription drug therapy would be provided to providers, practitioners, prescription drug card sponsors, eligible entities under Part D, M+C plans, and MA plans beginning January 1, 2004.

Conference Agreement

The conference agreement does not include this provision.

Extension of demonstration for end-stage renal disease (ESRD) managed care

Present Law

Medicare beneficiaries with ESRD cannot enroll in a managed care plan. If they develop ESRD while a member of a plan they can continue their enrollment in the plan. The Deficit Reduction Act of 1984 established a demonstration project for ESRD managed care, which was subsequently extended by the Omnibus Budget Reconciliation Act of 1993.

House Bill

No provision.

Senate Bill

Section 226. The Secretary would be required to extend the demonstration project for ESRD managed care through December 31, 2007. The terms and conditions in place during 2002 would apply. The monthly capitation rate for enrollees would be set based on the reasonable medical and direct administrative costs of providing the benefits to participants.

Conference Agreement

The conference agreement does not include this provision.

MA annual coordinated election period

Present Law

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, P.L. 107–188 changed the annual coordinated election period from the month of November to November 15th through December 31st in 2002, 2003, and 2004. Once the temporary provisions expired, the reporting dates and deadlines return to the pre-P.L.107–188 dates.

In addition, P.L. 107–188 continues to allow Medicare beneficiaries to make and change election to an M+C plan on an ongoing basis through 2004. Then beginning in 2005, individuals may only make changes on the more limited basis, originally scheduled to be phased in beginning in 2002. Since the beginning of the M+C program, beneficiaries have been able to make and change election to an M+C plan on an ongoing basis. Beginning in 2005, elections and changes to elections will be available on a more limited basis. Beneficiaries can make or change elections during the annual coordinated election period. Current Medicare beneficiaries may also change their election at any time during the first 6 months of 2005 (or first 3 months of any subsequent year). Additionally, there are special enrollment rules for newly eligible aged beneficiaries as well as special enrollment periods for all enrollees under limited situations, such as an enrollee who changes place of residence.

House Bill

Section 231. The annual coordinated election period would be permanently changed to November 15 through December 31.

Senate Bill

Section 201. [§1851(e)]. Medicare beneficiaries would retain their ability to make and change elections to an M+C plan through 2005. The current law limitation on changing elections that begins in 2005, would be delayed until 2006. Further, the annual coordinated election period for 2003 through 2006 would begin on November 15 and end on December 31. Beginning in 2007, the annual coordinated election period would be during the month of November.

[§1851(e)(3)]. Additionally, the Secretary would conduct a special information campaign to inform MA eligible beneficiaries about plans. The campaign would begin on November 15, 2005 and ending on December 31, 2005.

Conference Agreement

The conference agreement does not include this provision.

Cause for intermediate sanctions

Present Law

The Secretary is authorized to carry out specific remedies in the event that an M+C organization: (1) fails substantially to provide medically necessary items and services required to be provided, if the failure adversely affects the Medicare enrollee; (2) imposes premiums on enrollees that are in excess of those allowed; (3) acts to expel or refuses to re-enroll an enrollee in violation of Federal requirements; (4) engages in any practice that would have the effect of denying or discouraging enrollment (except as permitted by law) of eligible beneficiaries whose medical condition or history indicates a need for substantial future medical services; (5) misrepresents or falsifies information to the Secretary or others; (6) fails to comply with rules regarding physician participation; or (7) employs or contracts with any individual or entity that has been excluded from participation in Medicare.

House Bill

No comparable provision.

Senate Bill

Section 208. In addition to specifications included in current law, the Secretary could also carry out remedies if an organization charged any Medicare enrollee an amount in excess of the MA monthly beneficiary obligation for qualified prescription drug coverage, provided coverage that was not qualified prescription drug coverage, offered prescription drug coverage but did not make standard prescription drug coverage available, or provided coverage for drugs other than that relating to prescription drugs covered under Part D, as an enhanced or additional benefit.

Conference Agreement

The conference agreement does not include this provision.

Evaluate fee-for-service modernization projects

Present Law

No provision.

House Bill

No explicit provision. H.R. 1 would establish chronic care improvement benefits under fee-for-service (Section 721) and under MA and EFFS (Section 722).

Senate Bill

Section 232. The Secretary would be required to review the results of the demonstrations required under Sections 442, 443, and 444 of this bill and report to Congress by January 1, 2008. [These demonstrations are the Medicare health care quality demonstration, the Medicare complex clinical care management payment demonstration, and the Medicare fee-for-service care coordination demonstration.] Beginning in 2009, the Secretary would be required to establish projects to provide Medicare beneficiaries in traditional Medicare coverage of enhanced benefits or services (preventive services not already covered under Medicare, chronic care coordination services, disease management services or other benefits determined by the Secretary). The purpose of the projects would be to evaluate whether the enhanced benefits or services improved the quality of care, improved health care delivery systems, and reduced expenditures under the Medicare program. The projects would be conducted in regions comparable to the regions designated as ''highly competitive.'' The Secretary would be required to submit annual reports to Congress and the GAO beginning no later than April 1, 2010. The GAO would be required to report by January 1, 2011 and biennially thereafter for as long as the projects were being conducted.

Conference Agreement

The conference agreement does not include this provision.

Establish MA enrollment goal

Present Law

No provision.

House Bill

No provision.

Senate Bill

Section 241. This provision would establish an MA enrollment goal of at least 15% of Medicare beneficiaries by January 1, 2010. If the goal were not met, a bipartisan commission would be established as provided for in Section 242.

Conference Agreement

The conference agreement does not include this provision.

Establish national bipartisan commission on Medicare reform

Present Law

No provision.

House Bill

No provision.

Senate Bill

Section 242. If the enrollment goal described in Section 241 were not met, the National Bipartisan Commission on Medicare Reform would be established. The Commission would review and analyze the long-term financial condition of the Medicare program; identify problems that threaten the financial integrity of the Medicare Trust Funds; and analyze potential solutions to the identified problems. The Commission would be required to make recommendations, including issues facing Medicare, such as solvency, financing of the Medicare Trust Funds, and benefits.

The Commission would have 17 members—four appointed by the President, 12 appointed by Congressional leaders, and one appointed jointly by the President and Congressional leaders to serve as Chairperson. The Commission would be required to submit a report and an implementation bill to the President and Congress no later than April 1, 2014.

Conference Agreement

The conference agreement does not include this provision.

Establish congressional consideration of reform proposals

Present Law

No provision.

House Bill

No provision.

Senate Bill

Section 243. Congressional leaders would be required to introduce the implementation bill required by Section 242. Hearings would be required by appropriate committees as well as floor consideration.

Conference Agreement

The conference agreement does not include this provision.

Authorize appropriations

Present Law

No provision.

House Bill

No provision.

Senate Bill

Section 244. Appropriations would be authorized for such sums as necessary to carry out the provisions regarding the National Bipartisan Commission on Medicare Reform for fiscal years 2012 through 2013.

Conference Agreement

The conference agreement does not include this provision.

Enhanced benefits

Present Law

M+C plans may offer supplemental benefits in addition to any required benefits under Parts A and B of Medicare and any additional required benefits.

House Bill

Section 221 (a). Plans could include supplemental benefits in their bids. The Secretary's authority to negotiate bids would include these supplemental benefits.

Senate Bill

Section 202. [§1852(a)(3)]. MA plans could choose to provide beneficiaries with enhanced medical benefits that the Secretary could approve. The Secretary could deny any submission for enhanced benefits believed to discourage enrollment by MA eligible individuals. The Secretary could not approve any enhanced medical benefit that provided for the coverage of any prescription drug, other than those relating to covered prescription drugs under Part D.

Conference Agreement

The conference agreement does not include this provision.

Incentive for Enrollment

Present Law

M+C plans cannot offer cash or monetary rebates as an inducement for enrollment.

House Bill

Section 221 (d). For MA plans, the ability to offer cash or monetary rebates would be limited to the rebates (based on the calculation of average per capita monthly savings) established under this bill.

Senate Bill

No provision.

Conference Agreement

The conference agreement does not include this provision.

TITLE III—COMBATTING WASTE, FRAUD AND ABUSE

Medicare Secondary Payor (MSP) Provisions (Section 301 of the Conference Agreement, Section 301 of the House Bill, and Section 461 of the Senate Bill).

Present Law

In certain instances, Medicare is prohibited from making payment for a health care claim if payment is expected to be made promptly under workmen's compensation law or plan, under automobile or liability insurance (including a self-insured plan) or under no-fault insurance on behalf of a beneficiary. Medicare is permitted to make a conditional payment in certain circumstances including if Medicare could reasonably expect payment to be made under a workers compensation plan or no-fault insurance claim but Medicare determines that the payment will not be made promptly, as determined in accordance with regulations).

House Bill

The Secretary would be able to make a conditional Medicare payment if a workmen's compensation law or plan, an automobile or liability insurance policy or plan (including a self-insured plan), or a no-fault insurance plan, has not made or cannot reasonably be expected to make prompt payment (as determined in accordance with regulations). This payment would be contingent on reimbursement by the primary plan to the Medicare Trust Funds. This provision on conditional payment would be effective as if included in the enactment of title III of the Medicare and Medicaid Budget Reconciliation Amendments of 1984 (P.L. 98–369) (which was contained in the Deficit Reduction Act of 1984).

The list of primary plans for which conditional payment could be made would be clarified; an entity engaging in a business, trade, or profession would be deemed as having a self-insured plan if it carries its own risk. A primary plan, as well as an entity that receives payment from a primary plan, would be required to reimburse the Medicare Trust Funds for any payment made by the Secretary if the primary plan was obligated to make payment. The Secretary's authority to recover payment from any and all responsible entities and bring action, including the collection of double damages, to recover payment under the Medicare Secondary Payer provisions also would be clarified. This provision clarifying the conditional payment provisions would be effective upon enactment.

Senate Bill

Identical provision.

Conference Agreement

The conference agreement clarifies that the Secretary may make a conditional Medicare payment if a workmen's compensation law or plan, an automobile or liability insurance policy or plan (including a self-insured plan), or a no-fault insurance plan, has not made or cannot reasonably be expected to make prompt payment (as determined in accordance with regulations). This payment is contingent on reimbursement by the primary plan to the Medicare Trust Funds. This provision on conditional payment is effective as if included in the enactment of title III of the Medicare and Medicaid Budget Reconciliation Amendments of 1984 (P.L. 98–369) (which was contained in the Deficit Reduction Act of 1984).

The list of primary plans for which conditional payment could be made is also clarified; an entity engaging in a business, trade, or profession would be deemed as having a self-insured plan if it carries its own risk. A primary plan, as well as an entity that receives payment from a primary plan, is required to reimburse the Medicare Trust Funds for any payment made by the Secretary if the primary plan was obligated to make payment. The Secretary's authority to recover payment from any and all responsible entities and to bring action, including the collection of double damages, to recover payment under the Medicare Secondary Payer provisions also is clarified. This provision clarifying the conditional payment provisions is effective as if included in the enactment of section 953 of the Omnibus Reconciliation Act of 1980.

Payment for Durable Medical Equipment; Competitive Acquisition of Certain Items and Services (Section 302 of the Conference Agreement, Section 302 of the House Bill, and Section 430 of the Senate Bill).

Present Law

Medicare pays for durable medical equipment (DME), using a different fee schedule for each class of covered items. Under the fee schedule, covered items are classified into six major categories, one of which is prosthetics and orthotic devices. In general, fee schedule payments are a weighted average of either local or regional prices, subject to national limits (both floors and ceilings), that are updated each year by the consumer price index for urban consumers (CPI-U) for the 12–month period ending with June of the previous year.

Medical devices are classified into three categories: Class I devices represent minimal potential for harm, and are subject to the least regulatory control (e.g., elastic bandages and enema kits). Class II devices are moderate risk (e.g., some surgical lasers). Class III devices are devices that sustain or support life, are implanted, or present potential unreasonable risk (e.g., implantable infusion pumps and heart valve replacements) and are subject to premarket approval, the most stringent regulatory control.

BBA 97 authorized the Secretary to conduct up to five demonstration projects to test competitive bidding as a way for Medicare to price and pay for Part B services other than physician services. The Secretary was required to establish up to three competitive acquisition areas for this purpose. Three competitive bidding demonstrations for durable medical equipment, prosthetics, orthotics, and supplies were implemented, two in Polk County, Florida and one in the San Antonio, Texas area.

House Bill

The Secretary would be required to establish and implement competitive acquisition programs for durable medical equipment, medical supplies, items used in infusion, drugs and supplies used in conjunction with durable medical equipment, medical supplies, home dialysis supplies, blood products, parental nutrition, and off-the-shelf orthotics (requiring minimal self-adjustment for appropriate use) that would replace the Medicare fee schedule payments. Enteral nutrients and class III devices, those that sustain or support life, are implanted, or present potential unreasonable risk (e.g., implantable infusion pumps and heart valve replacements) and are subject to premarket approval by the Food and Drug Administration would not be covered by the program.

In starting the programs, the Secretary would be required to establish competitive acquisition areas, but would be able to exempt rural areas and areas with low population density within urban areas that are not competitive, unless a significant national market exists through mail order for a particular item or service. The programs would be phased-in over 3 years with at least one-third of the areas implemented in 2005 and two-thirds of the areas implemented in

2006. High-cost items and services would be required to be phased-in first. The Secretary would be able to exempt items and services for which competitive acquisition would not be likely to result in significant savings. The Secretary would be required to establish a process where existing rental agreements for covered DME items entered into contract before implementation of this program would not be affected. The supplier would be required to provide for appropriate servicing and replacement of these rental items. Also, the Secretary may establish a process where a physician would be able to prescribe a particular brand or mode of delivery of an item or service if such item is clinically more appropriate than other similar items.

Certain requirements for the competitive acquisition program would be established. Specifically, the Secretary would be allowed to award contracts in an area only when the following conditions were met: entities met quality and financial standards specified by the Secretary or the Program Advisory and Oversight Committee; total amounts paid under the contracts would be expected to be less than would otherwise be paid; beneficiary access to multiple suppliers would be maintained; and beneficiary liability would be limited to 20% of the applicable contract award price. Contracts would be required to be re-competed at least every three years. The Secretary would be required to award contracts to multiple entities submitting bids in each area for an item or service and would also have the authority to limit the number of contractors in a competitive acquisition area to the number needed to meet projected demand for covered items and services. The similarity of the clinical efficiency and the value of specific products would be considered when establishing the categories and products that would be subject to bidding. The Secretary would not be able to pay for items furnished by a contractor unless the contractor has submitted a bid to supply the item and the contract has been awarded. The Secretary would be permitted to waive certain provisions of the Federal Acquisition Regulation that are necessary for the efficient implementation of this program, other than those relating to confidentiality of information. The Secretary would also be able to contract with an appropriate entity to address beneficiary complaints, provide beneficiary outreach and education services, and monitor the quality of items and services provided. The Secretary would be required to report to Congress annually on savings, reductions in cost-sharing, access to items and services, and beneficiary satisfaction under the competitive acquisition program.

A Program Advisory and Oversight Committee with members appointed by the Secretary would be established. The Committee would be required to provide advice and technical assistance to the Secretary regarding the implementation of the program, data collection requirements, proposals for efficient interaction among manufacturers and distributors of the items and services, providers, and beneficiaries, and other functions specified by the Secretary. The provisions of the Federal Advisory Committee Act would not apply to this Committee. The Secretary would be required to conduct a demonstration program on using competitive acquisition for clinical laboratory tests that are furnished without a face-to-face encounter between the individual and the hospital personnel or physician performing the test. The same quality and financial conditions specified for the DME competitive acquisition program would apply for clinical laboratory test competitive acquisition. An initial report to Congress would be required of the Secretary not later than December 31, 2005 with progress and final reports as the Secretary would determine appropriate.

The covered items and services included in the competitive acquisition program would be paid as determined under this program. The Secretary would be able to use this payment information to adjust the payment amounts for DME not in a competitive acquisition area. In this instance, the inherent reasonableness rule would not be applied. Orthotics in a competitive acquisition program would also be paid the amounts determined by this program. The Secretary would be able to use this payment information to adjust the payment amounts for such items. The provision would be effective upon enactment.

Senate Bill

Medicare would not increase the DME fee schedule amounts in any of the years from 2004 through 2010 and would update the amounts by the CPI–U in each subsequent year. Payments for orthotic devices that have not been custom-fabricated would be similarly affected. Class III medical devices would be exempt from the freeze in DME payments. Prosthetics, prosthetic devices, and custom-fabricated orthotics would be updated by the percentage change in the CPI–U. The provision would also subject DME companies to an accreditation and quality assurance process. The Secretary would be required to designate independent accreditation organizations no later than 6 months from enactment after consultation with an expert outside advisory panel. The application of quality standards would be phased in over a 3–year period. The provision would be effective upon enactment.

Conference Agreement

The conference agreement requires the Secretary to establish and implement quality standards for suppliers of: items and services of durable medical equipment, prosthetics and orthotics, and certain other items and services. Suppliers of the following items and services are included in the conference agreement: items of durable medical equipment, prosthetic devices, orthotics and prosthetics, medical supplies, home dialysis supplies and equipment, therapeutic shoes, parenteral and enteral nutrients, equipment, and supplies, electromyogram devices, salivation devices, blood products, and transfusion machines. The Secretary is explicitly authorized to establish the quality standards by program memorandum on a prospective basis after consultation with representatives of relevant parties. The standards are required to be posted on the Internet website of CMS. The Secretary is required to designate one or more independent accreditation organizations not later than one year after the date the quality standards are implemented. The quality standards may not be less stringent than the quality standards otherwise in place.

The Secretary is required to establish standards for clinical conditions for payment for covered durable medical equipment that include the specification of types or classes of covered items that require, as a condition of payment, a face-to-face examination and a prescription for the item. Standards are required to be established for those covered items for which there has been a proliferation of use, consistent findings of charges for covered items that are not delivered, or consistent findings of falsification of documentation to provide for payment of such covered items. Beginning with the date of enactment, payment may not be made for motorized or power wheelchairs unless a physician, physician assistant, nurse practitioner, or a clinical nurse specialist has conducted a face-to-face examination of the individual and written a prescription for the item. Medicare payment is not permitted unless the item meets the standards established for clinical condition of coverage.

The conference agreement also establishes competitive acquisition programs for durable medical equipment (including items used in infusion and drugs), medical supplies, home dialysis supplies, therapeutic shoes, enteral nutrients, equipment, and supplies, electromyogram devices, salivation devices, blood products, and transfusion medicine, and off-the-shelf orthotics (requiring minimal self-adjustment for appropriate use) that would replace the Medicare fee schedule payments. Exclusions from the competitive acquisition are: inhalation drugs; parenteral nutrients, equipment, and supplies; and class III devices, that is those that sustain or support life, are implanted, or present potential unreasonable risk (e.g., implantable infusion pumps and heart valve replacements) and are subject to premarket approval by the Food and Drug Administration.

In starting the programs, the Secretary is required to establish competitive acquisition areas, but would be able to exempt rural areas and areas with low population density within urban areas that are not competitive, unless a significant national market exists through mail order for a particular item or service. The programs will be phased-in so that competition under the programs occurs in 10 of the largest metropolitan statistical areas in 2007; 80 of the largest metropolitan statistical areas in 2009; and remaining areas after 2009. The Secretary is permitted to phase-in first items and services with the highest cost and highest volume, or those items and services that the Secretary determines have the largest savings potential. The Secretary may exempt items and services for which competitive acquisition would not be likely to result in significant savings. The Secretary is required to establish a process where existing rental agreements for covered DME items entered into contract before implementation of this program would not be affected. The supplier would be required to provide for appropriate servicing and replacement of these rental items. Also, the Secretary may establish a process where a physician would be able to prescribe a particular brand or mode of delivery of an item or service within a particular healthcare procedure code (HCPCS) if the physician determines that use of the item or service would avoid an adverse medical outcome on the beneficiary, as determined by the Secretary, although this could not affect the amount of payment otherwise applicable.

Certain requirements for the competitive acquisition program are established by the conference agreement. Specifically, the Secretary cannot award contracts in an area unless the following conditions were met: (1) entities meet quality standards established by the Secretary; (2) entities meet financial standards specified by the Secretary, taking into account the needs of small providers; (3) total amounts paid under the contracts are expected to be less than would otherwise be paid; and (4) beneficiary access to multiple suppliers would be maintained. Contracts are subject to terms and conditions that the Secretary may specify and are required to be recompeted at least every 3 years. The Secretary is required to award contracts to multiple entities submitting bids in each area for an item or service and has the authority to limit the number of contractors in a competitive acquisition area to the number needed to meet projected demand for covered items and services.

Payment for competitively priced items and services will be based on bids submitted and accepted. The Secretary is required to determine a single payment amount for each item or service in each competitive acquisition area. Medicare payment is required to be equal to 80 percent of the payment amount determined, with beneficiaries paying the remaining 20 percent (after meeting

the Part B deductible). Payment for any item or services can be made only on an assignment-related basis that is the supplier bills Medicare and accepts Medicare payment as payment in full. The use of advanced beneficiary notices is not precluded by this program.

In establishing the categories and products that would be subject to bidding, the Secretary is permitted to consider the clinical efficiency and the value of specific items within HCPCs codes, including whether some items have a greater therapeutic advantage to individuals. The Secretary is required to take appropriate steps to ensure that small suppliers of items and services have an opportunity to be considered for participation in this program. The Secretary cannot pay for items furnished by a contractor unless the contractor has submitted a bid to supply the item and the contract has been awarded. The Secretary is permitted to waive certain provisions of the Federal Acquisition Regulation that are necessary for the efficient implementation of this program, other than those relating to confidentiality of information. The Secretary is permitted to contract with an appropriate entity to address beneficiary complaints, provide beneficiary outreach and education services, and monitor the quality of items and services provided. The Secretary is also permitted to contract with entities to implement the competitive bidding program. The conference agreement prohibits administrative or judicial review of the establishment of payments amounts, the awarding of contracts, the designation of competitive acquisition areas, the phased-in implementation, the selection of items and services for competitive acquisition or the bidding structure and number of contractors. The Secretary is required to report to Congress by July 1, 2009, on savings, reductions in cost-sharing, access to items and services, and beneficiary satisfaction under the competitive acquisition program.

A Program Advisory and Oversight Committee with members appointed by the Secretary is required to be established. The Committee is required to provide advice to the Secretary regarding the implementation of the program, data collection requirements, proposals for efficient interaction among manufacturers and distributors of the items and services, providers, and beneficiaries, the establishment of quality standards, and other functions specified by the Secretary. The provisions of the Federal Advisory Committee Act do not apply to this Committee. The Committee is required to end on December 31, 2009.

The Secretary is required to conduct a demonstration program on using competitive acquisition for clinical laboratory tests that are furnished without a face-to-face encounter between the individual and the hospital personnel or physician performing the test. The terms and conditions of the demonstration are to include the application of CLIA quality standards. An initial report to Congress is required of the Secretary no later than December 31, 2005, with progress and final reports as the Secretary determines appropriate.

For durable medical equipment, prosthetic devices, prosthetics and orthotics, the update will be 0 percentage points in 2004 through 2008. After 2008, for those items not included in competitive bidding the update will be the consumer price index (CPI). For 2005, the payment amount for certain items, oxygen and oxygen equipment, standard wheelchairs, nebulizers, diabetic lancets and testing strips, hospital beds and air mattresses, will be reduced. The Secretary will take the payment amount otherwise determined and reduce it by the percentage difference between the amount of payment otherwise determined for the specific item for 2002 and the amount of payment for the specific item and HCPC code under chapter 89 of title 5, United States Code (which was identified in the column entitled a median FEHBP Price in the table entitled ''A Summary of Medicare Prices Compared to VA, Medicaid, Retail, and FEHP Prices for 16 Items'' that was included in the Testimony of the Inspector General before the Senate Committee on Appropriations, June 12, 2002). An OIG report on oxygen will be available in the spring of 2004.

For class III medical devices the update in 2004, 2005, and 2006 is equal to the percentage increase in the consumer price index for all urban consumers (CPI–U) for the 12-month period ending with June of the previous year. In 2007 the percentage change for class III medical devices is to be determined by the Secretary after taking into account recommendations made by the Comptroller General in a report on class III medical devices. In 2008 the update is determined by the amount paid in 2007 updated by the CPI. In subsequent years the CPI is the update.

For covered items and services furnished beginning January 1, 2009, items and services included in the competitive acquisition program would be paid as determined under that program and the Secretary would be able to use this payment information to adjust the payment amounts for DME, off-the-shelf orthotics, and other items and services that are supplied in an area that is not a competitive acquisition area. The inherent reasonableness authority for DME, off-the-shelf orthotics, medical supplies, home dialysis supplies, therapeutic shoes, enteral nutrients, equipment, and supplies, electromyogram devices, salivation devices, blood products, and transfusion medicine is not eliminated but, if the Secretary uses the competitive acquisition program information to adjust payments, then inherent reasonableness authority cannot be used.

The Inspector General of the Department of Health and Human Services (the Inspector General) is required to study the extent to which (if any) suppliers of covered items of DME that are subject to the competitive acquisition program are soliciting physicians to prescribe certain brands or modes of delivery of covered items based on profitability. The report is due to Congress no later than July 1, 2009.

The provision is effective upon enactment.

Competitive Acquisition of Covered Outpatient Drugs and Biologicals (Section 303 of the Conference Agreement, Section 303 of the House Bill, and Section 432 of the Senate Bill).

Adjustment to the Physician Fee Schedule (Section 303(a) of the Conference Agreement, Section 303(a) of the House Bill and Section 432(b) of the Senate Bill).

Present Law

The relative value associated with a particular physician service is the sum of three components: physician work, practice expense, and malpractice expense. Practice expense includes both direct costs (such as clinical personnel time and medical supplies used to provide a specific service to an individual patient) as well as indirect costs such as rent, utilities, and business costs associated with running a practice). When the physician fee schedule was implemented, reimbursement for practice expenses was based on historic charges. The Social Security Act Amendments of 1994 (PL. 103–432) required the Secretary to develop a methodology for a resource based system for calculating practice expenses for use in CY1998. BBA 1997 delayed the implementation of the methodology until CY1999 and established a transition period with full implementation by CY2002. BBRA required the Secretary to establish a data collection process and data standards for determining practice expense relative values. Under this survey process, the Secretary was required to use data collected or developed outside HHS, to the maximum extent practicable, consistent with sound data collection practices.

The Secretary is required to periodically review and adjust the relative values affecting physician payment to account for changes in medical practice, coding changes, new data on relative value components, or the addition of new procedures. Under the budget-neutrality requirement, changes in these factors cannot cause expenditures to differ by more than $20 million from what would have been spent if such adjustments had not been made.

House Bill

The Secretary would be required to increase the practice expense relative value for the physician fee schedule in CY2005 using survey data that includes information on the expense associated with administering drugs and biologicals. The supplemental data provided by entities and organizations would be included if consistent with the Secretary's criteria for acceptable survey data and submitted by December 31, 2004. Using existing processes for coding considerations, the Secretary would be required to promptly evaluate existing codes for the administration of covered outpatient drugs and biologicals to ensure accurate reporting and billing for these services. Any payment increase in CY2005 that resulted from using supplemental survey data or reevaluating codes would not be subject to budget neutrality provisions, would be exempt from administrative and judicial review, and would be treated as a change in law and regulation in the sustainable growth rate determination. Nothing in this section would prevent the Secretary from providing for practice expense adjustments in subsequent years, subject to the budget neutrality provisions. The Secretary would be required to consult with the Comptroller General of the United States (GAO) and groups representing the affected physician specialties before publishing the notice of proposed rulemaking. Also, the Secretary would be required to adjust the non-physician work pool methodology so that practice expense relative values for these services are not disproportionately reduced as a result of the above changes. The provision would be effective upon enactment.

Senate Bill

The Secretary would be required to establish the practice expense relative value for the physician fee schedule in CY2004 using the survey data collected from a physician specialty organization as of January 1, 2003 if the data cover the practice expenses for oncology administration services and meet the Secretary's criteria for acceptable survey data. The Secretary would also be required to review and appropriately modify Medicare's payment policy for the administration of more than one anticancer chemotherapy agent to an individual patient on a single day. The increase in expenditures resulting from this provision would be exempt from the budget-neutrality requirement. Also, the Secretary would be required to adjust the non- physician work pool methodology so that practice expense relative values for these services are not disproportionately reduced as a result of the above changes. The provision would be effective upon enactment.

The Secretary would not be able to revise payment amounts for a category of outpatient drugs or biologicals unless the Secretary concurrently adjusts the payment amounts for administration of such category of drug or biological. The provision would be effective upon enactment.

The provisions affecting the practice expense relative values, multiple chemotherapy agents administered on a single day, and treatment of other services currently in the non-physician work pool would not be subject to administrative or judicial review under Sections 1869 and 1878 of the Social Security Act (SSA) or otherwise. The provision would be effective upon enactment.

Conference Agreement

Beginning in 2004, the Secretary is required to make adjustments in practice expense relative value units for certain drug administration services when establishing the physician fee schedule. The Secretary is required to use the survey data submitted by the American Society of Clinical Oncology (ASCO) in 2002 because it meets criteria established under the BBRA for use.

The Secretary is required to add work relative value units to certain drug administration services, equal to the work relative value units for a level 1 office medical visit for an established patient. These services are classified, as of October 1, 2003, within any of the following groups of procedures: therapeutic or diagnostic infusions (excluding chemotherapy), chemotherapy administration services, and therapeutic, prophylactic or diagnostic injections. Only those services for which national relative value units, but no work relative value units have been assigned by October 1, 2003 are included. These specified drug administration services are intended to be those classified as of October 1, 2003, within HCPCs codes 90780–90781, 96400, 96408–96425, 96520, 96530 and 90782–90788, and as subsequently may be modified by CMS, to provide work relative value units for CPT code 99211 for a level 1 office medical visit for an established patient.

Starting in 2005, the Secretary is required to use supplemental survey data to increase practice expense relative values for other drug administration services in the physician fee schedule if that supplemental survey data include information on the expense associated with administering drugs and biologicals, the survey meets criteria for acceptance, and the survey is submitted by March 1, 2004, for 2005, or March 1, 2005 for 2006. This provision will apply only to a specialty that received 40% or more of its Medicare payments in 2002 from drugs and biologicals and would not apply to the ASCO survey submitted in 2002.

The Secretary is also required to promptly evaluate existing drug administration codes for physicians' services to ensure accurate reporting and billing for these services. These codes should take into account levels of complexity of the administration and resource consumption. The Secretary is required to use existing processes for considering coding changes and for incorporating appropriate changes in the relative values for such services. As part of this process, the Secretary is required to consult with representatives of physician specialties affected by the changes in payment for drugs under this section and, within the scope of existing authority, expedite appropriate conclusions resulting from these coding evaluations.

The adjustments in practice expense relative value units for certain drug administration services based on the ASCO survey data are exempt from the budget neutrality requirements in 2004. Adjustments in practice expense relative value units for other drug administration services in 2005, 2006, or 2007 based on the surveys or coding changes described above are also exempt. Nothing in this section shall prevent the Secretary making these practice expense adjustments in subsequent years, subject to the budget neutrality provisions.

The Secretary is required to make adjustments to the non-physician work pool methodology so that the practice expense relative values for other services in the pool are not affected by the changes to practice expenses for drug administration. This provision is intended to protect the services in the non-physician work pool from payment reductions resulting from changes made to the AWP payment methodology. The budget neutrality waiver was included in this section to ensure that the increase in practice expense relative value units for drug administration services (resulting from the use of new supplemental survey data) would not be offset by decreases in the other non-physician work pool services. The Secretary is further required to review and appropriately modify Medicare's payment policy in effect on October 1, 2003, for the administration of more than one drug or biological to an individual on a single day through the push technique. The increase in expenditures resulting from this provision will be exempt from the budget-neutrality requirement in 2004. The Conferees strongly urge the Secretary to make payment for these multiple pushes.

A transitional adjustment or additional payment for services furnished from April 1, 2004, through December 31, 2005 will be made for drug administration services. This Part B payment is to be made to the physician and equals a percentage of the payment otherwise made. The percent is 32 in 2004, and 3 in 2005.

MedPAC is required to review the payment changes as they affect payments for items and services furnished by oncologists and for drug administration services furnished by other specialists. This review will also include an examination of the effect of such changes on the quality of Part B services and beneficiary satisfaction with such care. The Commission is required to submit a report to the Secretary and Congress by January 1, 2006 on oncologists' payments and by January 1, 2007 on drug administration services furnished by other specialists. The reports may include recommendations for further adjustments. The Secretary could make appropriate adjustments to payments as part of the rulemaking for physician payments for 2007.

Section 303 exempts all physician specialties, other than oncology, from the payment adjustments made to both physicians' services and expenses for the administration of drugs and biologicals in this section, and does not apply to inhalation drugs in Section 305. Section 304 requires the Secretary to disregard this exemption and apply the adjustments in section 303 to these other specialties. The intent in drafting the two sections in this manner is to segregate the savings achieved from adjustments to payments to oncologists from savings derived from other physician specialties. The specialties to which the provisions apply are the specialties as used by the carriers in administering Medicare.

Application of Market based Payment Systems (Sections 303(b) through Sections 303(d) of the Conference Agreement, Section 303(b) of the House Bill and Section 432(a) of the Senate Bill).

Present Law

Although Medicare does not currently provide an outpatient prescription drug benefit, coverage of certain outpatient drugs is authorized by statute. Specifically, under Medicare Part B, outpatient prescription drugs and biologicals are covered if they are usually not self-administered and are provided incident to a physician's services. Drugs and biologicals are also covered if they are necessary for the effective use of covered durable medical equipment. In addition, Medicare will pay for certain self-administered oral cancer and anti-nausea drugs, erythropoietin (used to treat anemia), immunosuppressive drugs after covered Medicare organ transplants and hemophilia clotting factors. Vaccines for diseases like influenza, pneumonia, and hepatitis B are considered drugs and are covered by Medicare. Payments for covered outpatient drugs are made under Medicare Part B and are generally calculated using the average wholesale price (AWP).

The AWP is intended to represent the average price used by wholesalers to sell drugs to their customers. It has been based on prices reported by drug manufacturers, that are published in industry reference publications or drug price compendia. There are no uniform criteria for reporting these numbers. Moreover, these reported prices do not reflect the discounts that manufacturers and wholesalers customarily offer to providers and physicians. AWP has never been defined in either statute or regulation, but it is used to set reimbursement amounts for drugs and biologicals covered under the Medicare Part B benefit

The Balanced Budget Act of 1997 (BBA 97, P.L. 105–33) specified that Medicare payment for covered outpatient prescription drugs would equal 95 percent of AWP. Current Medicare payment rates are 95% of AWP for brand name drugs produced by a single manufacturer (referred to single source drugs.) Medicare pays 95% of the lower of (a) the median AWP of all generic drugs or (b) the lowest brand-name product AWP for drugs with 2 or more competing brand names drugs (referred to as multisource or multiple source drugs) or those drugs with available generic equivalents. Although Medicare uses a Healthcare Common Procedure Coding System (HCPCS) code to identify and pay for physician administered drugs, AWPs are reported on the basis of national drug codes (NDC), which are maintained by the Food and Drug Administration (FDA). Every drug sold in the United States has a unique NDC that provides information on its chemical molecule, drug manufacturer, dosage, dosage from and package size. In addition, there may be several multiple source or generic drugs within a specific HCPCS code.

There is substantial evidence that indicates that AWPs for many Medicare-covered products far exceed the acquisition cost paid by suppliers and physicians. Reliance on AWP (instead of a market based price) has caused significantly increased payments, as some use AWP to inflate payments made for drugs to influence physician prescribing practices. This has resulted in Medicare paying more than $1 billion per year in excess overpayments for these products. Because Medicare beneficiaries are also required to pay coinsurance amounts equal to 20 percent of the Medicare payment amount, the increased Medicare payment amounts resulting from inflated AWPs cause Medicare beneficiaries to pay hundreds of millions of extra dollars in inflated co-payments every year.

Some physicians assert that the overpayment for drugs covers underpayment for practice expenses. They contend that Medicare does not adequately reimburse them for the practice expenses associated with providing care in outpatient settings. This section reduces the overpayment for drugs and biologics, while increasing physician practice expenses.

Since 1992, the HHS Office of the Inspector General OIG (OIG) has raised concerns about how certain drug manufacturers have established AWPs for certain of their Medicare-covered drugs that were much higher than the prices generally paid by the health care providers to those drug companies. This difference—commonly referred to by the industry and the health care community as the ''spread''—results in a profit to providers

each time they administer such drugs to Medicare patients. For example, in 1999, an oncologist could purchase 10 mgs of doxorubicin, a chemotherapy agent, for $10.08, while Medicare's reimbursement for that same dose was $42.92, resulting in a profit to the providers of $32.84. The OIG, based on a review of 24 of the Medicare-covered drugs, estimate that such practices result in Medicare making $750 million each year in overpayments to these providers.

Subsequently, the findings of this report were updated with more current drug pricing. This updated report found that, of the $3.7 billion Medicare spent for 24 drugs in 2000, if Medicare paid the actual wholesale prices available to physicians and suppliers for these 24 drugs, the program and its beneficiaries would have saved $887 million a year.

In addition to the financial toll on the U.S. Treasury, these large spreads also affect Medicare beneficiaries, who are often required to pay dramatically inflated co-payments for the drugs they receive. These co-payments sometimes even exceed the actual price that the provider has paid for the drug. For example, leucovorin calcium, a chemotherapy agent, had a beneficiary co-payment of $3.60 per dosage, while the OIG estimated a provider could buy the same drug for $2.94, and would receive a total reimbursement (including beneficiary co-payment) of $18.02 per dose. OIG estimated that if Medicare had paid reimbursements equal to widely available wholesale prices, beneficiaries would have paid $175 million less in coinsurance.

A September, 2001, GAO report found that physicians can obtain Medicare-covered drugs at prices significantly below current Medicare payments. GAO found that the average discount from AWP ranged from 13 percent to 34 percent, and that two drugs had discounts of 65 percent and 86 percent.

Evidence also suggests that certain types of health care providers may also be making treatment decisions based at least in part upon the amount of profit they can reap from the use of certain drugs. In one particularly disturbing example, a respiratory therapy drug, ipratropium bromide, saw its utilization skyrocket after certain drug manufacturers began to build a large spread in its price. In 1995, Medicare reimbursed providers $14 million dollars for their use of ipratropium bromide. After the spread was created, utilization increased dramatically, to the point where Medicare paid $250 million for the same drug in 1999, and over $300 million in 2000 and 2001.

In its recommendations to the Congress, the GAO urged CMS to take steps to begin reimbursing providers for Part B-covered drugs and related services at levels reflecting providers' acquisition costs using information about actual market transaction prices. The GAO also recommended that CMS should evaluate expanding competitive bidding approaches to setting payment levels, and that CMS should monitor beneficiary access to covered drugs in light of any changes to reimbursement.

The GAO also debunked some common myths generally held by many in the health care community. Specifically, the GAO found that despite concerns that the discounts available to large purchasers would not be available to physicians with a small number of drug claims, physicians with low volumes reported that their purchase prices were the same or less than the widely available prices GAO documented. GAO also believes that Medicare should pay for each service appropriately and not rely on overpayments for some services to offset inadequate payments for complementary services. The Committee shares this view, and believes the legislation achieves this goal.

The Committee on Ways and Means, the Committee on Energy and Commerce and the Senate Finance Committee have all conducted independent investigations and held public hearings on the problems associated with using AWP as a reimbursement benchmark. All three Committees have also examined the reimbursement for drug administration through the Medicare physician payment structure. Both reimbursement systems were found to have serious flaws in methodology and application.

More recently, the Centers for Medicare and Medicaid Services issued a proposed rule on August 20, 2003, to improve the way that Medicare pays for covered drugs and asked for public input on the best way to achieve that goal. The rule solicited comments on four differing approaches:

Medicare would pay the same amounts for covered drugs that private insurers pay; Medicare would apply a discount of 10 to 20 percent from the inflated average wholesale price in 2004 and then establish more reasonable payment updates in future years; Medicare would use existing sources of market-based prices and would develop additional sources to monitor market changes over time, such as drug price catalogs; or Medicare would establish a competitive bidding process for drugs and would also require drug companies to report their average sales prices.

Because of the serious flawed reimbursement methodology in the current system, and absent a change in the statute, CMS has indicated they will move forward with the rule.

House Bill

New sections 1847A and 1847B would be established. Under 1847A, the Secretary would be required to establish a competitive acquisition program to acquire and pay for covered outpatient drugs. Under this program, at least 2 contractors would be established in each competitive acquisition area (which would be defined as an appropriate geographic region) throughout the United States. Each year, a physician would be able to select a contractor who would deliver covered drugs and biologicals to the physician; alternatively, a physician would be able to elect payment under the use of the average sales price payment methodology established by 1847B.

Under the competitive acquisition program, there would be 2 categories of drugs under this program: the oncology category (which would include drugs determined by the Secretary as typically primarily billed by oncologists or are otherwise used to treat cancer) which would be implemented beginning in 2005 and the non-oncology category which would be implemented beginning in 2006. In this case, covered drugs means certain drugs currently covered under Section 1842(o) of the SSA which are not covered as part of the competitive acquisition for durable medical equipment. Blood clotting factors, drugs and biologicals furnished as treatment for end-stage renal disease (ESRD), radiopharmaceuticals, and vaccines would not be considered covered drugs under the competitive acquisition program. The Secretary would also be able to exclude other drugs and biologicals or classes of drugs and biologicals that are not appropriate for competitive bidding or would not produce savings.

Certain contractor selection and contracting requirements for the competitive acquisition program would be established. Specifically, the Secretary would be required to establish an annual selection process for a contractor in each area for each of the 2 categories of drugs. The Secretary may not award the 2-year contract to any entity that does not have the capacity to supply covered outpatient drugs within the applicable category or does not meet quality, service, and financial performance and solvency standards established by the Secretary. Specifically the entity would be required to have (1) arrangements to ship covered drugs at least 5 days of the week and on an emergency basis; (2) procedures for the prompt response and resolution of physician and beneficiary complaints and inquiries; (3) grievance resolution procedures, including review by the Medicare Provider Ombudsman established in this legislation. The Secretary would not be able to contract with an entity that has had its license for distributing drugs (including controlled substances) suspended or revoked by the Federal or a State government or that has been excluded from program participation. A contractor would be required to comply with a specified code of conduct, including conflict of interest provisions as well as all applicable provisions relating to the prevention of fraud and abuse. A contract would be able to include the specifications with respect to secure facilities, safe and appropriate storage of covered drugs, examination of drugs, record keeping, written policies and procedures, and compliance personnel. Those contractors may be required to comply with additional product integrity safeguards for drugs susceptible to counterfeiting or diversion. Contracts would be able to be terminated by either the Secretary or the entity with appropriate advance notice. The Secretary would make the list of the available contractors accessible to physicians on an ongoing basis, through a directory posted on the Internet and provided by request.

The Secretary would be able to limit the number of qualified entities in each category and area, but not below two. The Secretary would be required to base selection on bid prices for covered drugs, bid prices for distribution of those drugs, ability to ensure product integrity, customer service, past experience with drug distribution, and other factors. This bid price would include all costs related to the delivery of the drug or biological to the selecting physician or other delivery point as well as all dispensing and shipping costs. Costs relating to the administration of the drug or biological or waste, spillage or spoilage would not be included. As part of the awarded contract, the selected contractor would be required to disclose the reasonable, net acquisition costs regularly (but not more often than once a quarter) as specified by the Secretary. The selected contractor would also be required to disclose appropriate price adjustments over the period of the contract to reflect changes in reasonable, net acquisition costs.

The Secretary would be able to reject the contract offer of an entity for a category of drugs and biologicals if the Secretary establishes that the aggregate average bid price exceeds the average sales price (as determined under Section 1847B discussed subsequently). Nothing in the section would prevent a bidder from submitting a contract offer to cover all areas of the United States; nothing would prevent requiring a bidder to submit a contract offer to cover all areas of the United States. The amount of the bid price submitted under a contract offer would be required to be the same for all portions of the area. The Secretary would be permitted to waive certain provisions of the Federal Acquisition Regulation that are necessary for the efficient implementation of this program, other than those relating to confidentiality of information.

The Secretary would be required to compute an area average of the bid prices submitted, in contract offers accepted for the category and the area, for each year or other

contract period. The Secretary would apply special rules and alternative payment amounts to establish a price for specific covered drugs including new drugs and biologicals, oral anti-cancer and immunosuppressive drugs. Generally, the Secretary would not be able to adjust payments for drugs under this section unless supplemental data is used to adjust the practice expense payment adjustment. Also, if the Secretary excludes a class of drugs or biologicals or a specific item from the competitive acquisition program, Medicare's payment would be based on the average sales price methodology discussed subsequently. Beneficiary liability would be limited to 20% of the payment basis for the covered drug or biological.

The contractor supplying the physician in the area would submit the claim for the drug and would collect the cost-sharing amount from the beneficiary after administration of the drug.Both program payment and beneficiary cost sharing amounts would only be made to the contractor; would only be made upon the administration of the drug; and would be based on the average bid of prices for the drug and biological in the area. The Secretary would be required to establish a process for recovery of payments billed at the time of dispensing for drugs that were not actually administered. The Secretary would be required to establish an appeals process for physicians that is comparable to those provided to a physician who prescribes durable medical equipment or a laboratory test.

The appropriate contractor, as selected by the physician, would supply covered drugs directly to the physician, except under the circumstances when a beneficiary is presently able to receive a drug at home. The Secretary would be able to specify other nonphysician office settings where a beneficiary would be able to receive a covered drug directly. However, the contractor would not be able to deliver drugs to a physician without first receiving a prescription as well as other necessary information specified by the Secretary. A physician would not be required to submit a prescription for each individual treatment. The Secretary would establish requirements, including adequate safeguards against fraud and abuse and consistent with safe drug practices, in order for a physician to maintain a supply of drugs that may be needed in emergency situations. In order to maintain such an inventory, a physician would be required to demonstrate that the drugs would be immediately required, not reasonably foreseen as immediately required, not able to be delivered by the contractor in a timely manner, and administered in an emergency situation. No applicable State requirements relating to the licensing of pharmacies would be waived.

The Secretary would be able to establish an advisory committee to assist in the implementation of this program. The Secretary would be required to report to Congress on savings, reductions in cost-sharing, access to items and services, the availability of contractors as well as beneficiary and satisfaction under the competitive acquisition program. These reports would be due each year from 2005, 2006, and 2007.

Alternatively, physicians would be able to elect payment for covered outpatient drugs under a separate methodology established in Section 1847B. Subject to the applicable beneficiary coinsurance and deductible amount, a single and multiple source drugs would be paid 112% of the applicable price in 2005 and 2006 and 100% of the price subsequently. The applicable price for all the products within multiple source drug codes would be the reported volume-weighted average of the average sales price; the applicable price for a single source drug would be the lesser of the manufacturer's average sales price for the NDC code or the reported wholesale acquisition cost. The payment amount would be determined without regard to any special packaging, labeling or identifiers on the dosage form or product or package.

Starting for calendar quarters on or after April 1, 2004, the average sales price would be calculated by NDC code each calendar quarter by dividing a manufacturer's total sales by the total number of units sold in that quarter. Certain sales would be exempt from the calculation: (1) those sales that are exempt from the Medicaid drug rebate program including those to the Indian Health Service, the Department of Veterans Affairs, a state Veterans home, the Department of Defense, or the Public Health Services as well as any price charged under the Federal Supply Schedule or used under a state pharmaceutical assistance program; and (2) those sales that do not reflect market prices, as determined by the Secretary. The average sales price would take into account volume discounts, prompt pay discounts, cash discounts, chargebacks and certain rebates. The Secretary would be able to disregard the average sales price during the first quarter of a new drug's sales if the price data is not sufficient to determine an average amount payable. The average sales price would be determined by the manufacturer on a quarterly basis; to the extent that data on rebates and chargebacks is reported on a lagged basis, the manufacturer would apply the 12-month rolling average methodology to estimate the amount of such discounts, as specified by the Secretary. The wholesale acquisition cost would be the manufacturer's list price for the drug to wholesalers or direct purchasers in the United States for the most recent available month, not including discounts or other price reductions, as reported in wholesale price guides or other pricing publications. Payment rates would be updated on a quarterly basis and based on the most recent calendar quarter. The Secretary would be able to use carriers, fiscal intermediaries or other contractors to determine the payment amounts. Certain standards would be established with respect to the definition of multiple source and single source drugs. Certain determinations of pharmaceutical equivalence and bioequivalence would be established. There would be no administrative or judicial review of the determination of the manufacturer's average sale price.

The Secretary would be able to use the wholesale acquisition cost or other reasonable measure of drug price instead of the manufacturer's average sale price in the case of certain public emergencies where there is a documented inability to access covered outpatient drugs and a related increase in price. The alternative price would be used until the price and availability of the drug or biological has stabilized and is substantially reflected in the manufacturer's average sale price.

The Secretary would be required to submit an annual report to the Committees of jurisdiction on the trends in average sales prices, the administrative costs, and total value of payment as well as a comparison of the average manufacturer's sale price with the price established under the Medicaid drug rebate program. The provision would be effective upon enactment.

Senate Bill

Drugs or biologicals furnished before January 1, 2004 would be paid at 95% of the AWP. In 2004, existing drugs and biologicals would be paid the lower of the AWP or 85% of the listed AWP as of April 1, 2003. In subsequent years, this price would be increased by change the consumer price index (CPI) for medical care for the previous year ending in June. Existing drugs and biologicals are those first available for payment on or before April 1, 2003. After January 1, 2004, payments for influenza virus, pneumococcal pneumonia, and hepatitis B vaccines would be equal to the AWP.

The Secretary would be required to establish a process to determine whether the widely available market price to physicians and suppliers for drugs and biologicals furnished in a year is different from the AWP amounts. This determination would be based on: (1) any report on market price published by the Inspector General (IG) of the Department of Health and Human Services (HHS) or GAO after December 31,1999; (2) a review of market prices by the Secretary including information from insurers, private health plans, manufacturers, wholesalers, distributors, physician supply houses, specialty pharmacies, group purchasing arrangements, physicians, suppliers or any other appropriate source as determined by the Secretary; (3) data submitted by the manufacturer of the drug or biological or by another entity; and (4) other appropriate information as determined by the Secretary. If the market price for a drug or biological determined through this process differs from the AWP amount, that market price shall be treated as the AWP amount when determining Medicare's payment for a drug or biological in 2004 and subsequently. The Secretary would be able to make subsequent determinations with respect to the widely available market price for a given drug or biological. If not, the prior market price determination will be considered as the basis for Medicare's payment amount for such an item.

If, however, the first market price determination for a given drug or biological would result in a payment amount that is 15% less than would otherwise be made, the Secretary would provide for an appropriate transition period where the price is reduced in annual increments equal to 15% of Medicare's payment amount in the previous year. At the end of the transition period, the market price (as determined) would serve as basis for Medicare's payment amount. This transition period would not apply to a drug or biological where a generic version of that drug or biological first enters the market on or after January 1, 2004. The generic version would not be required to be marketed under the chemical name of the given drug or biological.

New drugs and biologicals, those that are first available for Medicare payment after April 1, 2003, would be subject to certain requirements in order to obtain a code and receive Medicare payment. A manufacturer would be required to provide the Secretary with necessary and appropriate information on the estimated price that the manufacturer expects physicians and suppliers to pay to routinely obtain the drug or biological; the manufacturer would be able to provide the Secretary with other appropriate information as well. During the first year that the drug or biological is available for Medicare payment, the manufacturer would be required to provide the Secretary with updated information on the actual market prices paid by physicians or suppliers for such drugs and biologicals. These market prices would be equal to the lesser of the average wholesale price for the drug or biological or the amount determined by the Secretary based on information originally submitted by the manufacturer supplemented by other appropriate information. The market price of the drug or biological during the second year after becoming available for Medicare payment is subject to the same conditions as in the first year. In subsequent years, the market price would be equal to the lesser of the

average wholesale price or the widely available market price as determined by the Secretary in the same fashion as for existing drugs. If no market price determination occurs, then Medicare's payment for the drug or biological in the prior year is updated by the change in the CPI for medical care for the previous year ending in June.

The provision would be effective upon enactment.

With respect to home infusion drugs and biologicals, the Secretary would be able to make separate payments for these drugs and biologicals furnished through covered DME on or after January 1, 2004, if such payments are determined to be appropriate. Total amount of payments for the infusion drugs in the year could not exceed the total amount of spending that would have occurred without enactment of this legislation. The provision would be effective upon enactment.

Conference Agreement

Certain categories of drugs and biologicals will continue to be paid at 95 percent of the AWP; these include a drug or biological furnished before January 1, 2004; blood clotting factors furnished during 2004; a drug or biological furnished during 2004 that was not available for Part B payment as of April 1, 2003; pneumococcal, influenza, and hepatitis B vaccines; and a drug or biological (other than erythropoietin) furnished in connection with renal dialysis services that are separately billed by renal dialysis facilities; and radiopharmaceuticals and blood products. In general, payments for other drugs furnished in 2004 will equal 85 percent of the average wholesale price (determined as of April 1, 2003). Beginning in 2005, drugs and biologicals, except for pneumococcal, influenza, and hepatitis B vaccines and those associated with certain renal dialysis services, will be paid using either the average sales price methodology or through the competitive acquisition program. Infusion drugs furnished through covered durable medical equipment starting January 1, 2004 will be paid at 95% of the AWP in effect on October 1, 2003; those infusion drugs which may be furnished in a competitive acquisition area starting January 1, 2007 will be paid on the competitive price. Intravenous immune globulin will be paid at 95% of AWP in 2004 and paid according to the average sales price method beginning in 2005.

The Secretary is authorized to substitute a different percent of the April 1, 2003 AWP, based on the Secretary's NPRM, but not less than 80%. Also, the Secretary may adjust the price based on data submitted by the manufacturer of the drug or biological by October 15, 2003.

New sections 1847A and 1847B are established in the Social Security Act. New Section 1847A establishes the use of the average sales price methodology for payment for drugs and biologicals (except for pneumococcal, influenza, and hepatitis B vaccines, or drugs or biologicals furnished in connection with certain renal dialysis services, blood or blood products or radiopharmaceuticals) furnished starting January 1, 2005. This methodology does not apply in the case of a physician who elects to participate in the newly established competition acquisition program established in new Section 1847B; payments for drugs and biologicals will be paid under that section instead.

Medicare's payment under the average sales price methodology will equal 106% of the applicable price for a multiple source drug or single source drug, subject to the applicable beneficiary deductible and coinsurance requirements. The manufacturer will be required to specify the unit associated with each National Drug Code (NDC) as part of its Medicaid reporting requirements. Unit is defined as the lowest identifiable quantity of the drug or biological by NDC (including package size) that is dispensed, exclusive of any diluents without reference to volume measures pertaining to liquids. After 2004, the Secretary may establish the counting method and unit for the manufacturer to report.

The applicable price for all drug products within the same multiple source drug billing and payment code is the volume-weighted average of the sales prices. The applicable price for single source drugs is the lesser of the manufacturer's average sales price for an NDC or the wholesale acquisition cost (WAC). A limited number of single source drugs and biologicals are currently included in the same HCPCs codes, along with other similar single source products. The Conferees intend to exempt these products from the definition of single source drugs or biologicals, and continue to allow these products to be treated as multiple source drugs and be included within the same HCPCs code. The payment amount is determined without regard to any special packaging, labeling or identifiers on the dosage form or product or package. In the section, the term ''payment and billing code'' shall mean the HCPCs code for such drug or biological.

A manufacturer's average sales price is calculated by NDC code for each calendar quarter by dividing a manufacturer's total sales by the total number of units sold in that quarter. Certain sales are exempt from the calculation: (1) certain sales that are exempt from the Medicaid drug rebate program including those to the Indian Health Service, the Department of Veterans Affairs, a state Veteran's home, the Department of Defense, or the Public Health Services; and (2) sales that are nominal in amount, as used in the Medicaid rebate program. The average sales price will take into account volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks and certain rebates (not including Medicaid rebates). After 2004, the Secretary may include other price concessions that result in a price reduction to the purchaser as may be recommended by the Inspector General.

The Secretary will be able to disregard the average sales price during the first quarter of a new drug's sales if the price data is not sufficient to determine an average amount payable. The average sales price will be calculated by the manufacturer on a quarterly basis; to the extent that data on rebates and chargebacks is reported on a lagged basis, the manufacturer will apply the 12–month rolling average methodology to estimate the amount of such discounts, as specified by the Secretary. After 2004, the Secretary may establish a uniform methodology to estimate and apply such costs. Payment rates will be updated on a quarterly basis. The Secretary may contract with appropriate entities to determine the payment amounts. The Secretary may implement any provision of this section by program instruction or otherwise.

To monitor market prices, the Inspector General will conduct studies, which may include market surveys, to determine market prices of drugs and biologicals paid under this section. The Inspector General will compare average sales price under Medicare with the widely available market price and the average manufacturer price. The Secretary may disregard the average sales price reported by a manufacturer if this price exceeds the market price or average manufacturer price by a threshold percentage. In 2005 the threshold is 5%; in 2006 and subsequent years, the percentage threshold will be specified by the Secretary. If the Inspector General finds that the average sales price for a drug or biological exceeds the widely available market price or average manufacturer price by the applicable threshold, the Inspector General will inform the Secretary at specified times, and the Secretary will substitute a payment amount equal to the lesser of the widely available market price or 106 percent of the average manufacturer price.

The section requires that in order to have a drug covered under both Medicare and Medicaid, a manufacturer must submit information quarterly on the manufacturer's average sales price, total number of units, wholesale acquisition cost and sales made at nominal price. The Conferees intend that if a manufacturer knowingly (as defined by section 3729(b) of the False Claims Act) submits false information, that such submission be considered a ''false record or statement'' made or used ''to get a false or fraudulent claim paid or approved by the government'' for purposes of section 3729(a)(2) of title 31, United States Code, known as the False Claims Act. Thus if a manufacturer knowingly submits any false information, the manufacturer would be fully subject to liability under the False Claims Act.

The Conferees intend that that the Secretary, in making determinations to use the widely available market price, rather than the ASP, would provide a number of procedural and substantive safeguards to ensure the reliability and validity of the data used to make such determinations. These safeguards would include notice and comment rulemaking, identification of the specific sources of information used to make such determinations, and explanations of the methodology and criteria for selecting such sources.

If the Secretary determines that a manufacturer has misrepresented the average sales price of a drug, the Secretary may apply a civil monetary penalty of up to $10,000 for each price discrepancy and for each day in which the price misrepresentation was applied. In this subsection for drugs furnished in a year after 2004, the widely available market price is the price that a prudent physician or supplier would pay for a drug or biological, taking into account discounts, rebates and other price concessions routinely made available. The Secretary will consider information from one or more of the following sources including manufacturers, wholesalers, distributors, physician supply houses, specialty pharmacies, group purchasing arrangements, physician and supplier surveys as well as information on market prices from insurers and private health plans.

The Secretary will be able to use the wholesale acquisition cost or other reasonable measure of drug price instead of the manufacturer's average sale price in the case of certain public emergencies where there is a documented inability to access covered outpatient drugs and a related increase in price (which is not reflected in the manufacturer's average sale price for one or more quarters). The alternative price will be used until the price and availability of the drug or biological has stabilized and is substantially reflected in the manufacturer's average sale price.

There will be no administrative or judicial review of determinations of payment amounts including the assignment of NDCs to billing and payment codes; the identification of units and package size; the method to allocate rebates, chargebacks, and other price concessions to a quarter, the manufacturer average sales price when it is used for Medicare's price determinations, and the disclosure of the average manufacturer price under certain situations.

The Secretary will conduct a study on the sales of drugs and biologicals to large volume purchasers such as pharmacy benefit managers to determine whether the price at which drugs and biologicals are sold to these purchasers represents the price made available to physicians. The Secretary will submit a report to Congress, including recommendations, on whether sales to large volume purchasers should be excluded from the computation of the manufacturer's average sale price. Upon completion of this report, the Secretary may require that manufacturers separately report these prices, which may also then be excluded from future calculations of ASP, if the Secretary determines that doing so would be better reflect prices available to prudent physicians.

Under the new Section 1847B, the Secretary would be required to establish a competitive acquisition program to acquire and pay for competitively biddable drugs and biologicals. Under the program, competitive acquisition areas (defined as an appropriate geographic region) will be established throughout the United States. Each year, a physician would be able to select a contractor who would deliver covered drugs and biologicals to the physician; alternatively, a physician would be able to elect payment using the methodology established by Section 1847A. Conferees intend this choice to be completely voluntary on behalf of the physician. Use of this system should reduce administrative and inventory costs for physicians. In addition, because physicians do not take title to the drug, their liability is reduced.

Under the competitive acquisition program, categories of competitively biddable drugs under this program will be established, and the program will be phased in beginning in 2006. In order to promote competition and the efficient operation of the program, the Secretary would be able to waive provisions of the Federal Acquisition Regulation, other than those relating to confidentiality of information and other provisions deemed appropriate by the Secretary.

Competitively biddable drugs and biologicals exclude pneumococcal, influenza, and hepatitis B vaccines or drugs or biologicals (other than erythropoietin) furnished in connection with renal dialysis services furnished starting January 1, 2006, radiopharmaceuticals, IVIG products and blood products. Conferees do not intend to exclude therapeutic vaccines, such as new vaccines used to treat cancer that may be in development. The Secretary will be able to exclude competitively biddable drugs and biologicals including classes of such drugs and biologicals that are not appropriate for competitive bidding, if such inclusion is not likely to result in significant savings or is likely to have an adverse impact on access to the drugs and biologicals. The Secretary may provide for payment of these excluded drugs and biologicals (or class of same) using the average sale price methodology established in Section 1847A. Conferees intend the use of the exclusion authority to apply in exceptional cases. Such authority is not intended to be a system wide replacement for competitive bidding.

The contractor supplying the physician in the area will submit the claim for the drugs and biologicals and will collect the cost-sharing amount from the beneficiary after administration of the drug. Both program payment and beneficiary cost sharing amounts will only be made to the contractor and will only be made upon the administration of the drug or biological. The Secretary is required to establish a process for recovery of payments billed at the time of dispensing of drugs or biologicals that were not actually administered as well as a process by which physicians submit information to contractors for the purposes of collection of any applicable deductible or coinsurance amounts. Payment could only be made to the contractor, provided the contractor has a contract and the physician elects that contractor for such category of drug or biological for the area. Alternatively, the physician may elect Section 1847A to apply.

Certain contractor selection and contracting requirements for the competitive acquisition program are established. Specifically, the Secretary is required to establish an annual selection process for a contractor in each area for each category of drugs and biologicals. The selection of the contractor will be made at the time the physician elects to participate in the program established under Section 1847B. The Secretary will make a list of contractors in the different competitive acquisition area who are available to physicians on an ongoing basis through a directory posted on the Internet website of the Centers for Medicare & Medicaid Services, and through the annual CMS ''Dear Doctor'' campaign.

The Secretary will conduct a competition among entities for the acquisition of at least one competitively biddable drug or biological that is a multiple source or a single source drug or biological within each billing and payment code within each category for each area. The competition within a HCPCS code for multiple source drug products is intended to produce competitive forces that will lower bid prices for drugs. Because multiple source drugs and generics within a HCPCS code are therapeutically equivalent, such competition will ensure access to appropriate therapeutic products. The Secretary may not award the 3-year contract to any entity that does not have the capacity to supply competitively biddable drugs or biologicals within the applicable category or does not meet quality, service, and financial performance and solvency standards established by the Secretary. Specifically, the entity would be required to have (1) sufficient arrangements to ship competitively biddable drugs and biologicals at least 5 days of the week in order for the timely delivery (including for emergency situations) of such drugs and biologicals; (2) procedures for the prompt response and resolution of physician and beneficiary complaints and inquiries regarding the shipment of these drugs; and (3) a grievance and appeals process. Review of complaints by the Medicare Provider Ombudsman has been established in Section 923 of this legislation. The Secretary will not be able to contract with an entity that has had its license for distributing drugs (including controlled substances) suspended or revoked by the Federal or a State Government or that has been excluded from program participation.

The Secretary will be able to limit the number of qualified entities in each category and area, but not below 2 for any category and area. The Secretary is required to base selection on bid prices for competitively biddable drugs and biologicals, bid prices for distribution of those drugs and biologicals, ability to ensure product integrity, customer service, past experience with drug and biologic distribution, and other factors.

The contract is subject to terms and conditions that the Secretary may specify. The contract will be for a term of 3 years, but may be terminated by either the Secretary or the entity with appropriate notice. The Secretary must require that all drugs and biological products distributed by a contractor be acquired directly from the manufacturer or from a distributor that has acquired the products directly from the manufacturer. Nothing in this provision relieves or exempts any contractor from the requirements of the Federal Food, Drug, and Cosmetic Act that relate to the wholesale distribution of prescription drugs or biologicals. Conferees want to ensure the safe distribution of drugs and to ensure counterfeiting and adulteration is minimized. Such measures include includes the safe and appropriate storage of drugs and biologicals, disposition of damaged and outdated drugs and biologicals and appropriate record keeping and compliance personnel.

Contractors will be required to comply with a code of conduct and fraud and abuse rules. Specifically, the contractor will comply with standards relating to conflicts of interest and all applicable provisions and guidelines relating to the prevention of fraud and abuse established by the Department of Justice and the Inspector General.

The appropriate contractor, as selected by the physician, will supply competitively biddable drugs and biologicals directly to the physician, except under the circumstances when a beneficiary is presently able to receive a drug at home or other non-physician office settings as the Secretary may provide. The contractor shall not deliver drugs to a physician without first receiving a prescription as well as other necessary information specified by the Secretary. However, a physician would not be required to submit a prescription for each individual treatment or change a physician's flexibility in terms of writing a prescription for a single treatment or course of treatment. Conferees do not intend contractors to mix drug products prior to a patient's visit, but may do so should it be clinically advised. If specialty pharmacies mix products under the program for a specific patient, it should be done only to the benefit of the patient. Such cases may include a physician office that lacks the ability to mix Part B drugs in compliance with medical, clinical and environmental standards. In no way do conferees intend the requirements for the competition program to impair a patient's access to health treatment as a result of changes in the patient's health status, including pre-mixed drugs or biologics.

The Secretary is required to establish rules allowing physicians to use drugs or biologics from their own inventories in emergency situations consistent with safe drug practices and with adequate safeguards against fraud and abuse. In order to resupply such an inventory, a physician will be required to demonstrate that the drugs are immediately required; that the immediate need could not reasonably have been foreseen, that the drugs could not be delivered by the contractor in a timely manner, and that the drugs were administered in an emergency situation. No applicable State requirements relating to the licensing of pharmacies are waived.

The Secretary is required to base selection of the contractors on several factors including bid prices. Bid prices are those in effect and available through the entity for the contract period and includes all costs related to the delivery of the drug or biological to the selecting physician or other delivery point as well as all dispensing and shipping costs. Costs relating to the administration of the drug or biological or waste, spillage or spoilage are not included. As part of the awarded contract, the selected contractor will be required to disclose the reasonable, net acquisition costs regularly (but not more often than once a quarter) as specified by the Secretary. The selected contractor will also be required to disclose appropriate price adjustments over the period of the contract to reflect changes in reasonable, net acquisition costs.

Payments would be based upon bids submitted and accepted, and the Secretary

would determine a single payment amount for each drug in an area. The Secretary will apply special rules and alternative payment amounts to establish a price for specific competitively biddable drugs and biologicals, including new drugs and biologicals (for which an average bid price has not been previously determined) and other exceptional cases specified in regulations. Medicare's payment for these drugs equals 80% of the payment amount after the Medicare beneficiary meets the applicable deductible. Generally, these coinsurance and deductible amounts will be collected by the contractor that supplies the drug or biological which may be collected in a similar manner as those collected for durable medical equipment.

Nothing in the section prevents a bidder from submitting a contract offer to cover all areas of the United States. Similarly, nothing would require a bidder to submit a contract offer to cover all areas of the United States. The amount of the bid price submitted under a contract offer is required to be the same for all portions of the area.

The Secretary will establish a procedure under which a prescribing physician has certain appeal rights that are similar to those provided to a physician who prescribes durable medical equipment or a clinical diagnostic laboratory test. Certain provisions specified in Section 1842(o)(3) with respect to assignment will also apply to claims for competitively biddable drugs and biologicals. Certain protections against liability in case of adverse medical necessity determination will apply to Medicare beneficiaries. There shall be no administrative or judicial review with respect to the establishment of payment amounts, contract awards, establishment of competitive acquisition areas, the phased in implementation, the selection of categories of competitively biddable drugs and biologicals for competitive acquisition or the bidding structure or number of contractors who are selected.

No later than July 1, 2008, the Secretary is required to report to Congress on savings, reductions in cost-sharing, access to competitively biddable drugs and biologicals, the range of choices of contractors available to providers as well as beneficiary and provider satisfaction under the competitive acquisition program. The report will also examine the information comparing prices for drugs in the competitive acquisition program and under the application of the average sales price methodology under Section 1847A.

In developing rules to implement this section, the Secretary should seek public comment on factors that disadvantage certain covered drugs based on drug forms and delivery and dispensing modes, and which may result in increased Medicare expenditures.

Items and Services Relating to Furnishing of Blood Clotting Factors (Section 303(e)(1) of the Conference Agreement and Section 303(f) of the House Bill).

Present Law

Medicare will pay for blood clotting factors for hemophilia patients who are competent to use such factors to control bleeding without medical supervision, as well as the items related to the administration of such factors.

House Bill

MedPAC would be required to submit to Congress specific recommendations with respect to payment for blood clotting factors and its administration in its 2004 annual report. The provision would be effective upon enactment.

Senate Bill

The Secretary is required to review the GAO report on payment for blood clotting factors and provide a separate payment for the administration of these factors. The total amount of payments for blood clotting factors furnished in CY2004 would not exceed the amount that would have otherwise been expended. In CY2005 and subsequently, this separate payment amount would be updated by the change in the CPI for medical care for the previous year ending in June. The provision would be effective upon enactment.

Conference Agreement

The Secretary is required to review the GAO report on payment for blood clotting factors and provide a separate payment for the administration of these factors. The payment amount may take into account the mixing (if appropriate) and delivery of factors to an individual, including special inventory management and storage requirements as well as ancillary supplies and patient training necessary for self-administration. The total amount of payments for blood clotting factors furnished in CY2005 can not exceed the amount that would have otherwise been expended. In CY2006 and subsequently, this separate payment amount would be updated by the change in the CPI for medical care for the previous year ending in June.

Pharmacy Supplying Fee for Certain Drugs and Biologicals (Section 303(e)(2), Section 303(g) of the House Bill and Section 432(b)(8) of the Senate Bill).

Present Law

Medicare pays for certain outpatient prescription drugs and biologicals. For instance, Medicare pays a dispensing fee in conjunction with inhalation therapy drugs used in nebulizers. Medicare does not pay a dispensing fee to pharmacists or providers who supply oral drugs.

House Bill

The Secretary would be required to provide for separate payments in the physician fee schedule to cover the administration and acquisition costs associated with covered drugs and biologicals furnished by a contractor under the competitive acquisition program. The provision would be effective upon enactment.

Senate Bill

Medicare would pay a dispensing fee (less the applicable deductible and coinsurance amounts) to licensed approved pharmacies for covered immunosuppressive drugs, oral anti-cancer drugs, and oral anti-nausea drugs used as part of an anti-cancer chemotherapeutic regimen. Medicare would be able to pay a dispensing fee (less the applicable deductible and coinsurance amounts) to licensed approved pharmacies for other drugs and biologicals. The provision would be effective upon enactment.

Conference Agreement

The Secretary is required to pay a supply fee (less the applicable deductible and coinsurance amounts) to licensed approved pharmacies for covered immunosuppressive drugs, oral anti-cancer drugs, and oral anti-nausea drugs used as part of an anti-cancer chemotherapeutic regimen. Such fee is not meant to be a dispensing fee. The intent of the Conferees is to not to include in such fee, amounts for cognitive services.

Linkage of Revised Drug Payments and Increases for Drug Administration (Section 303(f) of the Conference Agreement and Section 432(b)(1) of the Senate Bill).

Present Law

No provision.

House Bill

No provision.

Senate Bill

A linkage of revising drug payments to incorporate market prices and payment increases for drug administration would be established.

Conference Agreement

The Secretary cannot implement the revision in payment amount for categories of drug or biological administered by physicians unless the Secretary concurrently makes the practice expense payment adjustment on the basis of survey data as specified earlier.

Prohibition of Administrative and Judicial Review (Section 303(g) of the Conference Agreement and Section 432(d) of the Senate Bill).

Present Law

Medicare beneficiaries and, in certain circumstances, providers and suppliers of health care services may appeal adverse determinations regarding claims for benefits under Part A and Part B. Section 1869 of the SSA allows these parties who have been denied coverage of an item or service the right to appeal that decision through a series of administrative appeals and then into federal district court under certain circumstances. Section 1878 of the SSA allows providers who are dissatisfied with certain cost reporting determinations that affect their reimbursement amounts the right to appeal that decision in front of the Provider Reimbursement Review Board and then into federal district court if certain thresholds regarding the amount in dispute are met at each step of the appeals process.

House Bill

No provision.

Senate Bill

The provisions concerning Medicare's determination of payment amounts for existing and new drugs and biologicals including the administration of blood clotting factors, home infusion drugs and inhalation drugs would not be subject to administrative or judicial review under Sections 1869 and 1878 of the SSA or otherwise. The provision would be effective upon enactment.

Conference Agreement

The provisions concerning Medicare's determination of payment amounts, methods or adjustments including those with respect to a drug's widely available market price in 2004, the administration of blood clotting factors, and pharmacy supplying fees will not be subject to administrative or judicial review under Sections 1869 and 1878 of the SSA or otherwise. The provision would be effective upon enactment.

The provisions concerning Medicare's determination of the budget neutral adjustments, adjustments to the practice expense relative value units for certain drug administration services and other drug administration services will not be subject to administrative or judicial review under Section 1869 of the SSA or otherwise. The provision would be effective upon enactment.

The provisions concerning Medicare's treatment of other services currently in the non-physician work pool, payment for multiple chemotherapy agents furnished on a single day through the push technique, and the transitional adjustment will not be subject to administrative or judicial review under Sections 1869 and Section 1878 of the SSA or otherwise. The provision would be effective upon enactment.

Continuation of Payment Methodology for Radiopharmaceuticals (Section 303(h) of the Conference Agreement and Section 303(c) of the House Bill).

Present Law

Under certain circumstances, Medicare makes a separate payment for supplies furnished in connection with a procedure. Medicare will pay separately for pharmaceutical

or radiopharmaceutical supplies when procedures such as diagnostic radiolologic procedures or other diagnostic tests requiring a pharmacological stressing agent.

Although Medicare uses the Healthcare Common Procedure Coding System (HCPCS) codes to identify and pay for physician administered drugs, the AWPs are established for national drug codes (NDC) codes that are maintained by the Food and Drug Administration (FDA). Until January 1, 2003, each Medicare carrier would convert NDC codes into HCPCS codes in order to develop AWP-based payments for physicians in its area. To address the variation in carrier-established drug pricing methods, CMS implemented a single drug pricer (SDP), a centrally administered fee schedule for covered outpatient drugs on January 1, 2003. The SDP excludes radiopharmaceuticals, outpatient hospital drugs, and drugs paid by the durable medical equipment regional carriers (DMERCs).

House Bill

These provisions would not affect the existing carrier invoice pricing method used to pay for radiopharmaceuticals. The provision would be effective upon enactment.

Senate Bill

No provision.

Conference Agreement

The conference agreement will not change the Part B payment methodology for radiopharmaceuticals including the use by carriers of the invoice pricing method.

Conforming Amendments (Section 303(i) of the Conference Agreement and Section 303(d) of the House Bill).

Present Law

No provision.

House Bill

The provisions in this section would not affect the existing coverage for outpatient drugs. The collection of data to calculate the manufacturer's average sales price and the manufacturer's wholesale acquisition cost would be included as part of the Medicaid drug rebate program for calendar quarters beginning on or after April 1, 2004. Information on sales that were made at a nominal price would also be submitted and be subject to audit by the HHS Inspector General. The provision would be effective upon enactment.

Senate Bill

No provision.

Conference Agreement

The conference agreement includes conforming amendments to the existing statutory language. A pharmacy-dispensing fee will not be paid when payment for a drug is made under the average sales price or competitive acquisition program. The provisions in this section will not affect the existing coverage for outpatient drugs. The list of services paid for under Part B will be amended to include drugs paid for under Sections 1847, 1847A, and 1847B. Information by NDC (including package size) on the manufacturer's average sales price and total number of units; the manufacturer's wholesale acquisition cost; sales that were made at a nominal price will be included as part of the Medicaid drug rebate program for calendar quarters beginning on or after January 1, 2004. This information will be subject to audit by the Inspector General. The Secretary will be able to survey wholesalers and manufacturers that directly distribute covered outpatient drugs to verify average sales price (including wholesale acquisition cost) under the Medicaid drug rebate program. The provisions with respect to the Congressional review of agency rulemaking will not apply with respect to regulations that implement adjustments to the physician fee schedule or the application of market based payment systems. The existing requirement that the Secretary study the effect on AWP of Medicare's policy to pay for covered outpatient drugs at 95% of AWP is repealed.

Extension

Payment for Inhalation Drugs and Certain Other Drugs (Section 305 of the Conference Agreement, Section 602(c) of the House Bill, and Section 432(b)(7) of the Senate Bill).

Present Law

Medicare will cover outpatient prescription drugs and biologicals if they are necessary for the effective use of covered durable medical equipment (DME), including those drugs that must be put directly into the equipment such respiratory drugs given through a nebulizer (inhalation drugs).

House Bill

GAO would be required to conduct a study to examine the adequacy of current reimbursements for inhalation therapy under the Medicare program and submit the results of the study in a report to Congress no later than May 1, 2004.

Senate Bill

The Secretary would be able to increase payments for covered DME associated with inhalation drugs and biologicals and make separate payments for such drugs and biologicals furnished through covered DME on or after January 1, 2004, if such payments are determined to be appropriate. The associated spending attributed to the increased and separate payments for the covered DME and inhalation drugs and biologicals in the year would not exceed the 10% of the difference between the savings in total spending for these drug and biologicals attributed to the prescription drug pricing changes enacted in this legislation. The provision would be effective upon enactment.

Conference Agreement

Inhalation drugs or biologicals furnished through covered durable medical equipment that is not described in subparagraph (A)(iv) will be paid at 85% of AWP in 2004. In 2005, it will be the amount provided under the average sales price methodology.

GAO is required to conduct a study to examine the adequacy of current reimbursements for inhalation therapy under the Medicare program and submit the results of the study in a report to Congress no later than 1 year from the enactment date of this legislation.

Demonstration Project for Use of Recovery Audit Contractors (Section 305 of the Conference Agreement and Section 304 of the House Bill).

Present Law

No provision.

House Bill

The Secretary would be required to conduct a demonstration project for up to 3 years on the use of recovery audit contractors under the Medicare Integrity Program. The recovery audit contractors would identify underpayments and overpayments in the Medicare program and would recoup overpayments made to providers. Payment would be made to these contractors on a contingent basis, a percentage of the amount recovered by the contractors would be able to be retained by the Secretary and available to the program management account of Centers for Medicare & Medicaid Services (CMS), and the Secretary would be required to examine the efficacy of using these contractors with respect to duplicative payments, accuracy of coding, and other payment policies in which inaccurate payments arise. The demonstration project would be required to cover at least 2 states that are among the states with the highest per-capita utilization rates of Medicare services and have at least 3 recovery audit contractors. The Secretary would be able to waive Medicare statutory provisions to pay for the services of the recovery audit contractors. Recovery of an overpayment through this project would not prohibit the Secretary or the Attorney General from investigating and prosecuting appropriate allegations of fraud and abuse. Fiscal intermediaries, carriers, and Medicare Administrative Contractors would not be eligible to participate as a recovery audit contractor. The Secretary would be required to show preference to contracting with entities that have demonstrated more than 3 years direct management experience and a proficiency in recovery audits with private insurers or state Medicaid programs. Within 6 months of completion, the Secretary would be required to report to Congress on the project's savings to the Medicare program, including recommendations on the cost-effectiveness of extending or expanding the program. The provision would be effective upon enactment.

Senate Bill

No provision.

Conference Agreement

The conference agreement requires the Secretary to conduct a demonstration project for up to 3 years on the use of recovery audit contractors under the Medicare Integrity Program. The recovery audit contractors will identify underpayments and overpayments in the Medicare program and recoup overpayments made to providers. Payment may be made to these contractors on a contingent basis, a percentage of the amount recovered by the contractors is to be retained by the Secretary and available to the program management account of the Centers for Medicare & Medicaid Services (CMS), and the Secretary is required to examine the efficacy of using these contractors with respect to duplicative payments, accuracy of coding, and other payment policies in which inaccurate payments arise.

The demonstration project is required to cover at least 2 states that are among the states with the highest per-capita utilization rates of Medicare services and that have at least 3 recovery audit contractors. The Secretary is required to waive Medicare statutory provisions as necessary in order to pay for the services of the recovery audit contractors. The Secretary is required to show preference to contracting with entities that have demonstrated more than 3 years direct management experience and a proficiency in recovery audits with private insurers or state Medicaid programs. Fiscal intermediaries, carriers, and Medicare Administrative Contractors are not eligible to participate as a recovery audit contractor. Recovery of an overpayment through this project does not prohibit the Secretary or the Attorney General from investigating and prosecuting allegations of fraud or abuse arising from the overpayment. Within 6 months of completion, the Secretary is required to report to Congress on the project's savings to the Medicare program, including recommendations on the cost-effectiveness of extending or expanding the program. The provision is effective upon enactment.

Pilot Program for National and State Background Checks on Direct Patient Access Employees of Long-Term Care Facilities or Providers (Section 306 of the Conference Agreement and Section 620 of the Senate Bill).

Present Law

Nursing homes and home health agencies may request the Federal Bureau of Investigation (FBI) to search its all-state national data bank of arrest and convictions for the

criminal histories of applicants who would provide direct patient care, as long as states establish mechanisms for processing these requests. Most states have enacted laws that require or allow nursing homes and home health agencies to conduct these criminal background checks for certain categories of potential employees. The Attorney General may charge nursing homes and home health agencies fees of no greater than $50 per request.

To conduct a criminal background check, nursing homes and home health agencies must provide a copy of an applicants fingerprints, a statement signed by the applicant authorizing the search, and other information to the appropriate state agency. Such information must be provided no later than 7 days after its acquisition by the nursing home or home health agency. Nursing facilities or home health care agencies that deny employment based on reasonable reliance on information from the Attorney General are exempt from liability for any action brought by the applicant. The information received from either the state or Attorney General may be used only for the purpose of determining the suitability of the applicant for employment by the agency in a position involved in direct patient care.

HHS maintains a national health care fraud and abuse data base, the Healthcare Integrity and Protection Data Bank (HIPDB), for the reporting of final adverse actions, including health care related civil judgments and criminal convictions of health care practitioners, providers and suppliers. This information is currently available for self-query by government agencies, health plans, health care providers, suppliers and practitioners. All states also maintain their own registries of persons who have completed nurse aide training and competency evaluation programs and other persons for whom the state determines meet the requirements to work as a nurse aide. Included in these registries are data describing state findings of resident neglect, abuse and/or the misappropriation of resident property.

State agencies that survey providers to ensure they meet Medicare and/or Medicaid requirements for participation are referred to as survey and certification agencies, or state survey agencies. Under current law, state survey agencies are required to investigate allegations of resident neglect, abuse and/or the misappropriation of resident property in nursing homes.

House Bill

No provision.

Senate Bill

Medicare and/or Medicaid certified nursing homes, home health agencies, hospices, long-term care hospitals, intermediate care facilities for the mentally retarded (ICF/MRs), and other entities providing long-term care services would be required to initiate background checks for certain workers. These workers would include those licensed, certified, nonlicensed, or contracted employee of a long term care facility or provider (other than a volunteer) that has access to a patient or resident, including nurse assistants, nurse aides, home health aides, individuals who provide home care, and personal care workers and attendants.

Providers would be required to: (1) give written notice to workers about background checks, (2) obtain a written statement disclosing any conviction for a relevant crime or finding of patient or resident abuse from the worker, (3) receive written permission from workers authorizing a criminal background check, (4) obtain fingerprints or thumb prints of workers, (5) conduct self-queries of the HIPDB, and (6) comply with other information requirements specified by the Secretary. States would then be required to check state arrest and conviction data banks, and if appropriate, request the FBI to check national criminal history records on behalf of providers that are required to conduct these background checks.

The long-term care providers would be prohibited from employing a worker who has any conviction for a relevant crime or a finding of patient or resident abuse. Those found to violate these requirements would be subject to criminal penalty fines and/or imprisonment. Providers that are found to violate these requirements would face civil monetary fines. Providers would be permitted to provisionally employ workers pending completion of the criminal background checks as long as they comply with supervisory requirements. Special consideration would be given to rural facilities and home health providers.

Providers would be reimbursed for their costs associated with the requirements of this provision by the Secretary of HHS. The Attorney General could charge fees to any state requesting a search and exchange of records. States could also charge providers fees. Yet, providers could not charge fees to workers.

The nurse aide registry would be expanded to include all employees of providers, including non-licensed workers, and renamed an employee registry. Survey and certification agencies would be required to investigate abuse and neglect allegations and misappropriation of resident property concerning any individual employed or used by any participating health and long-term care providers. $10.2 million would be authorized to be appropriated for FY 2004, with compliance with these provisions phases in for various groups of providers.

Grants would be available to public or private non-profit entities to develop information on best practices in patient abuse prevention training (including behavior training and interventions) for managers and staff of hospital and health care facilities, and for other purposes.

Long-term care providers could access the HIPDB data bank and HIPDB would be expanded to include findings of abuse, neglect, or misappropriation of resident property. A report would be due to Congress no later than 2 years after enactment on the number of requests for searches and exchanges of records, the disposition of requests, and the cost of responding to such requests.

Conference Agreement

The conference agreement requires the Secretary to establish pilot projects in no more than 10 states for the purpose of expanding background checks for workers to other Medicare and Medicaid long-term care providers. Long-term care facilities or providers include Medicare- and/or Medicaid-certified nursing homes, home health agencies, hospices, long-term care hospitals, intermediate care facilities for the mentally retarded (ICF/MRs), and other entities that provide long-term care services (except for those paid through a self-directed arrangement).

States that agree to participate in this pilot project will be responsible for monitoring provider compliance and must establish procedures for workers to appeal or dispute the findings of the background checks. The Secretary will establish criteria for selecting those states seeking to participate and pay those states for the costs of conducting the pilot program (reserving 2% of the payments for the program's evaluation).

Long-term care providers in participating states are required to: (1) give notice to new workers about background checks, and (2) obtain a written statement disclosing any conviction for a relevant crime or finding of patient or resident abuse from the worker, (3) receive written permission from workers authorizing a criminal background check, (4) obtain a rolled set of finger prints of workers, (5) obtain any other information specified by the state; and (6) initiate a check of available registries that document findings of resident or patient neglect, abuse, or misappropriation of property (if no information about a conviction of a relevant crime or finding of abuse are found). Providers must also obtain information on the workers from the state through a 10–fingerprint background check to be conducted using state criminal records and the Integrated Automated Fingerprint Identification system of the Federal Bureau of Investigation. Disqualifying information for employment includes information about a conviction for a relevant crime, a finding of patient or resident abuse, or a felony conviction related to health care fraud or a controlled substance. Under the agreement, at least one state should test if providers could contract with employment agencies, subject to conditions specified by the state, to conduct these background checks.

Pending completion of the national and state criminal history background checks, states may permit providers to provisionally employ workers as long as they comply with supervisory requirements established by the state. These requirements would take into account the cost or other burdens associated with small rural providers as well as the nature of care delivered by home health or hospice providers.

The information obtained from the check may only be used for the purpose of determining the suitability of the applicant for employment. Providers are also protected from liability for denying employment based on reasonable reliance on information from the background checks. For fiscal years 2005 and 2006, $25 million is appropriated from funds not otherwise appropriated.

GAO Study (Section 303(e) of the House Bill).

Present Law

No provision.

House Bill

GAO would be required to conduct a study to assess the impact of amendments made by this section on the delivery of services and their impact on access to drugs by beneficiaries. The report would be due no later than 2007.

Senate Bill

GAO would be required to conduct a study that examines the impact of the drug payment and adjustment provisions on the access of Medicare beneficiaries' to covered drugs and biologicals. The report, including appropriate recommendations, would be due to Congress no later than January 1, 2006. The Inspector General would be required to conduct one or more studies that examine the market prices for Medicare covered drugs and biologicals, which are widely available to physicians and suppliers. The report would examine those drugs and biologicals that represent the largest portion of Medicare spending on such items and include a comparison of market prices with Medicare payment amounts.

Conference Agreement

No provision.

Study on Codes for Non-Oncology Codes (Section 303(h) of the House Bill).

Present Law

No provision.

House Bill

The Secretary would be required to submit a study to Congress within one year of enactment that examines the appropriateness of

establishing and implementing separate codes for non-oncology infusions that address the level of complexity and resource consumption. If deemed appropriate, the Secretary would be able to implement appropriate changes in the payment methodology. The provision would be effective upon enactment.

Senate Bill

No provision.

Conference Agreement

No provision.

Payment for Chemotherapy Drugs Purchased But Not Administered by Physicians (Section 432(b)(9) of the Senate Bill).

Present Law

Medicare does not pay for chemotherapy drugs that purchased by physicians, are not dispensed, and must be discarded.

House Bill

No provision.

Senate Bill

The Secretary would be able to compensate a physician for chemotherapy drugs that are purchased with a reasonable intent to administer to a Medicare beneficiary but which cannot be administered despite the physician's reasonable efforts, because the beneficiary is too sick or the beneficiary's condition changes and the physician must discard the drugs. The Secretary would be able to increase the Medicare payment amount for all covered chemotherapy drugs, but the total amount of the increase could not exceed one percent of the payment for chemotherapy drugs. The beneficiary's cost sharing amounts would not be affected. The provision would be effective upon enactment.

Conference Agreement

No provision.

Extension of Medicare Secondary Payer Rules for Individuals with End-Stage Renal Disease (Section 450F of the Senate Bill).

Present Law

Generally, Medicare is the primary payer, that is, it pays health claims first, with an individual's private or other public plan filling in some or all of the coverage gaps. In certain cases, the beneficiary's other coverage pays first, while Medicare is the secondary payer. This is known as the Medicare secondary payer (MSP program). The MSP provisions apply to group health plans for the working aged, large group health plans for the disabled, and, for 30 months, employer health plans for the end-stage renal disease (ESRD) population.

House Bill

No provision.

Senate Bill

This provision would extend the limited time period that employer health plans are primary payer for beneficiaries with end-stage renal disease from 30 months to 36 months. The provision would apply for items and services furnished beginning January 1, 2004.

Conference Agreement

No provision.

TITLE IV—RURAL PROVISIONS

Subtitle A—Provisions Relating to Part A Only

Equalizing Urban and Rural Standardized Payment Amounts under the Medicare Inpatient Hospital Prospective Payment System (Section 401 of the Conference Agreement, Section 402 of the House Bill, and Section 401 of the Senate Bill).

Present Law

Medicare pays for inpatient services in acute hospitals in large urban areas using a standardized amount that is 1.6% more than the standardized amount used to pay hospitals in other areas (both rural areas and smaller urban areas). The Consolidated Appropriations Act of 2003 (P.L. 108–7) provided for a temporary payment increase for rural and small urban hospitals; all Medicare discharges from April 1, 2003, to September 30, 2003, will be paid on the basis of the large urban area amount. This temporary increase was further extended to discharges through March 31, 2004 by P.L. 108–89, which permitted the Secretary to delay implementation of the payment increase until November 1, 2003, if necessary.

Under Medicare's prospective payment system for inpatient services, separate standardized amounts are used to establish payments for discharges from short-term general hospitals in Puerto Rico. The separate amounts are a blended calculation based on an equal proportion of the federal national amount and the local amount, which are computed using data from hospitals in Puerto Rico. Presently, two local amounts are calculated: one for hospitals in large urban areas and one for hospitals in other areas.

House Bill

Beginning for discharges in FY2004, the standardized amount for hospitals located in areas other than large urban areas would be equal to the amount used to pay hospitals located in large urban areas. Technical conforming amendments would also be adopted.

Senate Bill

Medicare would pay hospitals in rural and small urban areas in the fifty states using the standardized amount used to pay hospitals in large urban areas starting for discharges in FY2004. The Secretary would compute one standardized amount for hospitals in Puerto Rico equal to that for urban areas.

Conference Agreement

Medicare will pay hospitals in rural and small urban areas in the fifty states using the standardized amount that would be used to pay hospitals in large urban areas starting for discharges in FY2004. The Secretary will compute one local standardized amount for all hospitals in Puerto Rico equal to that for hospitals in large urban areas in Puerto Rico starting for discharges in FY2004. The existing single standardized amount will continue for hospitals that are not in Puerto Rico are not affected. Hospitals in Puerto Rico will receive the legislated payment increase starting for discharges on April 1, 2004.

Enhanced Disproportionate Share Hospital (DSH) Treatment for Rural Hospitals and Urban Hospitals with Fewer than 100 Beds (Section 402 of the Conference Agreement, Section 401 of the House Bill, and Section 404 of the Senate Bill).

Present Law

Medicare makes additional payments to certain acute hospitals that serve a large number of low-income Medicare and Medicaid patients as part of its inpatient prospective payment system (IPSS). As specified by BIPA, starting with discharges occurring on or after April 1, 2001, all hospitals are eligible to receive Medicare disproportionate share hospital (DSH) payments when their DSH patient percentage or threshold amount exceeds 15%. Different formulas are used to establish a hospital's DSH payment adjustment, depending upon the hospital's location, number of beds and status as a rural referral center (RRC) or sole community hospital (SCH). Although a SCH or RRC can qualify for a higher DSH adjustment, generally, the DSH adjustment that a small urban or rural hospital can receive is limited to 5.25%. Large (100 beds and more) urban hospitals and large rural hospitals (500 beds and more) are eligible for a higher adjustment that can be significantly greater; the amount of the DSH adjustment received by these larger hospitals will depend upon its DSH percentage. Certain urban hospitals (Pickle hospitals) receive DSH payments under an alternative formula that considers the proportion of a hospital's patient care revenues that are received from state and local indigent care funds.

House Bill

Starting for discharges after October 1, 2003, a hospital that is not a large urban hospital that qualifies for a DSH adjustment would receive its DSH payments using the current DSH adjustment formula for large urban hospitals, subject to a limit. The DSH adjustment for any of these hospitals, except for rural referral centers, would be capped at 10%. A Pickle hospital receiving a DSH adjustment under the alternative formula would not be affected.

Senate Bill

Starting for discharges after October 1, 2004, a hospital that qualifies for a DSH adjustment when its DSH patient percentage exceeds the 15% DSH threshold would receive the DSH payments using the current formula that establishes the DSH adjustment for a large urban hospital. A Pickle hospital receiving a DSH adjustment under the alternative formula would not be affected.

Conference Agreement

Starting for discharges after April 1, 2004, a hospital that is not a large urban hospital that qualifies for a DSH adjustment will receive its DSH payments using the current DSH adjustment formula for large urban hospitals, subject to a limit. The DSH adjustment for any of these hospitals, except for rural referral centers, will be capped at 12%. A Pickle hospital receiving a DSH adjustment under the alternative formula will not be affected by this provision.

Adjustment of the Medicare Inpatient Hospital Prospective Payment System Wage Index to Revise the Labor-Related Share of Such Index (Section 403 of the Conference Agreement, Section 416 of the House Bill, and Section 402 of the Senate Bill).

Present Law

Medicare's payments to acute hospitals are adjusted, either increased or decreased as appropriate, by the wage index of the area where the hospital is located or where it has been reassigned. Presently, approximately 71 percent of the standardized amount for each hospital discharge is adjusted by the area wage index. Decreasing this proportion or labor-related share would increase Medicare payments to hospitals in areas with wage indices below one and decrease Medicare payments to hospitals in areas with wage indices above one.

House Bill

For discharges occurring on or after October 1, 2003, the Secretary would be required to decrease the labor-related share to 62 percent of the standardized amount only if such change would result in higher total payments to the hospital. This provision would be applied without regard to certain budget-neutrality requirements.

Senate Bill

For cost reporting periods beginning on or after October 1, 2004, the Secretary would be required to decrease the labor-related share to 62 percent of the standardized amount only if such change would result in higher total payments to the hospital. This provision would be applied without regard to certain budget-neutrality requirements.

Conference Agreement

For discharges on or after October 1, 2004, the Secretary is required to decrease the

labor-related share to 62 percent of the standardized amount when such change will result in higher total payments to the hospital. This provision is applied without regard to certain budget-neutrality requirements. For discharges on or after October 1, 2004, the Secretary is also required to decrease the labor-related share to 62 percent of the standardized amount for hospitals in Puerto Rico when such change results in higher total payments to the hospital.

More Frequent Update in Weights Used in Hospital Market Basket (Section 404 of the Conference Agreement and Section 404 of the House Bill).

Present Law

Medicare's standardized amounts, which serve as the basis of its payment per discharge from an acute hospital, are increased annually using an update factor that is determined in part by the projected increase in the hospital market basket. The market basket is a fixed-weight hospital input price index, which measures the average change in the price of goods and services that hospitals purchase in order to furnish inpatient care. The Centers for Medicare and Medicaid Services (CMS) revises the cost category weights, reevaluates the price proxies for such categories, and rebases (or changes the base period) for the market basket every 5 years. CMS implemented a revised and rebased market basket using 1997 cost data to set the FY2003 Medicare hospital payment rates.

House Bill

The Secretary would be required to revise the market basket weights to reflect the most currently available data and to establish a schedule for revising the cost category weights more often than once every 5 years. The Secretary would be required to submit a report to Congress by October 1, 2004 on the reasons for and the options considered in establishing such a schedule.

Senate Bill

No provision.

Conference Agreement

The Secretary is required to revise the market basket weights to reflect the most currently available data and to establish a schedule for revising the cost category weights more often than once every 5 years. The Secretary is required to publish the reasons for and the options considered in establishing such a schedule in the final rule establishing FY2006 inpatient hospital payments.

Improvements to the Critical Access Hospital (CAH) Program (Section 405 of the Conference Agreement, Section 405 of the House Bill, and Section 405 of the Senate Bill).

Increase in Payment Amounts (Section 405(a) of the Conference Agreement and Section 405(a) of the House Bill).

Present Law

Generally, a critical access hospital (CAH) receives reasonable cost reimbursement for care rendered to Medicare beneficiaries. CAHs may elect either a cost-based hospital outpatient service reimbursement or an all-inclusive rate, which is equal to a reasonable cost reimbursement for facility services plus 115 percent of the fee schedule payment for professional services. Ambulance services that are owned and operated by CAHs are reimbursed on a reasonable cost basis if these ambulance services are 35 miles from another ambulance system.

House Bill

Inpatient, outpatient, and covered skilled nursing facility services provided by a CAH would be reimbursed at 102 percent of reasonable costs of services furnished to Medicare beneficiaries. This provision would apply to cost reporting periods beginning on or after October 1, 2003.

Senate Bill

No provision.

Conference Agreement

Inpatient, outpatient, and covered skilled nursing facility services provided by a CAH will be reimbursed at 101 percent of reasonable costs of services furnished to Medicare beneficiaries. This provision applies to cost reporting periods beginning on or after January 1, 2004.

Coverage of Costs For Certain Emergency Room On-Call Providers (Section 405(b) of the Conference Agreement, Section 405(b) of the House Bill, and Section 405(c) of the Senate Bill).

Present Law

BIPA required the Secretary to include the costs of compensation (and related costs) of on-call emergency room physicians who are not present on the premises of a CAH, are not otherwise furnishing services, and are not on-call at any other provider or facility when determining the allowable, reasonable cost of outpatient CAH services.

House Bill

Reimbursement of on-call emergency room providers would be expanded to include the costs associated with physician assistants, nurse practitioners, and clinical nurse specialists as well as emergency room physicians for covered Medicare services. This provision would apply to costs for services provided on or after January 1, 2004.

Senate Bill

The provision would expand reimbursement of on-call emergency room providers to include physician assistants, nurse practitioners, and clinical nurse specialists as well as emergency room physicians for covered Medicare services provided on or after January 1, 2005.

Conference Agreement

The provision expands reimbursement of on-call emergency room providers to include physician assistants, nurse practitioners, and clinical nurse specialists as well as emergency room physicians for the costs associated with covered Medicare services provided on or after January 1, 2005.

Authorization of Periodic Interim Payment (PIP) (Section 405(c) of the Conference Agreement, Section 405(d) of the House Bill, and Section 405(d) of the Senate Bill).

Present Law

Eligible hospitals, skilled nursing facilities, and hospices which meet certain requirements receive Medicare periodic interim payments (PIP) every 2 weeks; these payments are based on estimated annual costs without regard to the submission of individual claims. At the end of the year, a settlement is made to account for any difference between the estimated PIP payment and the actual amount owed. A CAH is not eligible for PIP payments.

House Bill

An eligible CAH would be able to receive payments made on a PIP basis for its inpatient services. The Secretary would be required to develop alternative methods based on the expenditures of the hospital for these PIP payments. This provision would apply to payments made on or after January 1, 2004.

Senate Bill

Starting with payments made on or after January 1, 2005, an eligible CAH would be able to receive payments made on a PIP basis for inpatient services. The provision would apply to payments for inpatient CAH services furnished on or after January 1, 2005.

Conference Agreement

An eligible CAH will be able to receive payments made on a PIP basis for its inpatient services. The Secretary is required to develop alternative methods for the timing of PIP payments to these CAHs. This provision applies to payments made on or after July 1, 2004.

Condition for Application of Special Professional Service Payment Adjustment (Section 405(d) of the Conference Agreement and Section 405(e) of the House Bill).

Present Law

As specified by BBRA, CAHs can elect to be paid for outpatient services using cost-based reimbursement for its facility fee and at 115 percent of the fee schedule for professional services otherwise included within its outpatient critical access hospital services for cost reporting periods starting on or after October 1, 2000.

House Bill

The Secretary would not be able to require that all physicians providing services in a CAH assign their billing rights to the entity in order for the CAH to be able to be paid on the basis of 115 percent of the fee schedule for the professional services provided by the physicians. However, a CAH would not receive payment based on 115 percent of the fee schedule for any individual physician who did not assign billing rights to the CAH. This provision would be effective as if it had been included as part of BBRA.

Senate Bill

No provision.

Conference Agreement

The Secretary cannot require that all physicians or practitioners providing services in a CAH assign their billing rights to the entity in order for the CAH to be able to be paid on the basis of 115 percent of the fee schedule for the professional services provided by the physicians. However, a CAH will not receive payment based on 115 percent of the fee schedule for any individual physician or practitioner who did not assign billing rights to the CAH. This provision applies to cost report periods starting on or after July 1, 2004 except for those CAHs that have already elected payment for physician services on this basis in the past; this provision will apply to those CAHs starting for cost reporting periods on or after July 1, 2003.

Revision in Bed Limitation for Hospitals (Section 405(e) of the Conference Agreement, Section 405(f) of the House Bill, and Section 405(a) of the Senate Bill).

Present Law

A CAH is a limited service facility that must provide 24-hour emergency services and operate a limited number of inpatient beds in which hospital stays can average no more than 96 hours. A CAH cannot operate more than 15 acute-care beds at one time, but can have an additional 10 swing beds that are set up for skilled nursing facility (SNF) level care. SNF beds in a unit of the facility that is licensed as a distinct-part skilled nursing facility at the time of the facility's application for CAH designation are not counted toward these bed limits.

House Bill

The Secretary would be required to specify standards for determining whether a CAH has seasonal variations in patient admissions that would justify a 5-bed increase in the number of beds it can maintain (and still retain its classification as a CAH). CAHs that operate swing beds would be able to use up to 25 beds for acute care services as long as no more than 10 beds at any time are used for non-acute services. Those CAHs with swing beds that made this election would not be eligible for the 5-bed seasonal adjustment. A CAH with swing beds that elects to operate 15 of its 25 beds as acute care beds would be eligible for the 5-bed seasonal adjustment.

These provisions would only apply to CAH designations made before, on, or after January 1, 2004.

Senate Bill

A CAH would be able to operate up to 25 swing beds or acute care beds, subject to the 96 hour average length of stay for acute care patients. The requirement that only 15 of the 25 beds be used for acute care at any time would be dropped. The provision would be effective for designations made on or after October 1, 2004.

Conference Agreement

A CAH will be able to operate up to 25 beds. The requirement that only 15 of the 25 beds be used for acute care at any time will be dropped. The provision will apply to CAH designations made before, on, or after January 1, 2004, but any election made pursuant to the regulations promulgated to implement this provision will only apply prospectively.

Provisions Relating to FLEX Grants (Section 405(f) of the Conference Agreement, Section 405(g) of the House Bill, and Section 405(f) of the Senate Bill).

Present Law

The Secretary is able to make grants for specified purposes to states or eligible small rural hospitals that apply for such awards. For example, the Medicare Hospital Flexibility Program awards grants to states for rural health care planning and implementation activities, rural network development and implementation, to establish or expand rural emergency medical services and for CAH designations.

The Secretary may also award grants to hospitals to assist eligible small rural hospitals in implementing data systems required under BBA 1997. Small rural hospitals are short term general hospitals with less than 50 beds that are located in rural areas.

Funding for the rural hospital flexibility grant program was $25 million from FY1999 through FY2001; $40 million in FY2002; and $25 million in 2003. The authorization to award the grants expired in FY2002.

House Bill

The authorization to award grants would be established from FY2004 through FY2008 from the Federal Hospital Insurance Trust Fund at amounts of up $25 million each year. The provision would be effective upon enactment.

Senate Bill

The provision would permit the Secretary to award grants under the Small Rural Hospital Improvement Program to hospitals that have submitted applications to assist eligible small rural hospitals in reducing medical errors, increasing patient safety, protecting patient privacy, and improving hospital quality. These grants would not exceed $50,000 and would be able to be used to purchase computer software and hardware, educate and train hospital staff, and obtain technical assistance. The provision would authorize appropriations of $40 million each year from FY2004 through FY2008 from the Federal Hospital Insurance Trust Fund for grants to states for specified purposes. States that are awarded grants would be required to consult with the hospital association and rural hospitals in the state on the most appropriate way to use such funds. The provision would also authorize $25 million each year from FY2004 through FY2008 for the Small Rural Hospital Improvement Program. This amount would be appropriated from amounts in the treasury not otherwise appropriated.

The provisions would be effective upon enactment. They would apply to grants awarded on or after the date of enactment and would apply to grants awarded prior to the date of enactment to the extent that the funds have not yet been obligated.

Conference Agreement

The authorization to award rural hospital flexibility grants is established at $35 million each year from FY2005 through FY2008. Starting with funds appropriated for FY2005 and in subsequent years, a state is required to consult with the hospital association and rural hospitals in the state on the most appropriate way to use such funds. A state may not spend more than 15% of the grant amount or the states federally negotiated indirect rate for administrative purposes. Beginning with FY2005 up to 5% of the total amount appropriated for grants will be available to the Health Resources and Services Administration for administering these grants.

Exclusion of Certain Beds from Bed Count and Removal of Barriers to Establishment of Distinct Part Units (Section 405(g) of the Conference Agreement and Section 405(g) of the Senate Bill).

Present Law

Beds in distinct part psychiatric or rehabilitation units operated by an entity seeking to become a CAH would not count toward the bed limit.

House Bill

No provision.

Senate Bill

The Secretary would not be able to count any beds in a distinct part psychiatric or rehabilitation unit operated by the entity seeking to become a CAH. The total number of beds in these distinct part units would not be able to exceed 25. A CAH would be able to establish a distinct part psychiatric or rehabilitation unit. The provision would apply to designations on or after October 1, 2003.

Conference Agreement

A CAH can establish a distinct part psychiatric or rehabilitation unit that meets the applicable requirements for such beds established for a short-term, general hospital, specifically, a subsection (d) hospital as defined in 1886(d)(1)(B). If the distinct part units do not meet these requirements during a cost reporting period, then no Medicare payment will be made to the CAH for services furnished in the unit during the period. Medicare payments will resume only after the CAH demonstrates that the requirements have been met. Medicare payments for services provided in the distinct part units will equal payments that are made on a prospective payment basis to distinct part units of short term general hospitals. The Secretary will not count any beds in the distinct part psychiatric or rehabilitation units toward the CAH bed limit. The total number of beds in these distinct part units cannot exceed 10. The provision will apply to cost reporting periods starting October 1, 2004.

Waiver Authority (Section 405(h) of the Conference Agreement).

Present Law

Currently to qualify as a CAH, the rural, for-profit, non profit or public hospital must be located more than 35 miles from another hospital or 15 miles in areas with mountainous terrain or those where only secondary roads are available. These mileage standards may be waived if the hospital has been designated by the state as a necessary provider of health care.

House Bill

No provision.

Senate Bill

No provision.

Conference Report

Currently to qualify as a CAH, the rural, for-profit, non profit or public hospital must be located more than 35 miles from another hospital or 15 miles in areas with mountainous terrain or those where only secondary roads are available. These mileage standards may be waived if the hospital has been designated by the state as a necessary provider of health care. This authority is eliminated 2 years after enactment.

Medicare Inpatient Hospital Payment Adjustment for Low-Volume Hospitals (Section 406 of the Conference Agreement and Section 403 of the Senate Bill).

Present Law

Medicare pays inpatient acute hospital services on a discharge basis without regard for the number of beneficiaries discharged from any given hospital. Under certain circumstances, however, sole community hospitals (SCHs) and Medicare dependent hospitals with more than a 5% decline in total discharges from one period to the next may apply for an adjustment to their payment rates to partially account for higher costs associated with a drop in patient volume due to circumstances beyond its control.

House Bill

No provision.

Senate Bill

The provision would require the Secretary to provide for a graduated adjustment to Medicare's inpatient payment rates to account for the higher unit costs associated with low-volume hospitals. Certain hospitals with fewer than 2,000 total discharges during the 3 most recent cost reporting periods would be eligible for up to a 25% increase in their Medicare payment amount starting for FY2005 cost reporting periods. Eligible hospitals would be located at least 15 miles from a similar hospital or those determined by the Secretary to be so located due to factors such as weather conditions, travel conditions, or travel time to the nearest alternative source of appropriate inpatient care. Certain budget-neutrality requirements would not apply to this provision.

Conference Agreement

The Secretary is required to provide for a graduated adjustment to Medicare's inpatient payment rates to account for the higher unit costs associated with low-volume hospitals starting for discharges occurring in FY2005. The Secretary shall determine the empirical relationship between the standardized cost per case, the number of discharges, and the additional incremental costs (if any) for low-volume hospitals; the percentage payment increase for these hospitals will be based on this relationship, but in no case will be greater than 25%. A low-volume hospital is a short-term general hospital (as defined by 1886(d)(B) of the Social Security Act or SSA) that is located more than 25 road miles from another such hospital and that has less than 800 discharges during the fiscal year. A discharge means an inpatient acute care discharge of an individual regardless of whether the individual is entitled to Part A benefits. Certain budget-neutrality requirements would not apply to this provision. The determination of the percentage payment increase is not subject to administrative or judicial review.

Treatment of Missing Cost Reporting Periods for Sole Community Hospitals (Section 407 of the Conference Agreement and Section 414 of the House Bill).

Present Law

Sole community hospitals (SCHs) are hospitals that, because of factors such as isolated location, weather conditions, travel conditions, or absence of other hospitals, are the sole source of inpatient services reasonably available in a geographic area, or are located more than 35 road miles from another hospital. The primary advantage of an

SCH classification is that these hospitals receive Medicare payments based on the current national PPS national standardized amount or on hospital-specific per discharge costs from either FY 1982, FY1987 or FY1996 updated to the current year, whatever amount will provide the highest Medicare reimbursement. The FY1996 base year option became effective for discharges on or after FY2001 on a phased in basis and will be fully implemented for SCH discharges on or after FY2004.

House Bill

A hospital would not be able to be denied treatment as a SCH or receive payment as a SCH because data are unavailable for any cost reporting period due to changes in ownership, changes in fiscal intermediaries, or other extraordinary circumstances, so long as data from at least one applicable base cost reporting period is available. The provision would apply to cost reporting periods beginning on or after January 1, 2004.

Senate Bill

No provision.

Conference Agreement

A hospital will not be able to be denied treatment as a SCH or receive payment as a SCH because data are unavailable for any cost reporting period due to changes in ownership, changes in fiscal intermediaries, or other extraordinary circumstances, so long as data from at least one applicable base cost reporting period is available. The provision applies to cost reporting periods beginning on or after January 1, 2004.

Recognition of Attending Nurse Practitioners as Attending Physicians to Serve Hospice Patients (Section 408 of the Conference Agreement, Section 409 of the House Bill, and Section 407 of the Senate Bill).

Present Law

Medicare covers hospice services to care for the terminal illnesses of the beneficiary. In general, beneficiaries who elect the hospice benefit give up other Medicare services that seek to treat the terminal illness or that duplicate services provided by the hospice. Services are provided primarily in the patient's home by a Medicare approved hospice. Reasonable and necessary medical and support services for the management of the terminal illness are furnished under a written plan-of-care established and periodically reviewed by the patient's attending physician and the hospice. To be eligible for Medicare's hospice care, a beneficiary must be certified as terminally ill by an attending physician and the medical director or other physician at the hospice and elect hospice treatment. An attending physician who may be an employee of the hospice is identified by the patient as having the most significant role in the determination and delivery of the patient's medical care when the patient makes an election to receive hospice care.

House Bill

A beneficiary electing hospice care would be able to identify a nurse practitioner as an attending physician. This nurse practitioner would not be able to certify the beneficiary as terminally ill for the purpose of entering hospice care. The provision would be effective upon enactment.

Senate Bill

A terminally ill beneficiary under hospice care would be able to receive services provided by a physician assistant, nurse practitioner, or clinical nurse specialist who is not an employee of the hospice program and who the beneficiary identifies, when electing hospice care, as the health care provider having the most significant role in the determination of medical care provided to the beneficiary. A physician assistant, nurse practitioner, or clinical nurse specialist so identified by the beneficiary would be able to periodically review the beneficiary's written plan of care. The amendments would apply to hospice care furnished on or after October 1, 2004.

Conference Agreement

The conference agreement expands the definition of attending physician in hospice to include a nurse practitioner. A nurse practitioner is not permitted to certify a beneficiary as terminally ill for the purposes of receiving the hospice benefit. The provision would be effective upon enactment.

Rural Hospice Demonstration Project (Section 409 of the Conference Agreement and Section 418 of the House Bill).

Present Law

Medicare's hospice services are provided primarily in a patient's home to beneficiaries who are terminally ill and who elect such services. Medicare law prescribes that the aggregate number of days of inpatient care provided to Medicare beneficiaries who elect hospice care in any 12-month period cannot exceed 20% of the total number of days of hospice coverage provided to these persons.

House Bill

The Secretary would be required to establish a demonstration project of no more than 5 years in 3 hospice programs to deliver hospice care to Medicare beneficiaries in rural areas. Those Medicare beneficiaries who lack an appropriate caregiver and are unable to receive home-based hospice care would be able to receive hospice care in a facility of 20 or fewer beds that offers a full range of hospice services within its walls. The facility would not be required to offer services outside of the home and the limit on the aggregate number of inpatient days provided to Medicare beneficiaries who elect hospice care would be waived. The Secretary would be able to require the program to comply with additional quality assurance standards. Payments for the hospice care would be made at the rates that would be otherwise applicable to Medicare. Upon completion of the demonstration project, the Secretary would be required to submit a report to Congress, including recommendations, regarding the extension of the project to hospice programs serving rural areas.

Senate Bill

No provision.

Conference Agreement

The conference agreement requires the Secretary to establish a demonstration project in 3 hospice programs to deliver hospice care to Medicare beneficiaries in rural areas. A project is not permitted to last longer than 5 years. Those Medicare beneficiaries who lack an appropriate caregiver and are unable to receive home-based hospice care could receive hospice care in a facility of 20 or fewer beds that offers a full range of hospice services within its walls. The facility will not be required to offer services outside of the home. The limit on the aggregate number of inpatient days provided to Medicare beneficiaries who elect hospice care is waived under the demonstration. The Secretary may require the program to comply with additional quality assurance standards. Payments for the hospice care will be made at the rates that would be otherwise applicable to Medicare. Upon completion of the demonstration project, the Secretary is required to submit a report to Congress, including recommendations, regarding the extension of the project to hospice programs serving rural areas.

Establishment of Essential Rural Hospital Classification (Section 403 of the House Bill).

Present Law

Under current law, a critical access hospital (CAH) is a limited service facility that must provide 24-hour emergency services and operate a limited number of inpatient beds in which hospital stays can average no more than 96 hours. A CAH is exempt from Medicare's inpatient prospective payment system (IPPS) and receives reasonable cost reimbursement for care rendered to Medicare beneficiaries. Certain acute care general hospitals, particularly those facilities identified as isolated or essential hospitals primarily located in rural areas, receive special treatment under IPPS.

House Bill

The definition of CAH hospitals and services would be amended to add an essential rural hospital. An essential rural hospital would apply for such a classification, would have more than 25 licensed acute care beds, and would be located in a rural area as defined by IPPS. The Secretary would have to determine that the closure of this hospital would significantly diminish the ability of beneficiaries to obtain essential health care services based on the certain criteria. Specifically, the Secretary would determine that high proportion of Medicare beneficiaries residing in the service area of the hospital received basic inpatient care from the hospital; a hospital with more than 200 licensed beds would have to provide specialized surgical care to a high percentage of beneficiaries residing in the area who were hospitalized during the most recent year for which data are available. Regardless of the size of the hospital, almost all physicians in the area would have to have admitting privileges and provide their inpatient services primarily at the hospital. Also, the Secretary would have to determine the closure of the hospital would have a significant adverse impact on the availability of health care service in the absence of the hospital. In making such determination, the Secretary may also consider: (1) whether ambulatory care providers in the hospital's area are insufficient to handle the outpatient care of the hospital; (2) whether beneficiaries would have difficulty accessing care; and (3) whether the hospital has a significant commitment to provide graduate medical education in a rural area. The essential rural hospital would have to have a quality of care score above the median score for hospitals in the State. A hospital classified as an essential rural hospital would not be able to change such classification and would not be able to be treated as a sole community hospital, Medicare dependent hospital or rural referral center under IPPS. A hospital that is classified as an essential rural hospital for a cost reporting period beginning on or after October 1, 2004 would be reimbursed 102% of its reasonable costs for inpatient and outpatient services provided by acute hospitals Beneficiary cost-sharing amounts would not be affected and required billing for such services would not be waived. The provision would apply to cost reporting periods beginning on or after October 1, 2004.

Senate Bill

No provision.

Conference Agreement

No provision.

Modification of the Isolation Test for Cost-Based CAH Ambulance Services (Section 405(c) of the House Bill and Section 405(b) of the Senate Bill).

Present Law

Ambulance services provided by a CAH or provided by an entity that is owned or operated by a CAH is paid on a reasonable cost basis and not the ambulance fee schedule, if

the CAH or entity is the only provider or supplier of ambulance services that is located within a 35-mile drive of the CAH.

House Bill

The 35-mile requirement would not apply to the ambulance services that are furnished after the first cost reporting period beginning after the date of enactment by a provider or supplier of ambulance services who is determined by the Secretary to be a first responder to emergencies. This provision would apply to ambulance services furnished on or after the first cost reporting periods that begins after the date of enactment.

Senate Bill

The provision would drop the requirement that the CAH or the related entity be the only ambulance provider with a 35-mile drive in order to receive reasonable cost reimbursement for the ambulance services. The provision would apply to services furnished on or after January 1, 2005.

Conference Agreement

No provision.

Exclusion of New CAHs from PPS Hospital Wage Index Calculation (Section 405(e) of the Senate Bill).

Present Law

Certain qualified small hospitals are converting to CAHs. After conversion, these facilities are paid on a reasonable cost basis and are not paid under the hospital inpatient prospective payment system (IPPS). Medicare's IPPS payments to acute hospitals are adjusted by the wage index of the area where the hospital is located or has been reassigned. Although the hospital wage index is recalculated annually, the wage index for any given fiscal year is based on data submitted as part of a hospital's cost report from 4 years previously. As established by regulation, starting for FY2004 payments, wage data from hospitals that have converted to CAHs will be excluded in the IPPS wage index calculation.

House Bill

No provision.

Senate Bill

The Secretary would be required to exclude wage data from hospitals that have converted to CAHs from the IPPS wage index calculation starting for cost reporting periods on or after January 1, 2004. The provision would be effective upon enactment.

Conference Agreement

No provision.

Rural Community Hospital Demonstration Program (Section 410A of the Conference Report and Section 414 of the Senate Bill).

Present Law

No provision

House Bill

No provision.

Senate Bill

The Secretary would be required to establish a 5-year rural community hospital (RCH) demonstration program in 4 areas including Kansas and Nebraska that will pay for acute inpatient services, outpatient services, and certain home health services in qualifying hospitals either on the basis of its reasonable costs (without regard to the amount of customary charges) or using the respective prospective payment systems for those services. In this instance, reasonable cost reimbursement of capital costs would include a return on equity payment of 150% of the average rate of interest on obligations issued for purchase by the Federal Hospital Insurance (HI) Trust Fund.

Eligible rural hospitals would be those (1) located in counties that have not been assigned to metropolitan statistical areas or those urban hospitals that have been designated as rural; (2) with less than 51 acute inpatient beds (psychiatric and rehabilitation beds in distinct part units would not be counted); (3) offering 24-hour emergency care services; and (4) have a provider agreement in effect and is open to the public as of January 1, 2003. Critical access hospitals would be able to participate in the demonstration. Entities with replacement facilities, obtaining a new provider number because of an ownership change, or with a binding agreement for the construction, reconstruction, lease, rental or financing of building on January 1, 2003 would not be prohibited from participating. A qualified-RCH based home health agency would be a provider based agency that is located in a county in which no main or branch office of another home health agency is located or is at least 35 miles from any main or branch office of another home health agency.

Consolidated billing associated with skilled nursing facilities would be permitted. The cost of Medicare beneficiaries' bad debt would be reimbursed at 100%. Beneficiary copayments for hospital outpatient services would established as under the hospital outpatient prospective payment system. No cost sharing would apply to clinical diagnostic laboratory services. The cost sharing amounts associated with other services would be established according to the payment methodology selected by the provider for the services in question. Funding for the demonstration project would be transferred in appropriate proportions from the HI and the Federal Supplementary Insurance trust funds. The Secretary would be required to ensure that aggregate payments under this demonstration program do not exceed what would have been spent if the program had not been implemented. The Secretary would be permitted to waive administrative, peer review as well as fraud and abuse requirements in Title 11 and other Medicare requirements in Title 18 of the Social Security Act. The Secretary would be required to submit a report including recommendations to Congress no later than 6 months after completion of the demonstration. The Secretary would be required to implement the demonstration no later than January 1, 2005, but not before October 1, 2004.

Conference Agreement

The Secretary is required to establish a demonstration program in rural areas to test different payment methods for under 50 bed rural hospitals. The hospitals are paid their costs for inpatient and extended care (swing-bed) services for 5 years, subject to a cap. The payment methodology is similar to the Tefra payment system used for Children's hospitals. The hospitals cannot be eligible for the CAH program.

Critical Access Hospital Improvement Demonstration Program (Section 415 of the Senate Bill).

Present Law

No provision

House Bill

No provision.

Senate Bill

The Secretary would be required to establish a 5-year critical access hospital (CAH) demonstration program in 4 areas including Kansas and Nebraska to test various methods to improve the CAH program. Participating CAHs would be able to maintain distinct part psychiatric and rehabilitation units of up to 10 beds that would not be counted toward the CAH-bed limit. These psychiatric and rehabilitation services would be paid on a reasonable cost basis (without regard to the amount of customary charges). Home health agencies operated by participating CAHs would be able to opt out of the home health prospective payment system (PPS) and would be reimbursed on the basis of reasonable costs (without regard to the customary charge limit). Distinct part skilled nursing facilities (SNF) operated by a CAH would be exempt from SNF-PPS and would be reimbursed on the basis of reasonable costs (without regard to the customary charge limit). Consolidated billing associated with skilled nursing facilities would be permitted. In this instance reasonable cost reimbursement of capital costs associated with inpatient, outpatient, extended care, post-hospital extended care, home health, and ambulance services would include a return on equity payment of 150% of the average rate of interest on obligations issued for purchase by the Federal Hospital Insurance (HI) Trust Fund.

Eligible CAHs in the 4 demonstration areas would have to apply to participate in the demonstration project. Funding for the demonstration project would be transferred in appropriate proportions from the HI and the Federal Supplementary Insurance trust funds. The Secretary would be required to ensure that aggregate payments under this demonstration program do not exceed what would have been spent if the program had not been implemented. The Secretary would be permitted to waive administrative, peer review as well as fraud and abuse requirements in Title 11 and other Medicare requirements in Title 18 of the Social Security Act. The Secretary would be required to submit a report including recommendations to Congress no later than 6 months after completion of the demonstration. The Secretary would be required to implement the demonstration no later than January 1, 2005, but not before October 1, 2004.

Conference Agreement

No provision.

Increase in Payments for Certain Services Furnished by Small Rural Hospitals Under Medicare Prospective Payment System for Hospital Outpatient Department Services (Section 424 in the Senate Bill).

Present Law

Under the OPPS, which was implemented in August, 2000, Medicare pays for covered services using a fee schedule based on ambulatory payment classifications (APCs). Beneficiary copayments are established as a percentage of Medicare's fee schedule payment and differ by APC. Certain hospitals, including rural hospitals with no more than 100 beds, are protected from financial losses that result from implementation of the new outpatient PPS under hold harmless provisions.

House Bill

No provision.

Senate Bill

The provision would increase Medicare payments for covered outpatient clinic and emergency room visits that are provided by rural hospitals with up to 100 beds on or after January 1, 2005 and before January 1, 2008. Applicable Medicare outpatient fee schedule amounts would be increased up by 5%. The beneficiary copayment amounts for these services would not be affected. The resulting increase in Medicare payments would not be considered as PPS payments when calculating whether a rural hospital's PPS payments are less than its pre-BBA payment amounts under the temporary hold harmless provisions. Also, the budget-neutrality provisions for Medicare's outpatient PPS would not be applicable. Finally, these increased payments would not affect Medicare payments for covered outpatient services after January 1, 2007.

Conference Agreement

No provision.

Subtitle B—Provisions Relating to Part B Only

2-Year Extension of Hold Harmless Provisions for Small Rural Hospitals and Sole Community Hospitals Under Prospective Payment System for Hospital Outpatient Department Services (Section 411 of the Conference Agreement, Section 407 of the House Bill, and Section 423 of the Senate Bill).

Present Law

The prospective payment system (PPS) for services provided by outpatient departments (OPD) was implemented in August, 2000 for most acute care hospitals. Under the OPD PPS, Medicare pays for covered services using a fee schedule based on ambulatory payment classifications (APCs). Rural hospitals with no more than 100 beds are paid no less under this PPS system than they would have received under the prior reimbursement system for covered OPD services because of hold harmless provisions. The hold harmless provisions apply to services provided before January 1, 2004.

House Bill

The hold harmless provisions governing OPD reimbursement for small rural hospitals would be extended until January 1, 2006. The hold harmless provisions would be extended to sole community hospitals located in a rural area starting for services furnished on or after January 1, 2004 until January 1, 2006. The Secretary would be required to conduct a study to determine if the costs, by APC groups, incurred by rural providers exceed those costs incurred by urban providers. If appropriate, the Secretary would provide a payment adjustment to reflect the higher costs of rural providers by January 1, 2005.

Senate Bill

The hold harmless provisions governing OPD reimbursement for small rural hospitals would be extended until January 1, 2006. These hold harmless provisions would be extended to sole community hospitals located in rural areas for services provided in 2006.

Conference Agreement

The hold harmless provisions governing OPD reimbursement for small rural hospitals are extended until January 1, 2006. The hold harmless provisions are extended to sole community hospitals located in a rural area starting for services furnished on or after January 1, 2004 until January 1, 2006. The Secretary is required to conduct a study to determine if the costs, by APC groups, incurred by rural providers exceed those costs incurred by urban providers. If appropriate, the Secretary will provide for a payment adjustment to reflect the higher costs of rural providers by January 1, 2006.

Establishment of Floor on Work Geographic Adjustment (Section 412 of the Conference Agreement, Section 605 of the House Bill, and Section 421 of the Senate Bill).

Present Law

Medicare's payment for physicians' services under a fee schedule has three components: the relative value for the service, geographic adjustment factors and a conversion factor into a dollar amount. A service's relative value is made up of a physician work component, a practice expense component, and a malpractice expense component. Each of these is then adjusted by a separate geographic adjustment factor and combined together to calculate an indexed relative value for that service provided in a given location. This locality adjusted relative value unit is multiplied by the conversion factor to calculate Medicare's payment for a service provided by a physician in a given area.

The geographic adjustment factors are indices that reflect the relative cost difference in a given area in comparison to the national average. An area with costs above the national average would have an index greater than 1.00; alternatively, an area with costs below the national average would have an index less than 1.00. The physician work geographic adjustment factor is based on a sample of median hourly earnings in six professional specialty occupational categories. Unlike the other geographic adjustments, the work adjustment factor reflects only one-quarter of the cost differences in an area. The practice expense adjustment factor is based on employee wages, office rents, medical equipments and supplies, and other miscellaneous expenses. The malpractice adjustment factor reflects differences in malpractice insurance costs.

The Secretary is required to periodically review and adjust the relative values affecting physician payment to account for changes in medical practice, coding changes, new data on relative value components, or the addition of new procedures. Under the budget-neutrality requirement, changes in these factors cannot cause expenditures to differ by more than $20 million from what would have been spent if such adjustments had not been made.

House Bill

For services furnished after January 1, 2004 and before January 1, 2006, the Secretary would be required to increase the value of any work geographic index that is below 1.00 to 1.00 unless the Secretary determines, based on the subsequent GAO study, that there is no sound economic rationale for such change. The provision would be effective upon enactment.

Senate Bill

For services furnished after January 1, 2004, the Secretary would be required to increase the value of any work geographic index that is below .980 to .980. The values for work index would be raised to 1.0 for services furnished in 2005, 2006, and 2007. The practice expense and malpractice geographic indices in low value localities areas would be raised to 1.00 for services furnished in 2005 through 2008.

Conference Agreement

The Secretary is required to increase the value of any work geographic index that is below 1.0 to 1.0 for services furnished on or after January 1, 2004 and before January 1, 2007.

Medicare Incentive Payment Program Improvements for Physician Scarcity (Section 413 of the Conference Agreement, Section 417 of the House Bill, and Section 422 of the Senate Bill).

Present Law

Physicians providing services in a health professional shortage area (HPSA) are entitled to an incentive payment from the Medicare program. This incentive payment is a 10% increase over the amount which would otherwise be paid under the physician fee schedule. Physicians are responsible for indicating their eligibility for this bonus on their billing forms.

House Bill

This provision would establish a new five percent bonus payment program for physicians providing care to Medicare beneficiaries in physician scarcity areas. The Secretary would calculate two measures of scarcity. A primary care scarcity area would be determined based on the number of primary care physicians per Medicare beneficiary—the primary care ratio. A specialty care scarcity area would be based on the number of specialty care physicians per Medicare beneficiary—the specialty care ratio. The number of physicians would be based on physicians who actively practice medicine or osteopathy, and would exclude physicians whose practice is exclusively for the Federal Government, physicians who are retired, or physicians who only provide administrative services.

The Secretary would rank each county or area based on its primary care ratio. Primary care scarcity counties or areas would be those counties or areas with the lowest primary care ratios, such that 20 percent of Medicare beneficiaries reside in these counties, when each county or area is weighted by the number of Medicare beneficiaries in the county or area. Specialty care scarcity counties or areas would be identified in the same manner, using the specialty care ratio. There would be no administrative or judicial review of the identification of counties or areas, or of a specialty of any physician.

To the extent feasible, the Secretary would treat a rural census tract of a metropolitan statistical area, as determined under the most recent modification of the Goldsmith Modification, as an equivalent area for purposes of qualifying as a primary care scarcity area or specialty care scarcity area.

The Secretary would be required to publish a list of all areas which would qualify as primary care scarcity counties or specialty care scarcity counties as part of the proposed and final rules to implement the physician fee schedule.

The provision would also include improvement to the Medicare Incentive Payment Program, which provides a 10 percent bonus to physicians in shortage areas. The Secretary would be required to establish procedures under which the Secretary, and not the physician furnishing the service, would be responsible for determining when a bonus payment should be made. As part of the physician proposed and final rule for the physician fee schedule, the Secretary would be required to include a list of all areas which would qualify as a health professional shortage area for the upcoming year.

Senate Bill

The Secretary would be required to establish procedures to determine when the physician is eligible for a bonus payment. The Secretary would also be required to (1) establish an ongoing program to educate physicians about the incentive program; (2) establish an ongoing study of the incentive program to determine whether beneficiaries' access to physician's services within the HPSA has improved; and (3) submit annual reports including appropriate recommendations for necessary administrative or legislative action concerning improvements to the program. GAO would be required to conduct an ongoing study of the MIP program on beneficiary access to services and submit a report, including appropriate recommendations, no later than 1 year from the date of enactment.

Conference Agreement

Additional Incentive Payment for Certain Physician Scarcity Areas (Section 413(a) of the Conference Agreement).

The Conference Agreement establishes a new 5 percent incentive payment program designed to reward both primary care and specialist care physicians for furnishing services in the areas that have fewest physicians available to serve beneficiaries. The incentive payment will be made in counties accounting for 20 percent of Medicare beneficiaries, which is likely to represent more than 20 percent of counties. As with the current HPSA bonus program, the 5 percent bonus would be added to the amount that Medicare pays after deducting beneficiary cost sharing so that beneficiaries do not pay cost-sharing on the incentive payment.

The Secretary will calculate two measures of scarcity. A primary care scarcity area will

be determined based on the number of primary care physicians per Medicare beneficiary—the primary care ratio. A specialty care scarcity area will be based on the number of specialty care physicians per Medicare beneficiary—the specialty care ratio. The number of physicians will be based on physicians who actively practice medicine or osteopathy, and will exclude physicians whose practice is exclusively for the Federal Government, physicians who are retired, or physicians who only provide administrative services.

The provision requires identification of the county in which the service is furnished in order to apply to the bonus. Currently, it is the understanding of the Conferees that the address where the service is furnished, including the 5-digit zip code, is contained on the Medicare claim form. Since some zip codes cross county boundaries, the provision allows the Secretary to assign zip codes to counties based on the dominant county of the zip code as determined by the US Postal Service or otherwise. However, nothing would preclude, nor require, the Secretary ultimately to use 9–digit zip codes to determine the county in which the service is furnished. The provision requires periodic review and revision of the counties eligible for the bonus, but not less often than once every three years. To the extent feasible, the Secretary will treat a rural census tract of a metropolitan statistical area, as determined under the most recent modification of the Goldsmith Modification, as an equivalent area for purposes of qualifying as a primary care scarcity area or specialty care scarcity area.

There will be no administrative or judicial review of the designation of the county or area as a scarcity area, the designation of an individual physician's specialty, the assignment of a physician to a county or the assignment of a postal zip code to the county or other area.

The Secretary will be required to publish a list of all areas which will qualify as primary care scarcity counties or specialty care scarcity counties as part of the proposed and final rules to implement the physician fee schedule.

The list of eligible counties will be published each year in the proposed and final rule implementing the physician fee schedule. The list of counties will be posted on the Internet website of the Centers for Medicare and Medicaid Services (CMS).

The new five percent bonus for physicians in either primary care scarcity counties or specialty care scarcity counties will increase financial incentives for physicians to provide care to Medicare beneficiaries in these areas with a shortage of physicians. This bonus payment will make it easier to recruit and retain physicians in these scarcity areas.

Improvement to Medicare Incentive Payment Program (Section 413(b) of the Conference Agreement).

The Conference Agreement requires the Secretary to pay the current law 10 percent Health Professional Shortage Area (HPSA) incentive payment for services furnished in full county primary care geographic area HPSAs automatically rather than having the physician identify that the services were furnished in such area. The implementation of the incentive payment will be the same as for the physician scarcity full county incentive payments, namely use of the 5 digit zip code with the dominant county of the zip code in cases where zip codes cross county boundaries. A physician will not need to report the HPSA modifier on the claim form for services furnished in full county HSPAs.

The Conference Agreement does not contain a requirement to automate payment of incentive payments for services furnished in partial county HPSAs. However, the provision does not preclude the Secretary from automating payment in partial county HPSAs if the Secretary determines that it is feasible to do so based on information on the Medicare claim form.

The Conference Agreement requires the Secretary to develop a user friendly web site through which physicians may obtain information on partial county HPSAs to facilitate reporting of the modifier to identify the applicability of the incentive payment in partial county HPSAs. The provision requires that before the beginning of a calendar year the Secretary will identify the HPSAs for which the incentive payments will be made for such calendar year. Since HRSA designates HPSAs, HRSA will transmit to CMS the list of applicable HPSAs with enough lead time for CMS to implement the incentive payments for the following calendar year.

Improvements to the Medicare Incentive Program will shift responsibility for identifying eligibility for the 10 percent bonus from physicians to the Secretary. A service furnished in a county that is both a full county HPSA and a scarcity county would receive both bonuses—a total incentive payment of 15 percent.

GAO Study of Geographic Differences in Payments for Physicians' Services (Section 413(c) of the Conference Agreement, Section 413 of the House Bill, and Section 444 of the Senate Bill).

Present Law

No provision.

House Bill

GAO would be required to study geographic differences in payment amounts in the physician fee schedule including: (1) an assessment of the validity of each component of the geographic adjustment factors; (2) an evaluation of the measures and the frequency with which they are revised; and (3) an evaluation of the methods used to establish the costs of professional liability insurance including the variation between physician specialties and among different states, the update to the geographic cost of practice index, and the relative weights for the malpractice component. The study, including recommendations concerning use of more current data and use of cost data rather than price proxies, would be due to Congress within 1 year of enactment.

Senate Bill

GAO would be required to study geographic differences in payment amounts in the physician fee schedule including: (1) an assessment of the validity of each component of the geographic adjustment factors; (2) an evaluation of the measures and the frequency with which they are revised; (3) an evaluation of the methods used to establish the costs of professional liability insurance including the variation between physician specialties and among different states, the update to the geographic cost of practice index, and the relative weighs for the malpractice component; (4) an evaluation of the economic basis for the floors on the geographic adjustments established previously in this legislation; (5) an evaluation of the effect of the geographic adjustments on physician retention, recruitment costs, physician mobility; (6) an evaluation of the appropriateness of extending such adjustment; (7) an evaluation of the adjustment of the work geographic practice cost index to reflect ¼ the area cost difference in physician work; (8) an evaluation of the effect of the geographic practice cost index on physician location and retention in higher cost areas; and (9) an evaluation of the 1/4 adjustment of such an index. The study would include recommendations concerning use of more current data and use of cost data rather than price proxies. The study would be due to Congress within 1 year of enactment.

Conference Agreement

GAO will study payment differences under the physician fee schedule for different geographic areas, including: (1) an assessment of the validity of the geographic adjustment factors for each component of the fee schedule; (2) an evaluation of the measures used for such adjustment, including the frequency of revisions; (3) an evaluation of the method used to determine professional liability insurance costs including the variation between physician specialties and among different states, the update to the geographic cost of practice index, and the relative weighs for the malpractice component; and (4) an evaluation of the effect of the physician work geographic adjustment as modified by this legislation on physician location and retention taking into account differences in recruitment costs and retention rates for physicians (including specialists) between large urban areas and other areas and the mobility of physicians over the last decade. The study, including recommendations concerning use of more current data and use of cost data rather than price proxies, is due to Congress within 1 year of the enactment date.

Payment for Rural and Urban Ambulance Services

Phase-In Providing Floor Using Blend of Fee Schedule and Regional Fee Schedule (Section 414(a) of the Conference Agreement and Section 622 of the House Bill).

Present Law

Traditionally, Medicare has paid suppliers of ambulance services on a reasonable charge basis and paid provider-based ambulances on a reasonable cost basis. BBA 1997 provided for the establishment of a national fee schedule which was to implemented in phases, in an efficient and fair manner. The required fee schedule became effective April 1, 2002 with full implementation by January, 2006. In the transition period, a gradually decreasing portion of the payment is to be based on the prior payment methodology (either reasonable costs or reasonable charges).

House Bill

Payments for ambulance services would be based on the ambulance specific amount blended with the national fee schedule amount or a combined rate of the national fee schedule and a regional fee schedule, whichever resulted in the larger payment. The blended rate during the phase-in period would incorporate a decreasing portion of the payment based on regional fee schedules calculated for each of nine census regions. Generally, the regional fee schedules would be based on the same methodology and data used to construct the national fee schedule. For services provided in 2004, the blended rate would be based on 20% of the national fee schedule and 80% of the regional fee schedule; in 2005 blended rate would be based on a 40% national and 60% regional split; in 2006, the blended rate would be based on a 60% national and 40% regional split; in 2007, 2008 and 2009, the blended rate would be based on a 80% national and 20% regional split; and in 2010 and subsequently, the ambulance fee schedule would be based on the national fee schedule.

Senate Bill

No provision.

Conference Agreement

Payments for ambulance services will be based on the ambulance specific amount blended with either the national fee schedule amount or a combined rate of the national

fee schedule and a regional fee schedule, whichever resulted in the larger payment. The blended rate during the phase-in period will incorporate a decreasing portion of the payment based on regional fee schedules calculated for each of nine census regions. Generally, the regional fee schedules will be based on the same methodology and data used to construct the national fee schedule. For 2004, starting for services on July 1, 2004, the blended rate is based on 20% of the national fee schedule and 80% of the regional fee schedule; for 2005, the blended rate is based on a 40% national and 60% regional split; in 2006, the blended rate is based on a 60% national and 40% regional split; in 2007, 2008 and 2009, the blended rate is based on a 80% national and 20% regional split; and in 2010 and subsequently, the ambulance fee schedule is based on the national fee schedule.

Adjustment in Payment for Certain Long Trips (Section 414(b) of the Conference Agreement and Section 622 of the House Bill).

Present Law

The fee schedule payment amount equals the base rate for the level of service plus payment for mileage and specified adjustment factors. Additional mileage payments are made in rural areas. BIPA increased payment for rural ambulance mileage for distances greater than 17 miles and up to 50 miles for services provided before January 1, 2004. The amount of the increase was at least one-half of the payment per mile established in the fee schedule for the first 17 miles of transport.

House Bill

Medicare's payments for ground ambulance services would be increased by one quarter of the amount otherwise established for trips longer than 50 miles occurring on or after January 1, 2004 and before January 1 2009. The payment increase would apply regardless of where the transportation originated. GAO would be required to submit an initial report to Congress on the access and supply of ambulance services in regions and states where ambulance payments are reduced by December 31, 2005. GAO would be required to submit a final report to Congress no later than December 31, 2007. The provision would apply to ambulance services furnished on or after January 1, 2004.

Senate Bill

No provision.

Conference Agreement

Medicare's payments for ground ambulance services will be increased by one quarter of the payment per mile rate otherwise established for trips longer than 50 miles occurring on or after July 1, 2004 and before January 1, 2009. The payment increase applies regardless of where the transportation originates.

Improvement in Payments to Retain Emergency Capacity For Ambulance Services in Rural Areas (Section 414(c) of the Conference Agreement and Section 410 of the House Bill).

Present Law

Traditionally, Medicare has paid suppliers of ambulance services on a reasonable charge basis and paid provider-based ambulances on a reasonable cost basis. BBA 1997 provided for the establishment of a national fee schedule which was to be implemented in phases, in an efficient and fair manner. The required fee schedule became effective April 1, 2002 with full implementation by January, 2006. In the transition period, a gradually decreasing portion of the payment is to be based on the prior payment methodology (either reasonable costs or reasonable charges).

The fee schedule payment amount equals the base rate for the level of service plus payment for mileage and specified adjustment factors. Additional mileage payments are made in rural areas. BIPA increased payment for rural ambulance mileage for distances greater than 17 miles and up to 50 miles for services provided before January 1, 2004. The amount of the increase was at least one-half of the payment per mile established in the fee schedule for the first 17 miles of transport.

House Bill

Starting for services provided January 1, 2004 the Secretary would be required to provide a percentage increase in the base rate of the fee schedule for ground ambulance services that originate in a qualified rural area. The increase would be estimated using the average cost per trip for the base rate in the lowest quartile as compared to the average cost for the base rate in the highest quartile of all rural counties. A qualified rural county is a rural area (a county not assigned to a metropolitan statistical area) with a population density of Medicare beneficiaries in the lowest quartile of all rural counties.

Senate Bill

No provision.

Conference Agreement

The Secretary will provide a percentage increase in the base rate of the fee schedule for ground ambulance services furnished on or after July 1, 2004 and before January 1, 2010 that originate in a qualified rural area. The payment increase is estimated using the average cost per trip for the base rate (not taking into account mileage) in the lowest quartile as compared to the average cost for the base rate (not taking into account mileage) in the highest quartile of all rural counties. The Secretary will determine the population density for each rural area using 2000 Census data and rank each county accordingly. The qualified rural areas are those with the lowest population densities that collectively represent a total of 25% of the population in those areas. To the extent feasible, the Secretary is required to treat certain rural census tracts in metropolitan statistical areas as a rural area. There will be no administrative or judicial review under Sections 1869 and 1878 of the SSA or otherwise with respect to the identification of a qualified rural area. In order to promptly implement this provision, the Secretary may use data furnished by GAO.

Temporary Increase for Ground Ambulance Services (Section 414(d) of the Conference Agreement and Section 425 of Senate Bill).

Present Law

The ambulance fee schedule payment amount equals the base rate for the level of service plus payment for mileage and specified adjustment factors. Additional mileage payments are made in rural areas. BIPA increased payment for rural ambulance mileage for distances greater than 17 miles and up to 50 miles for services provided before January 1, 2004. The amount of the increase was at least one-half of the payment per mile established in the fee schedule for the first 17 miles of transport.

House Bill

No provision.

Senate Bill

The payments for ground ambulance services originating in a rural area or a rural census tract would be increased by 5% for services furnished on or after January 1, 2005 through December 31, 2007. The fee schedule for ambulances in other areas would be increased by 2%. These increased payments would not affect Medicare payments for covered ambulance services in subsequent periods. The conversion factor for ambulance services would not be adjusted downward because of the Secretary's evaluation of the prior year's conversion factor.

Conference Agreement

The payments for ground ambulance services originating in a rural area or a rural census tract will be increased by 2% (after application of the long trip and low density payment increases) for services furnished on or after July 1, 2004 through December 31, 2007. The fee schedule for ambulances in other areas (after application of the long trip adjustment) will increase by 1%. These increased payments will not affect Medicare payments for covered ambulance services after 2007.

Implementation, GAO Report on Costs and Access, and Technical Amendments (Section 414(e)–(g) of the Conference Agreement).

Present Law

No provision.

House Bill

No provision.

Senate Bill

No provision.

Conference Agreement

The Secretary is able to implement the amendments made by Section 414 and revisions to the conversion factor on an interim, final basis or by program instruction. GAO is required to submit an initial report to Congress on cost differences among different types of ambulance providers, and the impact of payment reductions in the ambulance fee schedule on access, supply, and quality of ambulance services in regions and states with such reductions. Other technical amendments will also be adopted.

Providing Appropriate Coverage of Rural Air Ambulance Services (Section 415 of the Conference Agreement and Section 426 in the Senate Bill).

Present Law

Medicare pays for ambulance services under a fee schedule. Seven categories of ground ambulance services, ranging from basic life support to specialty care transport, and two categories of air ambulance services are established. Payment for ambulance services can only be made if other methods of transportation are contraindicated by the patient's medical conditions, but only to the extent provided in regulations.

House Bill

No provision.

Senate Bill

The regulations governing ambulance services would be required to ensure that air ambulance services be reimbursed if: (1) the air ambulance service is medically necessary based on the health condition of the patient being transported at or immediately prior to the time of the transport service; and (2) the air ambulance service complies with the equipment and crew requirements established by the Secretary. An air ambulance service would be considered medically necessary when requested: (1) by a physician or hospital in accordance with their responsibilities under the Emergency Medical Treatment and Active Labor Act; (2) as a result of a protocol established by a state or regional emergency medical service agency; (3) by a physician, nurse practitioner, physician assistant, registered nurse, or emergency medical responder who reasonably determines or certifies that patient's condition is such that the time involved in land transport significantly increases the patient's medical risks; or (4) by a Federal or State agency to relocate patients following a natural disaster, an act of war, or a terrorist act. Air ambulance services would be defined

as a fixed wing or rotary wing air ambulance services. The provision would apply to services furnished on or after January 1, 2005.

Conference Agreement

The regulations governing the use of ambulance services will provide that to the extent that any ambulance service (whether ground or air) may be covered, a rural air ambulance service will be at the air ambulance rate if: (1) the air ambulance service is reasonable and necessary based on the health condition of the patient being transported at or immediately prior to the time of the transport service; and (2) the air ambulance service complies with the equipment and crew requirements established by the Secretary. An air ambulance service is considered reasonable and necessary when requested: (1) by a physician or other qualified medical personnel who reasonably determines or certifies that an individual's condition is such that the time needed to transport the individual by land or the instability of land transportation poses a threat to the individual's survival or seriously endangers the individual's health or (2) such services is furnished pursuant to a protocol under which the use of an air ambulance is recommended that is established by a state or regional emergency medical services (EMS) agency and recognized or approved by the Secretary. The EMS agency cannot have an ownership interest in the entity furnishing such service. Also, there cannot be a financial or employment relationship or a common ownership arrangement between the person requesting the rural air ambulance service and the furnishing entity or a financial relationship between an immediate family member of such requester and such an entity. This prohibition does not apply to instances when a hospital and an entity furnishing the rural air ambulance services are under common ownership if remuneration (through employment or other relationship) is for provider based physician services furnished in a hospital which are reimbursed under Part A and is unrelated directly or indirectly to the provision of rural air ambulance services. A rural air ambulance service is defined as a fixed wing or rotary wing air ambulance service where the individual's point of pick up is in a rural area or rural census tract. The provision applies to services furnished on or after January 1, 2005.

Treatment of Certain Clinical Diagnostic Laboratory Tests Furnished To Hospital Outpatients in Certain Rural Areas (Section 416 of the Conference Agreement and Section 427 of the Senate Bill).

Present Law

Generally, hospitals that provide clinical diagnostic laboratory tests under Part B are reimbursed using a fee schedule. Sole community hospitals (SCHs) that provide some clinical diagnostic tests 24 hours a day qualify for a 2% increase in the amounts established in the outpatient laboratory fee schedule; no beneficiary cost-sharing amounts are imposed.

House Bill

No provision.

Senate Bill

SCHs that provide clinical diagnostic laboratory tests covered under Part B in 2005 and 2006 would be reimbursed their reasonable costs of furnishing the tests. No beneficiary cost sharing amounts would apply to these services.

Conference Agreement

Hospitals with under 50 beds in qualified rural areas (low density population rural areas established under Section 414(c) of this legislation) will receive 100% reasonable cost reimbursement for clinical diagnostic laboratory tests covered under Part B that are provided as outpatient hospital services. The Secretary will apply the rules that determine whether clinical diagnostic laboratory tests are furnished as an outpatient critical access hospital service to establish whether these clinical diagnostic laboratory tests are outpatient hospital services. The provision will apply to services furnished during a cost reporting period beginning during the 2-year period starting July 1, 2004.

Extension of the Telemedicine Demonstration Project (Section 417 of the Conference Agreement and Section 415 of the House Bill).

Present Law

BBA 1997 established a single 4-year demonstration project where an eligible health care provider telemedicine network would use high-capacity computer systems and medical infomatics to improve primary care and prevent health complications in Medicare beneficiaries with diabetes mellitus. The Informatics, Telemedicine, and Education Demonstration project uses modified home computers or home telemedicine units linked to clinical information systems to assist beneficiaries residing in medically under-served rural or medically underserved inner-city areas, interaction with a nurse case manager, video conferencing, and access to health information and medical data, in both Spanish and English. The demonstration will expire in February 2004.

House Bill

The demonstration project would be extended for 4 years and total funding would be increased from $30 million to $60 million. The provision would be effective upon enactment.

Senate Bill

No provision.

Conference Agreement

The demonstration project is extended for 4 years and total funding will be increased from $30 million to $60 million. The provision will be effective upon enactment.

Report on Demonstration Project Permitting Skilled Nursing Facilities to Be Originating Telehealth Sites (Section 418 of the Conference Agreement and Section 450H of the Senate Bill).

Present Law

Medicare will pay for use of certain telecommunications systems as a substitute for face-to-face encounters to provide consultations, office or other outpatient visits, individual psychotherapy and pharmacologic management services to eligible beneficiaries. With certain exceptions, Medicare beneficiaries are eligible for telehealth services only if they are presented from an originating site located in either a rural health professional shortage area or in a county that is not in a metropolitan statistical area. An originating site is the location of the beneficiary at the time the services being furnished by the telecommunications system occurs. Originating sites defined in statute include the office of a physician or practitioner, a hospital, a critical access hospital, a rural health clinic or a federally qualified health center.

House Bill

No provision.

Senate Bill

This provision would add types of providers to the list of originating sites that can bill Medicare for telehealth services. The additional providers are both those defined by the statute and those that would be defined by the Secretary. Providers defined in the statute are: a skilled nursing facility (1918(a)), a community mental health center (1861(ff)(2)(B)), and a facility operated by the Indian Health Service or by an Indian tribe, tribal organization, or an urban Indian organization (as defined in Senate Section 4 of the Indian Health Care Improvement Act). Providers that would be defined by the Secretary are: an assisted-living facility, a board-and-care home, a county or community health clinic, and a long-term care facility (as defined by the Secretary.) In addition, the Secretary would be required to encourage and facilitate the adoption of State provisions allowing for multi-state practitioner licensure across State boundaries. The provision would be effective upon enactment.

Conference Agreement

The Secretary will evaluate a demonstration project under which a skilled nursing facility is treated as an originating site for telehealth services. The Secretary will delegate the evaluation to the Administrator of the Health Resources and Services Administration who will consult with the Administrator for the Centers for Medicare & Medicaid Services. No later than January 1, 2005, the Secretary will submit a report to Congress on the evaluation including recommendations on mechanisms to ensure that permitting a skilled nursing facility to serve as an originating site for the use of telehealth services or any other services delivered via a telecommunications system does not substitute for in-person required visits furnished by physicians, physician assistants, nurse practitioners or clinical nurse specialists at specified intervals as required by the Secretary. If the Secretary concludes that it is advisable to permit a skilled nursing facility to be an originating site for telehealth services, and the Secretary can establish the mechanisms to ensure such permission does not serve as a substitute for in-person visits, the Secretary may deem a skilled nursing facility to be an originating site beginning on January 1, 2006.

Exclusion of Certain Rural Health Clinic and Federally Qualified Health Center Services from the Prospective Payment System for Skilled Nursing Facilities (Section 410 of the Conference Report and 408 of the House Bill and Section 429 of the Senate Bill).

Present Law

Under Medicare's prospective payment system (PPS), skilled nursing facilities (SNFs) are paid a predetermined amount to cover all services provided in a day, including the costs associated with room and board, nursing, therapy, and drugs; the daily payment will vary depending upon a patient's therapy, nursing and special care needs as established by one of 44 resource utilization groups (RUGs). Certain services and items provided an SNF resident, such as physicians' services, specified ambulance services, chemotherapy items and services, and certain outpatient services from a Medicare-participating hospital or critical access hospital, are excluded from the SNF–PPS and paid separately under Part B.

House Bill

Services provided by a rural health clinic (RHCs) and a federally qualified health center (FQHC) after January 1, 2004 would be excluded from SNF–PPS if such services would have been excluded if furnished by a physician or practitioner who was not affiliated with an RHC or FQHC. The provisions would apply to services furnished on or after January 1, 2004.

Senate Bill

Services provided by a rural health clinic (RHC) and a federally qualified health center (FQHC) after January 1, 2005 would be excluded from SNF–PPS if such services would have been excluded if furnished by a physician or practitioner who was not affiliated

with an RHC or FQHC. Outpatient services that are beyond the general scope of SNF comprehensive care plans that are provided by an entity that is 100% owned as a joint venture by two Medicare-participating hospitals or critical access hospitals would be excluded from the SNF–PPS. The provision would apply to services furnished on or after January 1, 2005.

Conference Agreement

Services provided by a rural health clinic (RHC) and a federally qualified health center (FQHC) after January 1, 2004 would be excluded from SNF–PPS if such services would have been excluded if furnished by a physician or practitioner who was not affiliated with an RHC or FQHC. The provisions would apply to services furnished on or after January 1, 2004.

Improvement in Rural Health Clinic Reimbursement (Section 428 in the Senate Bill).

Present Law

BBA 1997 extended the per visit payment limits that had existed for independent rural health clinics to provider-based rural health clinics (RHC) except for those clinics based in small rural hospitals with fewer than 50 beds. For services rendered from January 1, 2003 through February 28, 2003, the RHC upper payment limit is $66.46, which reflects a 2.6% increase in 2002 payment limit as established by the 2002 Medicare Economic Index (MEI). For services rendered from March 1, 2003 through December 31, 2003, the Medicare RHC upper payment limit is $66.72, which reflects a 3.0% increase in the 2002 payment limit as established by the 2003 MEI. The 2002 MEI was used as an update for 3 months because the delayed implementation of the 2003 MEI.

House Bill

No provision.

Senate Bill

The RHC upper payment would be increased to $80.00 for calendar year 2005. The MEI applicable to primary care services would be used to increase the payment limit in subsequent years. The provision would be effective upon enactment.

Conference Agreement

No provision.

Frontier Extended Stay Clinic Demonstration Project (Section 434 of the Conference Report and Section 457/Duplicative Provision 460 of the Senate Bill).

Present Law

No provision.

House Bill

No provision.

Senate Bill

The Secretary would be required to conduct a demonstration project that would treat frontier extended stay clinics as a Medicare provider. A frontier extended stay clinic is one that is located in a community where the closest acute care hospital or critical access hospital is at least 75 miles away or is inaccessible by public road. Such clinics are designed to address the needs of seriously or critically ill or injured patients who, due to adverse weather conditions or other reasons, cannot be transferred quickly to acute care referral centers; or patients who need monitoring and observation for a limited period of time. The provision would be effective upon enactment.

Conference Agreement

The Secretary would be required to conduct a demonstration project that would treat frontier extended stay clinics as a Medicare provider. A frontier extended stay clinic is one that is located in a community where the closest acute care hospital or critical access hospital is at least 75 miles away or is inaccessible by public road and is designed to address the needs of seriously or critically ill or injured patients who, due to adverse weather conditions or other reasons, cannot be transferred quickly to acute care referral centers; or patients who need monitoring and observation for a limited period of time. The Secretary is required to develop life safety code standards for these clinics such as sprinkler system because the patients stay overnight. The provision would be effective upon enactment and is budget neutral.

Subtitle C—Provisions Relating to Parts A and B

1-Year Increase for Home Health Services Furnished in a Rural Area (Section 421 of the Conference Agreement, Section 411 of the House Bill, and Section 451 of the Senate Bill).

Present Law

The Medicare home health PPS which was implemented on October 1, 2000 provides a standardized payment for a 60–day episode of care furnished to a Medicare beneficiary. Medicare's payment is adjusted to reflect the type and intensity of care furnished and area wages as measured by the hospital wage index. BIPA increased PPS payments by 10% for home health services furnished in the home of beneficiaries living in rural areas during the 2–year period beginning April 1, 2001, through March 31, 2003, without regard to certain budget-neutrality provisions applying to home health PPS. The temporary additional payment is not included in the base for determination of payment updates.

House Bill

The provision would extend a 5% additional payment for home health care services furnished in a rural area during FY2004 and FY2005 without regard to certain budget-neutrality requirements. The provision would be effective upon enactment.

Senate Bill

The provision would provide a temporary payment increase of 5% for home health care services furnished in a rural area on or after October 1, 2004 and before October 1, 2006 without regard to certain budget-neutrality requirements. The temporary additional payment would not be considered when determining future home health payment amounts. The provision would be effective upon enactment.

Conference Agreement

The conference agreement provides a 1–year, 5% additional payment for home health care services furnished in a rural area without regard to certain budget-neutrality requirements. The temporary additional payment begins for episodes and visits ending on or after April 1, 2004 and before April 1, 2005 and is not to be used in calculating future home health payment amounts.

Redistribution of Unused Resident Positions (Section 422 of the Conference Agreement and Section 406 of the House Bill).

Present Law

Medicare has different resident limits for counting residents in its indirect medical education (IME) adjustment and for reimbursement for a teaching hospital's direct medical education (DGME) costs. Generally, a hospital's IME adjustment depends on a hospital's teaching intensity as measured by the ratio of the number of interns and residents per bed. Prior to BBA 1997, the number of residents that could be counted for IME purposes included only those in the hospital inpatient and outpatient departments. Effective October 1, 1997, under certain circumstances a hospital may now count residents in non-hospital sites for the purposes of IME. Medicare DGME payment to a teaching hospital is based on its updated cost per resident (subject to a locality adjustment and certain payment corridors), the weighted number of approved full-time-equivalent (FTE) residents, and Medicare's share of inpatient days in the hospital. Medicare counts residents in their initial residency period (the lesser of the minimum number of years required for board eligibility in the physician's specialty or 5 years) as 1.0 FTE. Residents whose training has extended beyond their initial residency period count as 0.5 FTE. Residents in certain specialties are allowed additional years in their initial residency period. Residents who are graduates from foreign medical schools do not count unless they pass certain exams.

Generally, the resident counts for both IME and DGME payments are based on the number of residents in approved allopathic and osteopathic teaching programs that were reported by the hospital for the cost reporting period ending in calendar year 1996. The DGME resident limit is based on the unweighted resident counts. It may differ from the IME limit because in 1996 residents training in non-hospital sites were eligible for DGME payments but not for IME payments. Hospitals that established new training programs before August 5, 1997 are partially exempt from the cap. Other exceptions apply to certain hospitals including those with new programs established after that date. Hospitals in rural areas (and nonrural hospitals operating training programs in rural areas) can be paid for 130% of the number of residents allowed by their cap. Under certain conditions, an affiliated group of hospitals under a specific arrangement may combine their resident limits into an aggregate limit. Subject to these resident limits, a teaching hospital's IME and DGME payments are based on a 3-year rolling average of resident counts, that is, the resident count will be based on the average of the resident count in the current year and the 2 preceding years. The rolling average calculation includes podiatry and dental residents.

House Bill

A teaching hospitals total number of Medicare-reimbursed resident positions would be reduced for cost reporting periods starting January 1, 2004 if its resident reference level is less than its applicable resident limit. If so, the reduction would equal 75% of the difference between the hospitals limit and its resident reference level. The resident reference level would be the highest number of allopathic and osteopathic resident positions (before the application of any weighting factors) for the hospital during the reference period. A hospitals reference period would be the 3 most recent consecutive cost reporting periods for which a hospitals cost reports have been settled (or in the absence of such settled cost reports, submitted reports) on or before September 30, 2002. The Secretary would be able to adjust a hospitals resident reference level, upon the timely request for such an adjustment, for the cost reporting period that includes July 1, 2003.

The Secretary would be authorized to increase the applicable resident limits for hospitals by an aggregate number that does not exceed the overall reduction in such limits. No increase would be permitted for any portion of cost reporting period that occurs before July 1, 2004 or before the date of a hospital's application for such an increase. No increase would be permitted unless the hospital applied for such an increase by December 31, 2005. The Secretary would consider the need for an increase in the physician specialty and the location involved. The Secretary would first distribute the increased resident count to programs in hospitals located in rural areas and hospitals that are

not in large urban areas on a first-come-first-served basis. The hospital would have to demonstrate that the resident positions would be filled; not more than 25 positions would be given to any hospital. These hospitals would be reimbursed for DGME for the increase in resident positions at the locality adjusted national average per resident amount. Changes in a hospitals resident count established under this section would affect a hospitals IME adjustment. These provisions would not apply to reductions in residency programs that occurred as part of the voluntary reduction program or would affect the ability of certain hospitals to establish a new medical residency training programs. The Secretary would be required to submit a report to Congress no later than July 1, 2005 on whether to extend the application deadline for increases in resident limits. The provision would be effective upon enactment.

Senate Bill

No provision.

Conference Agreement

A teaching hospital's total number of Medicare-reimbursed resident positions will be reduced for cost reporting periods starting July 1, 2005 if its reference resident level is less than its applicable resident limit. Rural hospitals with less than 250 acute care inpatient beds would be exempt from such reductions. For other such hospitals, the reduction will equal 75% of the difference between the hospital's limit and its reference resident level. The resident reference level is the highest number of allopathic and osteopathic resident positions (before the application of any weighting factors) for the hospital during the reference period. This reference level is either (1) the resident level of the most recent cost reporting period of the hospital for which a cost report has been settled (or submitted, subject to audit) on or before September 30, 2002 or (2) the resident level for the cost reporting period that includes July 1, 2003, if requested on a timely basis by the hospital subject to audit. Upon this timely request at the discretion of the Secretary, a hospital's reference level will be adjusted to include the number of medical residents for the cost reporting period that includes July 1, 2003. Upon timely request of the hospital, the Secretary will adjust the reference resident level to include the number of medical residents that were approved in an application to the appropriate accrediting organization before January 1, 2002 if the program was not in operation by the cost reporting period in question (either September 30, 2002 or July 1, 2003 depending upon the hospital's circumstances and the Secretary's approval). The reduction will apply to hospitals that are members of the same affiliated group as of July 1, 2003.

The Secretary is authorized to increase the applicable resident limits for hospitals for portions of cost reporting periods occurring on or after July 1, 2005 by an aggregate number that does not exceed the overall reduction in such limits. The Secretary will take into account the demonstrated likelihood of the hospital filling the positions within the first 3 cost reporting periods beginning on or after July 1, 2005 when determining which hospitals would receive an increase in their resident levels. The Secretary will establish a priority order to distribute the increased resident count first to programs in hospitals located in rural areas, then to hospitals that are not in large urban areas and finally to other hospitals in a state where there is no other training program for a particular specialty. The Secretary shall consider giving special consideration to hospitals that train a large share of graduates from historically large medical colleges. Increases to limits with the same priority category will be determined by the Secretary. Not more than 25 additional FTEs will be given to any hospital. These hospitals will be reimbursed for DGME for the increase in resident positions at the locality adjusted national average per resident amount. Changes in a hospital's resident count established under this section will affect a hospital's IME adjustment; the IME adjustment will be calculated as if ''c'' is equal to 0.66 for these additional positions starting for discharges after July 1, 2005. These provisions will not apply to reductions in residency programs that occurred as part of the voluntary reduction program or will not affect the ability of certain hospitals to establish new medical residency training programs. The Secretary is required to submit a report to Congress no later than July 1, 2005 on whether to extend the application deadline for increases in resident limits. Requirement with respect to Federal information policy established by Chapter 35 of Title 44, United States Code will not apply to applications under this section.

Subtitle D—Other Provisions

Providing Safe Harbor for Certain Collaborative Efforts that Benefit Medically Underserved Populations (Section 431 of the Conference Agreement and Section 412 of the House Bill).

Present Law

People who knowingly and willfully offer or pay a kickback, a bribe, or rebate directly or indirectly to induce referrals or the provision of services under a Federal program may be subject to financial penalties and imprisonment. Certain exceptions or safe harbors that are not considered violations of the anti-kickback statute have been established.

House Bill

Remuneration in the form of a contract, lease, grant, loan or other agreement between a public or non-profit private health center and an individual or entity providing goods or services to the health center would not be a violation of the anti-kickback statute if such an agreement would contribute to the ability of the health center to maintain or increase the availability or quality of services provided to a medically underserved population. The Secretary would be required to establish standards, on an expedited basis, related to this safe harbor that would consider whether the arrangement (1) resulted in savings of Federal grant funds or increased revenues to the health center; (2) expanded or limited a patient's freedom of choice; and (3) protected a health care professional's independence regarding the provision of medically appropriate treatment. The Secretary would also be able to include other standards that are consistent with Congressional intent in enacting this exception. The Secretary would be required to publish an interim final rule in the Federal Register no later than 180 days from enactment that would establish these standards. The rule would be effective immediately, subject to change after a public comment period of not more than 60 days. The provision would be effective upon enactment.

Senate Bill

No provision.

Conference Agreement

Remuneration in the form of a contract, lease, grant, loan or other agreement between a public or non-profit private health center and an individual or entity providing goods or services to the health center would not be a violation of the anti-kickback statute if such an agreement would contribute to the ability of the health center to maintain or increase the availability or quality of services provided to a medically underserved population. The Secretary would be required to establish standards, on an expedited basis, related to this safe harbor that would consider whether the arrangement (1) results in savings of Federal grant funds or increased revenues to the health center; (2) expands or limits a patient's freedom of choice; and (3) protects a health care professional's independence regarding the provision of medically appropriate treatment. The Secretary would also be able to include other standards that are consistent with Congressional intent in enacting this exception. The Secretary would be required to publish a final regulation establishing these standards no later than 1 year from the date of enactment.

Office of Rural Health Policy Improvement (Section 432 of the Conference Agreement and Section 637 of the Senate Bill).

Present Law

Within the Department of Health and Human Services, the Office of Rural Health Policy advises the Secretary on the effects of current policies and proposed statutory, regulatory, administrative, and budgetary changes in Medicare and Medicaid program on the financial viability of small rural hospitals, the ability of rural areas to attract and retain physicians and other health professionals, and access to and the quality of health care in rural areas. In addition to advising the Secretary, the Office has other responsibilities including coordinating the activities within HHS that relate to rural health care.

House Bill

No provision.

Senate Bill

The list of explicit responsibilities of the Office is expanded to include administering grants, cooperative agreements, and contracts to provide technical assistance and other activities as necessary to support activities related to improving health care in rural areas. The provision would be effective upon enactment.

Conference Agreement

The functions of the Office of Rural Health Policy will be expanded; it will be authorized to administer grants, cooperative agreements, and contracts to provide technical assistance and other necessary activities to support activities related to improving rural health care. The provision is effective on enactment.

MedPAC Study on Rural Payment Adjustments (Section 433 of the Conference Agreement).

Present Law

No provision.

House Bill

NO PROVISION

Conference Agreement

MedPAC will study the effect on specified rural provisions in this legislation (specifically, Sections 401 through 405, 411, 416, and 504) including total payments, growth in costs, capital spending and other payment factors. An interim report on changes to the critical access hospital program (in Section 405) is due to Congress no later than 18 months from the date of enactment. MedPAC's final report on all topics is due to Congress no later than 3 years from the date of enactment.

TITLE V—PROVISIONS RELATING TO PART A

Subtitle A—Inpatient Hospital Services

Revision of Acute Hospital Payment Updates (Section 501(a) and 501(b) of the Conference Agreement and Section 501 of the House Bill).

Present Law

Each year, Medicare's operating payments to hospitals are increased or updated by a factor that is determined in part by the projected annual change in the hospital market basket (MB). Congress establishes the update for Medicare's inpatient prospective payment system (IPSS) for operating costs, often several years in advance. Currently, acute hospitals will receive the MB as an update for FY2004 and subsequently. CMS has asked hospital to report on 10 JCAHO/CMS measures, developed by the National Quality Foundation. For example, whether a patient with an acute myocardial infarction receives aspirin at arrival. As of October 9, 2003, 420 hospitals (out of the over 5,000 acute care hospitals that bill Medicare) had provided CMS with one of more measures.

House Bill

Acute hospitals would receive an operating update of the MB minus 0.4 percentage points for FY2004 through FY2006. The operating update would be the MB increase in FY2007 and subsequently. The provision would be effective upon enactment.

Senate Bill

No provision.

Conference Agreement

An acute hospital will receive an operating update of the MB in FY2004. An acute hospital will receive an operating update of the MB from FY2005 through FY2007 if it submits data on the 10 quality indicators established by the Secretary as of November 1, 2003. The Secretary will specify the form, manner, and time of the data submission except that any data collection and editing must be done before the start of the fiscal year. For FY2005, the Secretary will provide for a 30-day grace period for the submission of the required data. A hospital that does not submit data to the Secretary will receive an update of the MB minus 0.4 percentage points for the fiscal year in question. The Secretary will not take into account this reduction when computing the applicable percentage increase in subsequent years.

The Secretary is directed to compile and clarify the procedures and policies for billing for blood and blood costs in the hospital inpatient and outpatient settings as well as the operation of the collection of the blood deductible.

Inpatient rehabilitation facilities (IRF) provide Medicare patients with rehabilitation services. They are distinguished from acute care settings by a number of criteria including that 75 percent of their cases must be in ten categories—stroke, spinal cord injury, congenital deformity, amputation, major multiple trauma, fracture of femur, brain injury, and polyarthritis, including rheumatoid arthritis, neurological disorders, and burns. This criterion is commonly referred to as the ''75 percent rule.''

On September 2, 2003, CMS issued proposed changes in classifying IRFs. The Conferees are concerned that the rule, as written, would have severe consequences for access to inpatient rehabilitation hospital services. The Conferees concur with the Medicare Payment Advisory Commission (MedPAC) finding that further analysis should be conducted to identify which conditions are clinically appropriate for inclusion in the calculation of the 75 percent rule used to determine eligibility for reimbursement under the inpatient rehabilitation facility prospective payment system. The Conferees direct the GAO to issue a report, in consultation with experts in the field of physical medicine and rehabilitation to look at whether the current list of conditions represents a clinically appropriate standard for defining IRF services and, if not, which additional conditions should be added to the list. During the study period, the Committee urges the Secretary to delay implementation of the rule and not accept new IRF applications until the report is finished.

GAO Study and Report on Appropriateness of Payments Under the Prospective Payment System for Inpatient Hospital Services (Section 501(c) of the Conference Agreement and Section 413 of the Senate Bill).

Present Law

No provision.

House Bill

No provision.

Senate Bill

GAO would be required to use the most current data available to conduct a study to determine: (1) the appropriate level and distribution of Medicare payments in relation to costs to short-term general hospitals under the inpatient prospective payment system (IPPS) and (2) the need for geographic adjustments to reflect legitimate differences in hospital costs across geographic areas, kinds of hospitals, and types of cases. The study, including recommendations for necessary legislative and administrative action, would be due to Congress within 18 months of enactment.

Conference Agreement

GAO is required to use the most current data available to conduct a study to determine: (1) the appropriate level and distribution of Medicare payments in relation to costs for short-term general hospitals under the inpatient prospective payment system (IPPS) and (2) the need for geographic adjustments to reflect legitimate differences in hospital costs across geographic areas, kinds of hospitals, and types of cases. The study, including recommendations for necessary legislative and administrative action, is due to Congress within 24 months of enactment.

Revision of the Indirect Medical Education (IME) Adjustment Percentage (Section 502 of the Conference Agreement and Section 418 of the Senate Bill).

Present Law

A hospital's IME payment to a hospital is based on a percentage add-on to the PPS rate that is established by a curvilinear formula that currently provides a payment increase of approximately 5.5% for each 10% increase in the hospital's intern and resident-to-bed (IRB) ratio. The following formula is multiplied by a hospital's base payment rate for each Medicare discharge to determine the IME payment: $1.35 \times [(1+IRB)^{0.405} - 1]$. The multiplier of 1.35 increases the level of the IME adjustment to the existing target level of 5.5%. Congress has periodically changed the multiplier (or ''c'') to decrease or increase IME payments to teaching hospitals.

House Bill

No provision.

Senate Bill

The IME multiplier in 2004 and in 2005 would be 1.36; on or after 2005, the multiplier would be 1.355. This would increase payments to teaching hospitals by $300 million over 10 years. The provision would apply to discharges on or after October 1, 2003.

Conference Agreement

From April 1, 2004 until September 30, 2004, the IME multiplier is equal to 1.47; during FY2005, the IME multiplier is 1.42; during FY2006, the IME multiplier is 1.37; during FY2007, the IME multiplier is 1.32; and, starting October 1, 2007, the IME multiplier is equal to 1.35.

Recognition of New Medical Technologies Under Inpatient Hospital Prospective Payment System (Section 503 of the Conference Agreement and Section 502 of the House Bill).

Current Law

BIPA established that Medicare's inpatient hospital payment system should include a mechanism to recognize the costs of new medical services and technologies for discharges beginning on or after October 1, 2001. The additional hospital payments can be made by the means of a new technology groups, an add-on payment, a payment adjustment, or other mechanism, but cannot be a separate fee schedule and must be budget-neutral. A medical service or technology will be considered to be new if it meets criteria established by the Secretary after notice and the opportunity for public comment. The Centers for Medicare and Medicaid (CMS) published the final regulation implementing these provisions on September 7, 2001. This regulation changed the meeting schedule for decisions on the creation and implementation of new billing codes. (ICD–9–CM codes). The regulation also established that technology that provided a substantial improvement to existing treatments would qualify for additional payments. The add-on payment for eligible new technology would occur when the standard diagnosis related group (DRG) payment was inadequate; this threshold, which was established as one standard deviation above the mean standardized DRG. In these cases, the add-on payment for new technology would be the lesser of (a) 50% of the costs of the new technology or (b) 50% of the amount by which the costs exceeded the standard DRG payment; however if the new technology payments are estimated to exceed the budgeted target amount of 1% of the total operating inpatient payments, the add-on payments are reduced prospectively.

House Bill

The Secretary would be required to add new diagnosis and procedure codes in April 1 of each year but would not be required to affect Medicare's payment or DRG classification until the fiscal year that begins after that date. The Secretary would not be able to deny a service or technology treatment as a new technology because the service (or technology) has been in use prior to the 2–to–3 year period before it was issued a billing code and a sample of specific discharges where the service has been used can be identified. When establishing whether DRG payments are inadequate, the Secretary would be required to apply a threshold that is the lesser of 75% of the standardized amount (increased to reflect the difference between costs and charges) or 75% of one standard deviation for DRG involved. The Secretary would be required to provide additional clarification in regulation on the criteria used to determine whether a new service represents an advance in technology that substantially improves the existing diagnosis or treatment. The Secretary would be required to deem that a technology provide a substantial improvement on an existing treatment if the technology in question is a drug or biological that is designated under section 506 of the Federal Food, Drug, and Cosmetic Act, approved under section 314.510 or 601.41 of Title 21, Code of Federal Regulations, designated for priority review when the marketing application was filed, is a medical device for which an exemption has been granted under section 520(m) of such Act, or for which priority or expedited review has been provided under section 515(d)(5). For other technologies that may be substantial improvements, the Secretary would be required to: (1) maintain and update a public list of pending applications for specific services and technologies to be evaluated for eligibility for additional payment; (2) accept comments

recommendations and data from the public regarding whether a service or technology represents a substantial improvement; and (3) provide for a meeting at which organizations representing physicians, beneficiaries, manufacturers or other interested parties may present comments, recommendations, and data to the clinical staff of CMS regarding whether a service or technology represents a substantial improvement. These actions would occur prior to the publication of the proposed regulation. Before establishing an add-on payment as the appropriate reimbursement mechanism, the Secretary would be directed to identify one or more DRGs and assign the technology to that DRG, taking into account similar clinical or anatomical characteristics and the relative cost of the technology. The Secretary would assign an eligible technology into a DRG where the average cost of care most closely approximates the cost of the new technology. In such a case, no add-on payment would be made; the application of the budget-neutrality requirement with respect to annual DRG reclassifications and recalculation of associated DRG weights would not be affected. The Secretary would be required to increase the percentage associated with add-on payments from 50% to the marginal rate or percentage that Medicare reimburses inpatient outlier cases. The provisions would not affect the Secretary's authority to determine whether services are medically necessary and appropriate. Funding for this new technology would no longer be budget neutral.

The Secretary would be required to implement these provisions to new technology determinations beginning in FY2005. The Secretary would be required to automatically reconsider an application as a new technology that was denied for FY2004 as an application under these new provisions. If such an application is granted, the maximum time period otherwise permitted for such classification as a new technology would be extended by 12 months.

Senate Bill

No provision.

Conference Agreement

The Secretary is required to add new diagnosis and procedure codes in April 1 of each year but is not be required to affect Medicare's payment or DRG classification until the fiscal year that begins after that date. When establishing whether DRG payments are inadequate, the Secretary would be required to apply a threshold that is the lesser of 75% of the standardized amount (increased to reflect the difference between costs and charges) or 75% of one standard deviation for the DRG involved. The Secretary should collect at least 2 years of data before incorporating the technology into a permanent group. The Secretary is be required to: (1) maintain and update a public list of pending applications for specific services and technologies to be evaluated for eligibility for additional payment; (2) accept comments recommendations and data from the public regarding whether a service or technology represents a substantial improvement; and (3) provide for a meeting at which organizations representing physicians, beneficiaries, manufacturers or other interested parties may present comments, recommendations, and data to the clinical staff of CMS regarding whether a service or technology represents a substantial improvement. These actions will occur prior to the publication of the proposed regulation. Before establishing an add-on payment as the appropriate reimbursement mechanism, the Secretary is directed to identify one or more DRGs and assign the technology to that DRG, taking into account similar clinical or anatomical characteristics and the relative cost of the technology. The Secretary will assign an eligible technology into a DRG where the average cost of care most closely approximates the cost of the new technology. In such a case, no add-on payment would be made; the application of the budget-neutrality requirement with respect to annual DRG reclassifications and recalculation of associated DRG weights will not be affected. The Secretary should consider increasing the percent of payment associated with the add-on payments up to the marginal rate used for the inpatient outlier. Funding for new technology will no longer be budget neutral.

The Secretary is required to implement these provisions to new technology determinations beginning in FY2005. The Secretary is required to automatically reconsider an application as a new technology that was denied for FY2005 as an application under these new provisions. If such an application is granted, the maximum time period otherwise permitted for such classification as a new technology is extended by 12 months.

Increase in Federal Rate for Hospitals in Puerto Rico (Section 504 of the Conference Agreement, Section 503 of the House Bill, and Section 409 of the Senate Bill).

Present Law

Under Medicare's prospective payment system for inpatient services, a separate standardized amount is used to establish payments for discharges from short-term general hospitals in Puerto Rico. BBA 97 provides for an adjustment of the Puerto Rico rate from a blended amount based on 25% of the federal national amount and 75% of the local amount to a blended amount based on a 50/50 split between national and local amounts.

House Bill

Hospitals in Puerto Rico would receive Medicare payments based on a 50/50 split between federal and local amounts before October 1, 2003. From FY2004 through FY2007, an increasing amount of the payment rate would be based on federal national rates as follows: during FY2004, payment would be 59% national and 41% local; this would change to 67% national and 33% local during FY2005 and 75% national and 25% local during FY2006 and subsequently.

Senate Bill

Hospitals in Puerto Rico would receive Medicare payments based on a 50/50 split between national and local amounts until September 30, 2003. These hospitals would receive Medicare payments based on 100% of the federal rate for discharges on or after October 1, 2004 and before October 1, 2009. The rate for hospitals Puerto Rico would revert to a 50/50 split after October 1, 2009.

Conference Agreement

Hospitals in Puerto Rico will receive Medicare payments based on a 50/50 split between federal and local amounts before April 1, 2004. Starting April 1, 2004 through September 30, 2004, payment will be based on 62.5% national amount and 37.5% local amount; this will change to 75% national and 25% local after October 1, 2004 and in subsequent years.

Wage Index Adjustment Reclassification Reform (Section 505 of the Conference Agreement and Section 504 of the House Bill).

Present Law

Unlike other providers, acute hospitals may apply to the Medicare Geographic Classification Review Board (MGCRB) for a change in classification from a rural area to an urban area, or reassignment from one urban area to another urban area. The MGCRB was created to determine whether a hospital should be redesignated to an area with which it has close proximity for purposes of using the other area's wage index. If reclassification is granted, the new wage index will be used to calculating Medicare's payment for inpatient and outpatient services.

Generally, hospitals must demonstrate a close proximity to the areas where they seek to be reclassified. This proximity can be established if one of two conditions is met: (1) an urban hospital must be no more than 15 miles and a rural hospital must be no more than 35 miles from the area where it wants to be reclassified; or (2) at least 50% of the hospital's employees reside in the area. A rural referral center (RRC) or a sole community hospital (SCH) or a hospital that is both a RRC and a SCH does not have to meet the proximity test. After establishing appropriate proximity, a hospital may qualify for the payment rate of another area if it proves that its incurred costs are comparable to those of hospitals in that area under established criteria. To use an area's wage index, a rural hospital must demonstrate that its average hourly wage is equal to at least 82% of the average hourly wage of hospitals in the area to which it seeks redesignation; an urban hospital must demonstrate that its average hourly wage is at least 84% of such an area. Also an urban hospital cannot be reclassified unless average hourly wage is at least 108% of the average hourly wage of the area in which it is located; this standard is 106% for rural hospitals seeking reclassification to an area.

For redesignations starting in FY2003, the average hourly wage comparisons used to determine whether a hospital can use another area's wage index are based on 3 years worth of lagged data submitted by hospitals as part of their cost report. For instance, FY2003 wage index reclassifications were based on weighted 3-year averages of average hourly wages using data from FY1997, FY1998, and FY1999 cost reports. Wage index reclassifications are effective for 3 years unless the hospital notifies the MCGRB and withdraws or terminates its reclassification.

House Bill

The Secretary would be required to establish an application process and payment adjustment to recognize the commuting patterns of hospital employees. A hospital that qualified for such a payment adjustment would have average hourly wages that exceed the average wages of the area in which it is located and have at least 10% of its employees living in 1 or more areas that have higher wage index values. This qualifying hospital would have its wage index value increased by the percentage of its total employees who live in any area with a higher wage index value. The process would be based on the MGCRB reclassification process and schedule with respect to data submitted. Such an adjustment would be effective for 3 years unless a hospital withdraws or elects to terminate its payment. A hospital that receives a commuting wage adjustment would not be eligible for reclassification into another area by the MCGRB. These commuting wage adjustments would not affect the computation of the wage index of the area in which the hospital is located or any other area. It would also be exempt from certain budget neutrality requirements. The provisions would apply to discharges on or after October 1, 2004.

Senate Bill

No provision.

Conference Agreement

The Secretary is required to establish a process and payment adjustment to recognize the out-migration of hospital employees

who reside in a county and work in different area with a higher wage index. A hospital that receives such a payment adjustment will be located in a qualifying county that meets criteria established by the Secretary. This criteria will include (1) a threshold percentage of the weighted average of the area wage index or indices for the higher wage index areas; (2) a threshold of not less than 10 percent for minimum out-migration to a higher wage index area or areas and (3) a requirement that the average hourly wage of the hospitals in the qualifying county equals or exceeds the average hourly wage of all the hospitals in the area where the county is located. A qualifying hospital will have its wage index value increased by the percentage of the hospital employees residing in the qualifying county who are employed in any area with a higher wage value. The adjustment will equal the sum of the products of the difference between the wage index value of any higher wage area and the qualifying county multiplied by the number of hospital employee who reside in the qualifying county but are employed in any higher wage index area. The application process for this adjustment is based on the MGCRB reclassification process and schedule with respect to data submitted. Such an adjustment is effective for 3 years unless a hospital withdraws or elects to terminate its payment.

The Secretary may require acute hospitals and other hospitals as well as critical access hospitals to submit data regarding the location of their employee's residence or the Secretary may use data from other sources. A hospital that receives a commuting wage adjustment is not eligible for reclassification into another area by the MCGRB. The commuting wage adjustment does not affect the computation of the wage index of the area in which the hospital is located or any other area. It is also exempt from certain budget neutrality requirements. The thresholds and other qualifying criteria for the commuting wage adjustment is not subject to judicial review. The provisions apply to discharges on or after October 1, 2004. In initially implementing this adjustment, the Secretary may modify the deadlines otherwise applicable to data submission and actions on applications for geographic reclassification.

Limitation on Charges for Inpatient Hospital Contract Health Services Provided to Indians by Medicare Participating Hospitals (Section 506 of the Conference Agreement and Section 412 of the Senate Bill).

Present Law

The Indian Health Service (IHS) provides health care both directly, through tribes and tribal consortia, and through urban Indian organizations. The Indian Health Care Improvement Act (P.L. 94–437) authorized IHS to collect directly from Medicare, Medicaid, and other third party insurers for health services covered by those programs. In addition to care provided directly from IHS and tribal providers, contract health services are purchased by IHS and the tribes from more than 2,000 private providers, if the local facility is unable to provide the needed care. These health services are provided principally for members of tribes who live in contract health service delivery areas. Contract support funding across all IHS programs has been insufficient to cover all IHS and tribal costs. When the costs are not reimbursed through appropriations, the tribes and IHS use program funds to make up the difference.

House Bill

No provision.

Senate Bill

The amendment would prohibit hospitals that participate in Medicare and that provide Medicare covered inpatient hospital services under the contract health services program funded by the Indian Health Services from charging more than the Medicare established rates for these services. This provision would apply to contract health services programs operated by the Indian Health Service, an Indian tribe or tribal organization or an urban Indian organization. The provision would apply to Medicare participation agreements in effect or entered into by a date specified by the Secretary. In no case would this provision be applicable later than 6 months from the date of enactment.

Conference Agreement

Hospitals that participate in Medicare and that provide Medicare covered inpatient hospital services under the contract health services program funded by the Indian Health Services and operated by the Indian Health Service, an Indian tribe, an Indian tribal organization, or an urban Indian organization will be paid in accordance with regulations promulgated by the Secretary regarding admission practices, payment methodologies, and rates of payments. This will include the requirement to accept these rates as payment in full. This provision will apply to Medicare participation agreements in effect or entered into by a date specified by the Secretary. In no case will this date be later than 1 year after the date of enactment.

Clarifications to Certain Exceptions to Medicare Limits on Physician Referrals (Section 507 of the Conference Agreement, Section 505 of the House Bill and Section 453 of the Senate Bill).

Present Law

Physicians are generally prohibited from referring Medicare patients to facilities in which they (or their immediate family member) have financial interests. Physicians, however, are not prohibited from referring patients to whole hospitals (and several other entities) in which they have ownership or investment interests.

House Bill

The Medicare Payment Advisory Commission (MedPAC) would be required to conduct a study of specialty hospitals compared with other similar general acute hospitals including the number and extent of patients referred by physicians with an investment interest in the facility, the quality of care furnished, the impact of the specialty hospital on the acute general hospital, and the differences in the scope of services, Medicaid utilization and the amount of uncompensated care that is furnished. The report, including recommendations, would be due to Congress no later than 1 year from enactment.

Senate Bill

The exception for physician investment and self-referral would not extend to specialty hospitals. In this instance, a specialty hospital would be one that is primarily or exclusively engaged in the care and treatment of patients with cardiac or orthopedic conditions, those receiving a surgical procedure, or other specialized categories of patients or cases deemed appropriate. A specialty hospital would not include any hospital that is determined by the Secretary to be in operation, under development as of such date, with the same number of beds and physician investors as of June 12, 2002. The Secretary would consider the following factors in determining whether a hospital is under development: whether the architectural plans have been completed; funding has been received; zoning requirements have been met; necessary approvals from appropriate State agencies have been received and other appropriate evidence.

The rural provider exception would be modified. These rural providers would not include specialty hospitals and the Secretary would determine, with respect to the entity, that such services would not be available in such area but for the ownership or investment interest.

Conference Agreement

For a period of 18 months from the date of enactment, the ''whole hospital'' exception would be amended to exclude those circumstances in which a physician's ownership interest is in a subsection d hospital devoted primarily or exclusively to cardiac, orthopedic surgical, or other specialties designated by the Secretary. Specialty hospitals in operation or under development as of November 18, 2003 would be exempt from the provision. Within a period of 15 months from the date of enactment MedPAC, in consultation with the General Accounting Office (GAO), and HHS would study the effects of the whole-hospital exception for physician-ownership in specialty hospitals.

In order to qualify for exception from this provision, a specialty hospital must have been in operation or under development (as defined in this bill) as of November 18, 2003. Additionally, in order to maintain the exception, a specialty hospital may not increase the number of physician investors as of November 18, 2003; change or expand the field of specialization it treats; expand beyond the main campus; or increase the total number of beds in its facilities by more than the greater of 5 beds or 50 percent of the number of beds in the hospital as of November 18, 2003. The Secretary shall determine what constitutes the number of beds in a hospital that is considered under development as of November 18, 2003. The Secretary may evaluate all relevant development plans and documents in order to make this determination.

Long-term acute care hospitals, rehabilitation hospitals, psychiatric hospitals, cancer hospitals, and children's hospitals are not considered to be specialty hospitals for purposes of this section. When studying the effects of the whole-hospital exception, MedPAC, in consultation with GAO shall undertake a study in accordance with the legislation.

Effective Date

Beginning on the date of enactment, this provision would establish an 18–month moratorium on physician self-referrals to specialty hospitals. Hospitals in existence or under development as of November 18, 2003 would be exempt from the moratorium. A study would be completed within 15 months of date of enactment.

MedPAC Study and Report Regarding Medicare Disproportionate Share Hospital

Adjustments (Section 404A of the Senate Bill).

Present Law

No provision.

House Bill

No provision.

Senate Bill

The Medicare Payment Advisory Commission (MedPAC) would be required to conduct a study to determine (1) whether disproportionate share hospital (DSH) payments should be made in the same manner as Medicare's graduate medical education payments; (2) the extent that hospitals receiving Medicaid DSH payments also receive Medicare DSH payments; and (3) whether to add uncompensated care costs to the Medicare DSH formula. The report, including recommendations, would be due to Congress within 1 year from enactment. The provision would be effective upon enactment.

Conference Agreement

No provision.

Treatment of Grandfathered Long-Term Care Hospitals (Section 416/Duplicate Provision 420B of the Senate Bill).

Present Law

A hospital-in-a-hospital is a long-term hospital that is physically located in an acute care hospital and provides inpatient services that are paid at a higher rate than would apply if the long term hospital were treated by Medicare as an acute care hospital. The Centers for Medicare and Medicaid Services (CMS) has established certain requirements for a hospital-in-a-hospital to be excluded from the inpatient prospective payment system and be paid as a long-term hospital. For instance, a hospital-within-a-hospital has to be able to independently perform certain basic hospital functions. CMS exempted existing hospitals-with-a-hospital (those that were in existence on or before September 30, 1995) when these requirements were established. On May 19, 2003, CMS proposed to revise the conditions of the hospitals' exemption; a hospital-within-a hospital would only be exempt from the existing requirements if it continues to operate within the same terms and conditions that were in effect as of September 30, 1995.

House Bill

No provision.

Senate Bill

The Secretary would not be able to impose any special conditions on the operation, size, and number of beds or location of an existing long-term hospital in order to continue participating in Medicare or Medicaid or to continue being classified as a long-term hospital. The Secretary would not be able to adopt a proposed regulation that would implement such conditions or any revision to such regulation that have a comparable effect. The provisions would apply to cost reporting periods ending on or after December 31, 2002.

Conference Agreement

No provision.

Treatment of Certain Entities For Purposes of Payments Under the Medicare Program (Section 417 of the Senate Bill).

Present Law

Acute care hospitals may apply to the Medicare Geographic Classification Review Board (MGCRB) for a change in classification from a rural area to an urban area, or reassignment from one urban area to another urban area. The MGCRB was created to determine whether a hospital should be redesignated to an area with which it has close proximity for purposes of using the other area's standardized amount or wage index, or both. (If, as proposed, the standardized amount for all hospitals will equal the amount used to pay hospitals in large urban areas, a hospital's need to reclassify to use of another area's standardized amount will virtually disappear.) If reclassification is granted, the new wage index will be used to calculating Medicare's payment for inpatient and outpatient services. Hospital reclassifications are established on a budget-neutral basis so aggregate inpatient prospective payment system expenditures will not increase as a result.

Generally, hospitals must demonstrate a close proximity to the areas where they seek to be reclassified. After establishing appropriate proximity, a hospital may qualify for the payment rate of another area if it proves that its incurred costs are comparable to those of hospitals in that area. Aside from reclassifications through the MGCRB, hospitals have also been reclassified by law.

House Bill

No provision.

Senate Bill

Starting on or after October 1, 2003, Iredell County and Rowan County, North Carolina would be deemed to be located in the Charlotte-Gastonia-Rock Hill, North Carolina, South Carolina Metropolitan Statistical Area for the purpose of Medicare's inpatient and outpatient acute hospital reimbursement. The Secretary would be required to adjust the wage index values of all hospitals in North Carolina to assure that aggregate payments for hospital inpatient operating costs are not greater than they would have been without such a change.

Starting on or after October 1, 2003, Iredell County and Rowan County, North Carolina would be deemed to be located in the Charlotte-Gastonia-Rock Hill, North Carolina, and South Carolina Metropolitan Statistical Area for the purpose of Medicare's skilled nursing facility (SNF) and home health reimbursement. This change will be made in a way to ensure that aggregate payments for SNF and home health services in North Carolina are not greater than they would have been without such a change.

Conference Agreement

No provision.

Calculation of Wage Indices for Hospitals (Conference Report Section 508 and Section 419 of the Senate Bill).

Present Law

Acute hospitals may apply to the Medicare Geographic Classification Review Board (MGCRB) for a change in classification from a rural area to an urban area, or reassignment from one urban area to another urban area but no later than February 15, 2004. If reclassification is granted, the new wage index will be used to calculating Medicare's payment for inpatient and outpatient services. Generally, hospitals must demonstrate a close proximity to the areas where they seek to be reclassified. After establishing appropriate proximity, a hospital may qualify for the payment rate of another area if it proves that its incurred costs are comparable to those of hospitals in that area. The reclassification standards which are established by regulation are different for urban than for rural hospitals. It is easier for a rural hospital to reclassify to a different area. Aside from reclassifications through the MGCRB, hospitals have also been reclassified by law.

House Bill

No provision.

Senate Bill

The Secretary would be able to waive established reclassification criteria in calculating the wage index in a state when making payments for hospital discharges in FY2004. The provision would be effective upon enactment.

Conference Agreement

The Secretary shall establish by instruction not later than January 1, 2004 or otherwise a one-time process under which a hospital may appeal the wage index classification otherwise applicable to the hospital and select another area within the State (or at the discretion of the Secretary to a contiguous state. A qualifying hospital is not eligible for a wage index classification on the basis of distance and/or commuting. It also must meet such other criteria, such as quality, as the Secretary may specify by instruction or otherwise. The reclassification will be effective for three years beginning with April 1, 2004. Hospitals can waive reclassification under this provision during the three year period. The Secretary shall limit the additional expenditures to $900 million.

Subtitle B—Other Provisions

Payment for Covered Skilled Nursing Facility Services (Section 511 of the Conference Agreement and Section 511 of the House Bill).

Present Law

Medicare uses a system of daily rates to pay for care in a skilled nursing facility (SNF). There are 44 daily rates categories, known as resource utilization groups (RUGs) and each group reflects a different case mix and intensity of services, such as skilled nursing care and/or various therapy and other services.

House Bill

The per diem RUG payment for a SNF resident with acquired immune deficiency syndrome (AIDS) would be increased by 128%. This payment increase would not apply on after such date when the Secretary certifies that the SNF case mix adjustment adequately compensates for the facility's increased costs associated with caring for a resident with AIDS. The provision would be effective for services on or after October 1, 2003.

Senate Bill

No provision.

Conference Agreement

The conference agreement increases the per diem RUG payment for a SNF resident with acquired immune deficiency syndrome (AIDS) by 128% (the BBRA temporary RUG add-on does not apply in this case). This payment increase would not apply on after such date when the Secretary certifies that the SNF case mix adjustment adequately compensates for the facility's increased costs associated with caring for a resident with AIDS. The provision is effective for services on or after October 1, 2004.

Coverage of Hospice Consultation Services (Section 512 of the Conference Agreement and Section 512 of the House Bill).

Present Law

Current law authorized coverage of hospice services, in lieu of certain other Medicare benefits, for terminally ill beneficiaries who elect such coverage.

House Bill

Coverage of certain physician's services for certain terminally ill individuals would be authorized. Persons entitled to these services would be individuals who have not elected the hospice benefit and have not previously received these physician's services. Covered services would be those furnished by a physician who is the medical director or employee of a hospice program. Services would include evaluating the individual's need for pain and symptom management, counseling the individual with respect to end-of-life issues and care options, and advising the individual regarding advanced care planning. Payment for such services would equal the amount established for similar services under the physician fee schedule, excluding the practice expense component. The provision would apply to consultation services provided by a hospice program on or after January 1, 2004.

Senate Bill

No provision.

Conference Agreement

The conference agreement provides coverage of certain physician's services for certain terminally ill individuals. Beneficiaries entitled to these services are those who have not elected the hospice benefit and have not previously received these physician's services. Covered services are those furnished by a physician who is the medical director or employee of a hospice program. The covered services are: evaluating the beneficiary's need for pain and symptom management, including the individual's need for hospice care; counseling the beneficiary with respect to end-of-life issues and care options, and advising the beneficiary regarding advanced care planning. Payment for such services equals the amount established for similar services under the physician fee schedule, excluding the practice expense component. The

provision would apply to consultation services provided by a hospice program on or after January 1, 2005.

Increase for Hospitals with Disproportionate Indigent Care Revenues (Section 420A of the Senate Bill).

Present Law

Certain hospitals receive additional Medicare payments because they serve a disproportionate share of poor Medicare and Medicaid patients measured by a formula that incorporates the proportion of the hospital's Medicare inpatient days provided to poor Medicare beneficiaries (those who receive Supplemental Security Income or SSI) added to the proportion of total hospital days provided to Medicaid recipients. A few urban hospitals receive disproportionate share hospital (DSH) payments under the Pickle Amendment (named after former Representative Pickle from Texas) which establishes an alternative formula that considers the proportion of a hospital's patient care revenues that are received from state and local indigent care funds. If a hospital receives at least 30% of its patient care revenue from these indigent care funds, it qualifies as a ''Pickle'' hospital and will get a 35% increase in its Medicare operating payments. The Pickle hospitals receive a capital DSH adjustment of 14.16%. The capital adjustment is calculated with the presumption that other urban hospitals would have had a DSH patient share percentage of 65.4% in order to receive a 35% operating DSH adjustment. If so, 65.4% DSH adjustment entered into the capital formula (a complicated calculation involving ''e is the natural antilog of 1'') would equal 14.16%.

House Bill

No provision.

Senate Bill

Hospitals that qualify for the DSH adjustment under the Pickle amendment would receive a DSH operating and capital adjustment of 40% for discharges on or after October 1, 2003. The provision would be effective upon enactment.

Conference Agreement

No provision.

Equitable Treatment for Children's Hospitals (Section 450J of the Senate Bill).

Present Law

Outpatient hospital prospective payment contains a permanent ''hold harmless'' for cancer hospitals and children's hospitals. Under this hold harmless, payments to these hospitals cannot fall below what these hospitals would have received under the payment system in place before PPS.

House Bill

No provision.

Senate Bill

The provision would modify the hold harmless that certain children's hospitals receive. To receive the hold harmless a children's hospital would be required to be located in a state with an inpatient PPS waiver (Maryland is the only state that continues its waiver under 1814(b)(3)) and to have an outpatient PPS payment that is less than either what the hospital would have received under the previous payment system or the hospital's reasonable operating and capital costs. A children's hospital meeting these criteria would receive payment reflecting the greater difference between the outpatient PPS amount and the greater of either the previous payment system amount or the reasonable costs. The provision would be effective for services furnished on or after October 1, 2003.

Conference Agreement

No provision.

TITLE VI—PROVISIONS RELATING TO PART B

Subtitle A—Provisions Relating to Physicians' Services

Revision of Updates for Physicians' Services (Section 601 of the Conference Agreement, Section 601 of the House Bill, and Sections 464/Duplicative Provisions 622 and 629 of the Senate Bill).

Present Law

Medicare pays for services of physicians and certain non-physician practitioners on the basis of a fee schedule. The fee schedule, in place since 1992, is intended to relate payments for a given service to the actual resources used in providing that service. The fee schedule assigns relative values to services. These relative values reflect physician work (i.e., the time, skill, and intensity it takes to provide the service), practice expenses, and malpractice costs. The relative values are adjusted for geographic variations in costs. The adjusted relative values are then converted into a dollar payment amount by a conversion factor.

The law provides a specific formula for calculating the annual update to the conversion factor. The intent of the formula is to place a restraint on overall increases in spending for physicians' services. Several factors enter into the calculation of the formula. These include: (1) the sustainable growth rate (SGR), which is essentially a target for Medicare spending growth for physicians' services; (2) the Medicare economic index (MEI), which measures inflation in the inputs needed to produce physicians' services; and (3) an adjustment that modifies the update, which would otherwise be allowed by the MEI, to bring spending in line with the SGR target. The SGR target is not a limit on expenditures. Rather, the fee schedule update reflects the success or failure in meeting the target. If expenditures exceed the target, the update for a future year is reduced.

The annual percentage update to the conversion factor equals the MEI, subject to an adjustment (known as the update adjustment factor) to match target spending for physicians services under the SGR system. (During a transition period, 2001–2005, an additional adjustment is made to achieve budget neutrality.) The update adjustment sets the conversion factor at a level so that projected spending for the year will meet allowed spending by the end of the year. Allowed spending for the year is calculated using the SGR. However, in no case can the update adjustment factor be less than minus 7% or more than plus 3%.

The update adjustment factor is the sum of: (1) the prior year adjustment component, and (2) the cumulative adjustment component. The prior year adjustment component is determined by: (1) computing the difference between allowed expenditures for physicians' services for the prior year and the amount of actual expenditures for that year; (2) dividing this amount by the actual expenditures for that year; and (3) multiplying that amount by 0.75. The cumulative adjustment component is determined by: (1) computing the difference between allowed expenditures for physicians' services from April 1, 1996 through the end of the prior year and the amount of actual expenditures during such period; (2) dividing that difference by actual expenditures for the prior year as increased by the SGR for the year for which the update adjustment factor is to be determined; and (3) multiplying that amount by 0.33. Use of both the prior year adjustment component and the cumulative adjustment component allows any deviation between cumulative actual expenditures and cumulative allowed expenditures to be corrected over several years rather than a single year.

The law also specifies a formula for calculating the SGR. It is based on changes in four factors: (1) estimated changes in fees; (2) estimated change in the average number of Part B enrollees (excluding Medicare+Choice beneficiaries); (3) estimated projected growth in real gross domestic product (GDP) growth per capita; and (4) estimated change in expenditures due to changes in law or regulations. This system is designed to adjust for how well actual expenditures meet SGR target expenditures.

Provisions in the Consolidated Appropriations Resolution of 2003 (P.L. 108–7) permitted redeterminations of SGR for prior years. As a result, the conversion factor for 2003 was increased 1.6% over the 2002 level. Other aspects of the formula for the annual payment rate were not addressed. CMS reports an update factor of −4.5% for 2004.

House Bill

The update to the conversion factor for 2004 and 2005 would be not less than 1.5% and would be exempt from the budget neutrality adjustment. This modification would not be treated as a change in law and regulation in SGR determination.

The formula for calculating the sustainable growth rate would be modified. The GDP factor would be based on the annual average change over the preceding 10 years (a 10-year rolling average). This calculation would replace the current GDP factor which measures the 1-year change from the preceding year. The 10-year rolling average calculation of the GDP would apply to computations of the SGR starting in 2003.

Senate Bill

The provision expresses a sense of the Senate that Medicare beneficiary access to quality care may be compromised if Congress does not prevent cuts in 2004 and following years that stem from the sustainable growth rate (SGR) formula.

The provision provides a sense of the Senate that the reductions in Medicare's physician fee schedule are untenable if not destabilizing, primarily caused by the sustainable growth rate calculation, and that CMS should use its discretion to make certain exclusions and adjustments to the calculation.

Conference Agreement

The update to the conversion factor for 2004 and 2005 will not be not less than 1.5% and will be exempt from the budget neutrality adjustment, instead of −4.5% in 2004 and a smaller reduction in 2005. This modification would not be treated as a change in law and regulation in SGR determination.

The formula for calculating the sustainable growth rate will be modified. The GDP factor will be based on the annual average change over the preceding 10 years (a 10-year rolling average). This calculation will replace the current GDP factor which measures the 1-year change from the preceding year. The 10-year rolling average calculation of the GDP will apply to computations of the SGR starting in 2003.

Treatment of Physicians' Services furnished in Alaska (Section 602 of the Conference Agreement and Section 450K of the Senate Bill).

Current Law

Physicians who provide services to Medicare beneficiaries are paid based on a physician fee schedule, which has three components: the relative value for the service, a geographic adjustment factor and a conversion factor. The geographic adjustment factor is the sum of three geographic practice cost indices (GPCIs), namely a work GPCI, a practice expense GPCI, and a malpractice GPCI. An area with costs above the national

average would have a GPCI greater than 1.00; an area with costs below the national average would have a GPCI less than 1.00.

House Bill

No provision.

Senate Bill

For calendar year 2004, physicians providing Medicare services in Alaska would be paid 90 percent of the Veterans Affairs (VA) fee schedule for physician services that was used for fiscal year 2001. For calendar year 2005, this payment amount would be increased by the update amount for the Medicare physician fee schedule for 2005. If no VA fee schedule amount existed for a physician service, the payment amount would be the sum of the Medicare payment amount plus 90% of the percentage difference between the Medicare fee schedule and the VA fee schedule (on a claims-weighted basis). The provision would be effective for services furnished on or after January 1, 2004 and before January 1, 2006.

Conference Agreement

In calendar years 2004 and 2005, for physician services provided in Alaska, the Secretary is required to increase geographic practice cost indices to a level of 1.67 for each of the work, practice expense and malpractice cost indices.

Inclusion of Podiatrists, Dentists, and Optometrists under Private Contracting Authority (Section 603 of the Conference Agreement and Section 604 of the House Bill).

Present Law

Private contracting allows a physician and Medicare beneficiary not to submit a claim for a service which would otherwise be covered and paid for by Medicare. Under private contracting, physicians can bill patients at their discretion without being subject to upper payment limits specified by Medicare. If a physician decides to enter into a private contract with a Medicare beneficiary, that physician must agree to forego any reimbursement by Medicare for all Medicare beneficiaries for 2 years. The patient is not subject to the 2-year limit and is able to receive services from other physicians who do not have such private contracts and have Medicare pay for the services. Both physicians and practitioners may enter private contracts. In this instance, a physician is limited to a doctor of medicine and osteopathy; chiropractors, podiatrists, dentists, and optometrists are not included. Practitioners are physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, certified nurse midwives, clinical psychologists, and clinical social workers.

House Bill

Doctors of dental surgery or of dental medicine and doctors of podiatric medicine would be able to enter into private contracts with Medicare beneficiaries. The provision would be effective upon enactment.

Senate Bill

No provision.

Conference Agreement

Doctors of dental surgery or of dental medicine, doctors of podiatric medicine, and doctors of optometry will be able to enter into private contracts with Medicare beneficiaries. The provision will be effective upon enactment.

GAO Study on Access to Physicians' Services (Section 604 of the Conference Agreement and Sections 602(a) and 602(b) of the House Bill).

GAO Study on Beneficiary Access to Physicians' Services

Present Law

Periodic analyses by the Physician Payment Review Commission, and subsequently MedPAC, as well as CMS showed that access to physicians' services generally remained good for most beneficiaries through 1999. Detailed data are not available for a subsequent period; however, several surveys have showed a decline in the percentage of physicians accepting new Medicare patients.

House Bill

GAO would be required to conduct a study on access of Medicare beneficiaries to physician's services under Medicare. The study would include an assessment of beneficiaries' use of services through an analysis of claims data. It would also examine changes in use of physicians' services over time. Further, it would examine the extent to which physicians are not accepting new Medicare beneficiaries as patients. GAO would be required to submit a report to Congress on this study within 18 months of enactment. The report would determine whether data from claims submitted by physicians indicate potential access problems for beneficiaries in certain geographic areas. The report would determine whether access by beneficiaries to physicians' services has improved, remained constant, or deteriorated over time.

The Secretary would be required to request the Institute of Medicine to conduct a study on the adequacy of the supply of physicians (including specialists) in the country and the factors that affect supply. The Secretary would be required to submit the results of the study in a report to Congress no later than 2 years of the date of enactment.

Senate Bill

No provision.

Conference Agreement

GAO is required to conduct a study on access of Medicare beneficiaries to physicians' services under Medicare. The study will include an assessment of beneficiaries' use of physician services through an analysis of claims data. It will also examine changes in use of physicians' services over time. Further, it will examine the extent to which physicians are not accepting new Medicare beneficiaries as patients. GAO is required to submit a report to Congress on this study within 18 months of enactment. The report will determine whether data from claims submitted by physicians indicate potential access problems for beneficiaries in certain geographic areas. The report will also determine whether access by beneficiaries to physicians' services has improved, remained constant, or deteriorated over time.

Collaborative Demonstration-based Review of Physician Practice Expense Geographic Adjustment Data (Section 605 of the Conference Report and Section 421 of the Senate Bill).

Present Law

No provision.

House Bill

No provision.

Senate Bill

For services furnished after January 1, 2004, the Secretary would be required to increase the value of any work geographic index that is below .980 to .980. The values for work index would be raised to 1.0 for services furnished in 2005, 2006, and 2007. The practice expense and malpractice geographic indices in low value localities areas would be raised to 1.00 for services furnished in 2005 through 2008.

Conference Agreement

The Secretary is required to review and consider alternative data sources than those currently used to establish the geographic index for the practice expense component under Medicare's physician fee schedule no later than January 1, 2005. The Secretary will collaborate with state and other appropriate organizations representing physicians, and other appropriate persons. The Secretary will select 2 physician payment localities for this evaluation; one of the localities will be a rural area and one will be a statewide locality that includes both urban and rural areas. The Secretary will submit a report to Congress including recommendations on alternative data sources, including their accuracy and validity, the feasibility of using the alternative data, and the estimated impact of using these data for the practice expense adjustment. The report is due no later than January 1, 2006.

MedPAC Report on Payment for Physicians' Services (Section 606 of the Conference Agreement and Section 603 of the House Bill).

Present Law

Medicare pays for physicians' services on the basis of a fee schedule. The fee schedule assigns relative values to services. These relative values reflect physician work, practice expenses and malpractice expenses. Resource-based practice expense relative values were phased-in beginning in 1999. Beginning in 2002, the values were totally resource-based.

Certain services have a professional component and a technical component. The technical component does not include a relative value for physician work. A global value includes both the professional and technical components. The physician must bill for the global value if the physician furnishes both the professional component and the technical component.

House Bill

MedPAC would be required to report to Congress on the effects of refinements to the practice expense component of payments for physicians' services after full implementation of the resource-based payment in 2002. The report is to examine the following by specialty: (1) the effect of refinements on payments for physicians services; (2) interaction of the practice expense component with other components of and adjustments to payment for physicians' services; (3) appropriateness of the amount of compensation by reason of such refinements; (4) effect of such refinements on access to care by Medicare beneficiaries to physicians' services; and (5) effect of such refinements on physician participation under the Medicare program. The report would be due within 1 year of enactment. MedPAC would also be required to study the extent to which increases in the volume of physician services improves beneficiaries' health and well-being. MedPAC would be required to analyze the trends in components included in the sustainable growth rate calculation; the growth in volume of physician services provided to Medicare beneficiaries in comparison to other populations; the extent to which coverage determinations and new technology has affected growth in volume; the effect of demographic changes on volume; the effect of shifts in sites of services; and the extent to which the impact of law and regulations is taken into account.

Senate Bill

No provision.

Conference Agreement

MedPAC is required to report to Congress on the effects of refinements to the practice expense component of payments for physicians' services after full implementation of the resource-based payment in 2002. The report will examine the following by specialty: (1) the effect of refinements on payments for physicians' services; (2) the interaction of the practice expense component with other components of and adjustments to payment

for physicians' services; (3) the appropriateness of the amount of compensation by reason of such refinements; (4) the effect of such refinements on access to care by Medicare beneficiaries to physicians' services; and (5) the effect of such refinements on physician participation under the Medicare program. The report is due within 1 year of enactment. MedPAC is also required to study the extent to which increases in the volume of physician services improves beneficiaries' health and well-being. MedPAC is required to analyze the trends in components included in the sustainable growth rate calculation; the growth in volume of physician service provided to Medicare beneficiaries in comparison to other populations; the extent to which coverage determinations and new technology has affected growth in volume; the effect of demographic changes on volume; the effect of shifts in sites of services; and the extent to which the impact of law and regulations is taken into account. The report is due within 1 year of enactment.

GAO Report Section (Section 605(b) of the House Bill).

Present Law

No provision.

House Bill

As part of the previously mandated study of geographic differences in physician payments, GAO would be required to evaluate (1) whether a sound economic basis for raising the geographic work adjustment exists; (2) the effect of such adjustment of physician location and retention including differences in recruitment cost and physician mobility; and the appropriateness of establishing a floor of 1.00 on the work geographic adjustment. GAO would be required to submit the report to Congress and the Secretary by September 1, 2004.

Senate Bill

No provision.

Conference Agreement

No provision.

GAO Study and Report on the Propagation of Concierge Care (Section 447 of the Senate Bill).

Present Law

No provision.

House Bill

No provision.

Senate Bill

GAO would be required to conduct a study on concierge care provided to Medicare beneficiaries and its affect on their access to Medicare covered services and submit a report to Congress, including recommendations, no later than 12 months from enactment. In this instance, concierge care would be an arrangement where a physician or practitioner charges an individual seeking care a membership fee or other fee or requires the purchase of an item or service as a prerequisite for providing the care. The provision would be effective upon enactment.

Conference Agreement

No provision.

Subtitle B—Preventive Services

Coverage of An Initial Preventive Physical Examination (Section 611 of the Conference Agreement and Section 611 of the House Bill).

Present Law

Medicare covers a number of preventive services. However, it does not cover routine physical examinations.

House Bill

Medicare coverage of an initial preventive physical examination would be authorized. The physical examination would be defined as physicians' services consisting of a physical examination with the goal of health promotion and disease detection. It would include items and services (excluding clinical laboratory tests) consistent with the recommendations of the United States Preventive Services Task Force as determined by the Secretary. A covered initial preventive physical examination would be one performed no later than 6 months after the individual's initial coverage date under Part B. Initial preventive physical exams would be included in the definition of physicians' services for purposes of the physician fee schedule. The Part B deductible and coinsurance would be waived for initial preventive physical exams. The provision would apply to services furnished on or after January 1, 2004 for those individuals whose coverage begins on or after such date.

Senate Bill

No provision.

Conference Agreement

Medicare coverage of an initial preventive physical examination is authorized, subject to deductible and beneficiary cost sharing. The physical examination is defined as physicians' services consisting of a physical examination (including measurement of height, weight, and blood pressure, and an electrocardiogram) with the goal of health promotion and disease detection. The examination includes education, counseling, and referral with respect to specific screening services and other preventive services, but does not include clinical laboratory tests. The screening and preventive services are certain vaccines, screening mammography, screening pap smear and screening pelvic exam, prostate cancer screening tests, colorectal cancer screening tests, diabetes outpatient self management, bone mass measurement, screening for glaucoma, medical nutrition therapy, cardiovascular screening blood tests and diabetes screening tests. A covered initial preventive physical examination is performed no later than 6 months after the individual's initial coverage date under Part B. Initial preventive physical exams are included in the definition of physicians services for purposes of the physician fee schedule. The provision applies to services furnished on or after January 1, 2005, but only for those individuals whose coverage begins on or after such date.

The Conference encourages the United States Preventive Services Task Force to examine aortic aneurysm screening using ultrasound. Aortic aneurysms are a leading cause of death in the United States, and many in the medical community believe that most, if not all, of the approximately 15,000 known deaths each year would be prevented with appropriate screening.

Coverage of Cardiovascular Screening Blood Tests (Section 612 of the Conference Agreement, Section 612 of the House Bill, and Section 450D of the Senate Bill).

Present Law

Medicare covers a number of preventive services. However, it does not cover cardiovascular screening tests.

House Bill

Medicare coverage of cholesterol and blood lipid screening would be authorized. The screening would be defined as diagnostic testing of cholesterol and other lipid levels of the blood for the purpose of early detection of abnormal cholesterol and other lipid levels. The Secretary would be required to establish standards regarding the frequency and type of these screening tests, but not more often than once every 2 years. The provision would apply to services furnished on or after January 1, 2005.

Senate Bill

Medicare coverage of cardiovascular screening tests would be authorized. The screening would be defined as diagnostic testing for the early detection of cardiovascular disease including tests for cholesterol levels, lipid levels of the blood, and other appropriate tests for cardiovascular disease. The Secretary would be required to consult with appropriate organizations and to establish standards regarding the frequency and type of these screening tests, but not more often than once every 2 years. The provision would apply to services furnished on or after January 1, 2005.

Conference Agreement

Medicare coverage of cardiovascular screening blood tests is authorized. The screening is defined as a blood test for the early detection of cardiovascular disease (or abnormalities associated with an elevated risk of cardiovascular disease) including tests for cholesterol levels and other lipid or triglyceride levels as well as such other indications associated with the presence of (or an elevated risk for) cardiovascular disease as the Secretary may approve for all individuals or for some individuals determined to be at risk for such disease. These indications may include indications measured by noninvasive testing. The Secretary cannot approve an indication for any individual unless a blood test for such is recommended by the United States Preventive Services Task Force. The Secretary is required to consult with appropriate organizations and to establish standards regarding the frequency and type of these screening tests, but the frequency may not be more often than once every 2 years. The provision applies to services furnished on or after January 1, 2005.

Coverage of Diabetes Screening Tests (Section 613 of the Conference Agreement and Section 630 of the House Bill).

Present Law

On July 1, 1998, Medicare began covering diabetes self-management training services. These educational and training services are provided on an outpatient basis by physicians or other certified providers who have experience in diabetes self-management training services. Blood testing strips and home blood glucose monitors are used by diabetics to measure blood glucose levels to determine if these levels are being maintained adequately. Medicare covers blood testing strips and blood glucose monitors for all individuals with diabetes regardless of whether they are insulin-dependent. The Secretary is also required to consult with appropriate organizations to establish outcome measures to assess improvements in the health status of individuals with diabetes. Based on this information, the Secretary will make recommendations to Congress on changes to Medicare's coverage of services for these beneficiaries. Medicare does not presently cover laboratory diagnostic tests and other services that are used to screen for diabetes.

House Bill

Diabetes screening tests and services would be included as a covered medical service. In this instance, diabetes screening tests would include fasting plasma glucose tests and other appropriate tests provided to an individual at risk for diabetes. Individuals at risk for diabetes would have any or a combination of the following conditions: (1) have a family history of diabetes; (2) are overweight with a body mass index greater than or equal to 25 kg/m^2; (3) are habitually physically inactive; (4) are a member of a high-risk ethnic or racial group; (5) have previously been identified with an elevated impaired fasting glucose; (6) have hypertension;

(7) have dyslipidemia; (8) have a history of gestational diabetes mellitus or have delivered a baby weighing more than 9 pounds; or (9) have polycystic ovary syndrome. The Secretary would be required to establish standards, in consultation with appropriate organizations regarding the frequency of screening tests except the tests would not be covered more often that twice in the 12–month period following the date of the individual's most recent diabetes screening test. The provision would apply to tests furnished on or after 90 days from enactment.

Senate Bill

No provision.

Conference Agreement

Diabetes screening tests furnished to an individual at risk for diabetes for the purpose of early detection of diabetes are included as a covered medical service. In this instance, diabetes screening tests include fasting plasma glucose tests as well as other tests and modifications to those tests deemed appropriate by the Secretary after consultation with appropriate organizations. Individuals at risk for diabetes have any or a combination of the following conditions: (1) hypertension; (2) dyslipidemia; (3) obesity, with a body mass index greater than or equal to 30 kg/m^2; (4) previous identification of an elevated impaired fasting glucose; (5) previous identification of impaired glucose tolerance or (6) a risk factor of at least 2 of the following characteristics: overweight with a body mass index of greater than 25, but less than 30, kg/m^2; a family history of diabetes; a history of gestational diabetes mellitus or delivery of a baby weighing more than 9 pounds; or age of 65 years or more. The Secretary is required to establish standards, in consultation with appropriate organizations regarding the frequency of screening tests except the tests will not be covered more often that twice in the 12–month period following the date of the individual's most recent diabetes screening test. The provision applies to tests furnished starting January 1, 2005.

Improved Payment for Certain Mammography Services (Section 614 of the Conference Agreement, Section 614 of the House Bill, and Section 445 of the Senate Bill).

Present Law

Screening mammography coverage includes the radiological procedure as well as the physician's interpretation of the results of the procedure. The usual Part B deductible is waived for tests. Payment is made under the physician fee schedule.

Certain services paid under fee schedules or other payment systems including ambulance services, services for patients with end-stage renal disease paid under the ESRD composite rate, professional services of physicians and non-physician practitioners paid under the physician fee schedule, and laboratory services paid under the clinical diagnostic laboratory fee schedule are excluded from Medicare's outpatient prospective payment system (OPPS).

House Bill

Unilateral and bilateral diagnostic mammography as well as screening mammography services would be excluded from OPPS. The Secretary would be required to provide an appropriate adjustment to the physician fee schedule for the technical component of the diagnostic mammography based on the most recent cost data available. This adjustment would be applied to services provided on or after January 1, 2004.

Senate Bill

Unilateral and bilateral diagnostic mammography as well as screening mammography services would be excluded from OPPS. The Secretary would be required to provide an appropriate adjustment to the physician fee schedule for the technical component of the diagnostic mammography based on the most recent cost data available. This adjustment would be applied to services provided on or after January 1, 2005.

Conference Agreement

Screening mammography and diagnostic mammography will be excluded from OPPS. This provision will apply to screening mammography services furnished on or after the date of enactment and will apply to diagnostic mammography services furnished on or after January 1, 2005.

Waiver of Deductible for Colorectal Cancer Screening Tests (Section 613 of the House Bill).

Present Law

Covered colorectal screening tests for prevention purposes include (1) an annual fecal-occult blood test for individuals age 50 and older; (2) flexible sigmoidoscopy every 4 years for individuals age 50 and older; (3) colonoscopy for high-risk individuals every 2 years and for other individuals every 10 years; and (4) screening barium enemas every 4 years for individuals age 50 and older who are not at high risk of developing colorectal cancer or every 2 years for high risk individuals. Payment is made according to the applicable payment system for the provider performing the test.

Unless otherwise specified, Part B services are subject to beneficiary cost sharing amounts, including an annual deductible and coinsurance amount. Colorectal screening tests are subject to the deductible and coinsurance.

House Bill

The Part B deductibles would be waived for colorectal cancer screening tests. The provision would apply to items and services furnished on or after January 1, 2004.

Senate Bill

No provision.

Conference Agreement

No provision.

Subtitle C—Other Provisions

Hospital Outpatient Department (HOPD) Payment Reform (Section 621 of the Conference Report, Section 621(a) of the House Bill, and Section 436 of the Senate Bill).

Payment for Drugs (Section 621(a) of the Conference Agreement, Sections 621(a) and 621(d) of the House Bill, and Section 436 of the Senate Bill).

Present Law

Under hospital outpatient department (HOPD) prospective payment system (OPPS), the unit of payment is the individual service or procedure as assigned to one of about 570 ambulatory payment classifications (APCs) groups. Services are classified into APCs based on their Healthcare Common Procedure Coding System (HCPCS), a standardized coding system used to identify products, supplies, and services for claims processing and payment purposes. To the extent possible, integral services and items including drugs are bundled or packaged within each APC. For instance, an APC for a surgical procedure will include operating and recovery room services, anesthesia and surgical supplies. Medicare's payment for HOPD services is calculated by multiplying the relative weight associated with an APC by a geographically adjusted conversion factor. The conversion factor is updated on a calendar year schedule and the annual updates are based on the hospital market basket (MB). Currently, the CY2004 HOPD update will equal the projected change in the MB.

Medicare pays for covered outpatient drugs in one of three ways: (1) as a transitional pass-through payment; (2) as a separate APC payment; or (3) as packaged APC payment with other services.

Transitional pass-through payments are supplemental payments to cover the incremental cost associated with new medical devices, drugs and biologicals that are inputs to an existing service. The additional payment for a given item is established for 2 or 3 years and then the costs are incorporated into the APC relative weights. BBRA specified that pass-through payments would be made for current orphan drugs, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act; current cancer therapy drugs, biologicals, and brachytherapy; current radiophamaceutical drugs and biological products; and new drugs and biological agents.

Generally, CMS has established that a pass-through payment for an eligible drug is based on the difference between 95% of its average wholesale price and the portion of the otherwise applicable APC payment rate attributable to the existing drug, subject to a budget neutrality provision. The pass-through amount for new drugs with a substitute drug recognized in a separate drug APC payment is the difference between 95% of new drug's AWP and the payment rate for the comparable dose of the associated drugs APC.

CMS imputes the hospital costs for these drugs to establish the beneficiary copayment amounts as well as to project the amount of pass-through spending in order to calculate the uniform reduction to payments under the budget neutrality constraint. This imputed value is calculated by multiplying the average wholesale price (AWP) for the drug by the applicable cost-to-charge ratio which varies by the class of drug. For CY2003, the average ratio of cost to AWP for sole-source drugs manufactured by one entity is 0.71, for multiple source drugs is 0.68, and for multiple source drugs with generic competitors is 0.43. There is enormous variation within a category from close to zero to above 100% of AWP.

Current drugs and biologicals that have been in transitional pass-through status on or prior to January 1, 2000 were removed from that payment status effective January 1, 2003. CMS established separate APC payments for certain of these drugs, including orphan drugs, blood and blood products, and selected higher cost drugs in CY2003. CMS established a threshold of $150 per claim line for a drug to qualify for a separate APC payment as a higher-cost drug. Other drugs that had qualified for a transitional pass-through payment were packaged in to procedural APCs. For example, in some instances, brachytherapy seeds (radioactive isotopes used in cancer treatments) were packaged into payments for brachytherapy procedures. Essentially, the payment rates for these drug-related APCs are based on a relative weight calculated in the same way as procedural APCs are calculated. However, the cost to charge ratios are from only one department.

House Bill

Under Section 621(a), starting for services furnished on or after January 1, 2004, certain covered OPD drugs would be paid no more than 95% of AWP or be less than the transition percentage of the AWP from CY2004 through CY2006. In subsequent years, payment would be equal to average price for the drug in the area and year established by the competitive acquisition program under 1847A. The covered OPD drugs affected by this provision are radiopharmceuticals and outpatient drugs that were paid on a pass-through basis on or before December 31, 2002. These would not include drugs for which

pass-through payments are first made on or after January 1, 2003 or those drugs for which a temporary HCPCS code has not been assigned. Drugs for which a temporary HCPCS code has not been assigned would be reimbursed at 95% of the AWP.

The transition percentage to AWP for sole-source drugs manufactured by one entity is 83% in CY2004, 77% in CY2005, and 71% in CY2006. The transition percentage to AWP for innovator multiple source drugs is 81.5% in CY2004, 75% in CY2005, and 68% in CY2006. The transition percentage to AWP for multiple source drugs with generic drug competitors is 46% in CY2004 through CY2006. Generally, a multiple source drug is a covered drug for which there are 2 or more therapeutically equivalent drug products. An innovator multiple source drug is a multiple source drug that was originally marketed under an original new drug application approved by the Food and Drug Administration (FDA). A sole source drug is not a multiple source drug. The additional expenditures resulting from these provisions would not be subject to the budget neutrality requirement.

Starting in CY2004, the Secretary would be required to lower the threshold for establishing a separate APC group for higher costs drugs from $150 to $50 per administration. These separate drug APC groups would not be eligible for outlier payments. Starting in CY2004, Medicare's transitional pass-through payments for drugs and biologicals covered under a competitive acquisition contract would reflect the amount paid under that contract, not 95% of AWP.

Under Section 621(d), the Secretary would be required to study the hospital acquisition costs related to covered outpatient drugs that cost $50 per administration and more that are reimbursed under the HOPD–PPS. The study would encompass a representative sample of urban and rural hospitals. The report including recommendations on the usefulness of the cost data and frequency of subsequent data collection efforts would be due to Congress no later than January 1, 2006. The report would also discuss whether the data is appropriate for making adjustments to payments made under the competitive acquisition contract established by section 1847A and whether separate estimates can be made for overhead costs including handling and administering drugs. The provision would be effective upon enactment.

Senate Bill

A new payment mechanism for certain drugs and biologicals provided in hospital outpatient departments (OPD) would be established from January 1, 2005 and before January 1, 2007. The drugs and biologicals would be those for which hospitals received transitional pass-through payments prior to January 1, 2005 and those that would have been paid in such a manner but for the application of this provision or those that are assigned to drug specific APCs on or after the date of enactment. Payments made under this provision would be exempt from the budget neutrality requirement in FY2005 and FY2006.

In 2005, these drugs or biologicals furnished as part of a current OPD service would be paid as follows: a single source or orphan product would be paid at 94% of the AWP existing on May 1, 2003; a multiple source drug would be paid at 91% of the AWP existing on May 1, 2003; and a multiple source drug with generic equivalents would be paid at 71% of AWP on May 1, 2003. Drugs and biologicals that were furnished as part of other OPD services would be paid using the same applicable percentage of the AWP that would have been determined on May 1, 2003 if payment could have been made on that date. For 2006, these payment amounts would be increased by the percentage increase in the consumer price index for all urban consumers for the 12–month period ending in June of the previous year.

The Secretary would be required to contract with an eligible organization (a private nonprofit organization) to conduct a study to determine the hospital acquisition, pharmacy services, and handling costs for each of the drugs paid in this fashion. The study would be required to be accurate with 3% of the true mean hospital acquisition and handling costs for each drug and biological at the 95% confidence level; begin not later than January 1, 2005; and be updated annually. Each year, beginning January 1, 2006, the Secretary would be required to submit a report to Congress, including recommendations, on the drug costs. These drug costs would be used in determining the payment amounts for each drug and biological provided as part of a covered OPD service furnished on or after January 1, 2007.

Conference Agreement

Starting for services furnished on or after January 1, 2004, specified covered OPD drugs would be paid based on a percentage of the reference average wholesale price for the drug. The percentage of the reference price for sole-source drugs manufactured by one entity can be no less than 88% and no greater than 95% in CY2004 and no less than 83% and no greater than 95% in CY2005. The percentage of the reference price for innovator multiple source drugs can be no greater than 68% in CY2004 and CY2005. The percentage of the reference price for noninnovator multiple source drugs can be no greater than 46% in CY2004 and CY2006. The reference average wholesale price is the average wholesale price for the drug as of May 1, 2003.

A sole source drug is biological product approved under a biologics license application under section 351 of the Public Health Services Act or a single source drug produced or distributed under an original new drug application approved by the Food and Drug Administration (FDA) which includes a drug product marketed by appropriate cross-licensed producers or distributors as established in Section 1927(k)(7)(A)(iv) of the Social Security Act (the Act); an innovator multiple source drug is a multiple source drug that was originally marketed under an original new drug application approved by FDA as established in Section 1927(k)(7)(A)(ii) of the Act; and, a noninnovator multiple source drug is a multiple source drug that is not an innovator multiple source drug as established in 1927(k)(7)(A)(iii) of the Act. A biological includes any product that the Centers for Medicare and Medicaid services has determined to be a biological under section 1861(t)(1) of the Act.

It is the intent of the Conference that products eligible for the transitional payment under the hospital outpatient department section include all products paid by Medicare on a pass-through list as a drug or biologic prior to December 31, 2002, or as a radiopharmaceutical product as a pass-through product are in a separate ambulatory payment classification (APC). This section clarifies that radiopharmaceuticals are drugs under the hospital outpatient department section and that the term ''specified covered outpatient drug'' includes radiopharmaceuticals.

In subsequent years, payment will be equal to the average acquisition cost for the drug for that year (which may vary by hospital group taking into account hospital volume or other hospital characteristics) or if hospital acquisition cost data are not available, the average price for the drug in the year other than radiopharmacuticals established under Sections 1842(o), 1847A or 1847B as calculated and adjusted by the Secretary. The covered OPD drugs affected by this provision are outpatient drugs that were paid on a pass-through basis on or before December 31, 2002. These would not include drugs for which pass-through payments are first made on or after January 1, 2003; those drugs for which a temporary HCPCS code has not been assigned; or, during 2004 and 2005, orphan drugs. Drugs for which a temporary HCPCS code has not been assigned will be reimbursed at 95% of the AWP. Orphan drugs during this 2 year time period will be paid at an amount specified by the Secretary.

GAO is required to conduct an acquisition cost survey for each specified covered drug in 2004 and 2005. The surveys (those done by GAO and then subsequently by the Secretary) will be based on a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each specified covered outpatient drug. No later than April 1, 2005, GAO will furnish this survey data to the Secretary to use in setting payment rates for 2006. GAO will evaluate the 2006 payment rates and submit a report to Congress on their appropriateness no later than 30 days after the date the Secretary promulgates the proposed rule setting forth these rates.

Upon completion of their surveys, GAO will submit recommendations regarding the survey methodology and survey frequency to the Secretary for subsequent surveys. The Secretary will conduct periodic surveys to determine the hospital acquisition costs for each specified covered outpatient drug to set subsequent payment rates. GAO will report to Congress on the justification for the size of the sample used in order to assure the validity of the estimates; the extent of variation in hospital acquisition costs among hospitals based on the volume of covered OPD services or other relevant characteristics.

MedPAC will submit a report to the Secretary on the payment adjustment to ambulatory payment classifications for specified covered outpatient drugs that takes into account overhead and related expenses (such as pharmacy services and handling costs). The report will include (1) a description and analysis of the available data; (2) a recommendation as to whether the payment adjustment should be made; and (3) if such an adjustment should be made, a recommendation regarding the appropriate methodology. The Secretary is authorized to adjust the weights for ambulatory payment classification based on such a recommendation.

The additional expenditures that result from the previous changes will not be taken into account in establishing the conversion, weighting and other adjustment factors for 2004 and 2005, but will be taken into account in subsequent years.

For drugs and biologicals furnished in 2004 and 2005, the Secretary is required to lower the threshold for establishing a separate APC group for higher costs drugs from $150 to $50 per administration. These separate drug APC groups are not be eligible for outlier payments. Starting in CY2004, Medicare's transitional pass-through payments for drugs and biologicals covered under a competitive acquisition contract will equal the average price for the drug or biological for all competitive acquisition areas calculated and adjusted by the Secretary for that year.

Special Payment for Brachytherapy (Section 421(b) of the Conference Report, Section 621(b) of the House Bill and Section 450A of the Senate Bill).

Present Law

Current drugs and biologicals that have been in transitional pass-through status on or prior to January 1, 2000 were removed from that payment status effective January 1, 2003. The Center for Medicare and Medicaid Services (CMS) established separate APC payments for certain of these drugs, including orphan drugs, blood and blood products, and selected higher cost drugs in CY2003. CMS established a threshold of $150 per claim line for a drug to qualify for a separate APC payment as a higher-cost drug. Essentially, the payment rates for these drug-related APCs are based on a relative weight calculated in the same way as procedural APCs are calculated. Other drugs that had qualified for a transitional pass-through payment were packaged in to procedural APCs. For example, in some instances, brachytherapy seeds (radioactive isotopes used in cancer treatments) were packaged into payments for brachytherapy procedures.

Essentially, the payment rates for these drug-related APCs are based on a relative weight calculated in the same way as procedural APCs are calculated.

House Bill

From January 1, 2004 through December 31, 2006, Medicare's payments for brachytherapy devices would equal the hospital's charges adjusted to cost. The Secretary would be required to create separate APCs to pay for these devices that reflect to the number, isotope, and radioactive intensity of such devices. This would include separate groups for palladium-103 and iodine-125 devices. GAO would be required to study the appropriateness of payments for brachytherapy devices and submit a report including recommendations to Congress no later than January 1, 2005. The provision would be effective upon enactment.

Senate Bill

The Secretary would be required to conduct a 3-year demonstration project that would exclude brachytherapy devices from the OPPS and paid on the basis of the hospital's charges for each device, adjusted to cost. The Secretary would be required to create separate, additional groups of covered HOPD services for brachytherapy devices to reflect the number, isotope, and radioactive intensity of such devices. The Secretary would be required to assure that aggregate payments under this project would not exceed what otherwise would have been spent. The project would begin 90 days after the date of enactment. The Secretary would be required to submit a report on the evaluation of patient outcomes and cost effectiveness of the project to Congress no later than January 1, 2007.

Conference Agreement

The provision would require the Secretary to make payment for each brachytherapy device furnished under the hospital outpatient prospective payment system equal to the hospital's charges for the brachytherapy device adjusted to cost for all brachytherapy devices furnished on or after January 1, 2004 and before January 1, 2007. Charges for such devices will not be included in determining any outlier payment.

The provision also would require the Secretary to create and use ambulatory payment classification (APC) groups that classify brachytherapy devices separately from all the other services and items paid for under the hospital outpatient prospective payment system. The Secretary must reflect the number, the radioactive isotope and the radioactive intensity of the brachytherapy devices furnished to each patient, including the use of separate APCs for brachytherapy devices made from palladium-103 and iodine-125.

Limitation of Application of Functional Equivalence Test (Section 622 of the Conference Agreement, Section 621(c) of the House Bill, and Section 437 of the Senate Bill).

Present Law

In the November, 1 2002 Federal Register, CMS established a new concept of functional equivalence for drugs to an existing treatment. The transitional pass-through rate for a drug was reduced to zero starting for services in 2003.

House Bill

The Secretary would be prohibited from applying a functional equivalence standard or any similar standard in order to deem a particular drug or biological to be similar or functionally equivalent to another drug unless the Commissioner of the Food and Drug Administration establishes such a standard and certifies that the two products are functionally equivalent. The Secretary would be able to implement this standard after applicable rulemaking requirements.

This provision would apply to the application of a functional equivalent on or after the date of enactment. The provision prohibits the application of this standard to a drug or biological prior to June 13, 2003.

Senate Bill

The Secretary would be prohibited from publishing regulations that apply a functional equivalence standard to a drug or biological for transitional pass-through payments under OPPS. This prohibition would apply to the application of the functional equivalence standard on or after the date of enactment, unless such application was made prior to enactment and the Secretary applies such standard to the drug only for the purposes of transitional pass-through payments. This provision would not affect the Secretary authority to deem a particular drug to be identical to another drug if the 2 products are pharmaceutically equivalent and bioequivalent, as determined by the Commissioner of the Food and Drug Administration.

Conference Agreement

The Secretary is prohibited from publishing regulations, program memorandum local medical review policies or any other guidance (including the HOPD–PPS payment rate rules) that apply a functional equivalence or similar standard to a drug or biological for transitional pass-through payments under OPPS. This prohibition applies to the application of the functional equivalence standard on or after the date of enactment, unless such application was made prior to enactment and the Secretary applies such standard to the drug only for the purposes of transitional pass-through payments. This provision does not affect the Secretary's authority to deem a particular drug to be identical to another drug if the 2 products are pharmaceutically equivalent and bioequivalent, as determined by the Commissioner of the Food and Drug Administration.

Payment for Renal Dialysis Services (Section 623 of the Conference Agreement, Section 623 of the House Bill, Section 432(b)(5) of the Senate Bill).

Present Law

Dialysis facilities providing care to beneficiaries with end-stage renal disease (ESRD) receive a fixed prospectively determined payment amount (the composite rate) for each dialysis treatment, regardless of whether services are provided at the facility or in the patient's home. The composite rate includes the dialysis costs but excludes separately billable drugs and biologicals and laboratory services. Providers receive 95% of the AWP for separately billable injectable medications other than erythropoietin (EPO) administered during treatments at the facility. Medicare pays separately for EPO which is used to treat anemia for persons with chronic renal failure who are on dialysis. Congress has set Medicare's payment for (EPO) at $10 per 1,000 units whether it is administered intravenously or subcutaneously in dialysis facilities or in patients' homes.

BBRA increased the composite rates by 1.2% for dialysis services furnished in both 2000 and 2001. BIPA subsequently increased the 2001 update to 2.4%. The composite rate has not been increased since then.

Prior to BIPA, an increase in the composite rate would trigger an opportunity for facilities to request an exception to the composite rate in order to receive higher payments. BIPA prohibited the Secretary from granting new exceptions to the composite rate (after applications received after July 1, 2001).

In 2003, Secretary announced a demonstration project establishing a disease-management program that will allow organizations experienced with treating end-stage renal disease (ESRD) patients to develop financing and delivery approaches to better meet the needs of beneficiaries with ESRD. CMS is soliciting a variety of types of organizations to coordinate care to patients with ESRD, encourage the provision of disease-management services for these patients, collect clinical performance data and provide incentives for more effective care.

House Bill

The provision would increase the ESRD composite payment rate by 1.6% for 2004.

The prohibition on exceptions contained in BIPA section 422(a)(2) would not apply to pediatric ESRD facilities as of October 1, 2002. Pediatric facilities would be defined as a renal facility with 50% of its patients under 18 years old. The provision would be effective upon enactment.

The provision would require the Secretary to establish an advisory board for the ESRD disease management demonstration. The advisory board would be comprised of representatives of patient organizations, clinicians, the Medicare Payment Advisory Commission (MedPAC), the National Kidney Foundation, the National Institute of Diabetes and Digestive and Kidney Diseases of the National Institutes of Health, ESRD networks, Medicare contractors to monitor quality of care, providers of services and renal dialysis facilities furnishing ESRD services, economists, and researchers. The provision would be effective upon enactment.

Senate Bill

The composite rate for dialysis services furnished during 2004 would be increased by an amount to ensure that the sum of the total amount of the composite rate payments plus the payments that are billed separately for drugs and biologicals (but not EPO) would equal the composite rate payments plus payments made for separately billed drugs and biologicals (not including EPO) as if the drug pricing provisions of this legislation were not enacted. During 2005, the ESRD composite rate would be increased by 0.05% and further increased by 1.6%. During 2006, the ESRD composite rate of the previous year would be increased by 0.05% and then further increased by 1.6%. During 2007 and subsequently, the composite ESRD rate of the previous year would be increased by 0.05%. In any year after 2004, the Secretary would be required to provide for additional increases in the composite rate to account for any payment reductions for separately administered drugs and biologicals (but not EPO) in the same manner as in 2004. These payment amounts, methods or adjustments would not be subject to administrative or judicial review under the statutory appeals

processes as established by Senate section 1869 of the SSA, by the Provider Reimbursement Review Board established by Senate section 1878 of the SSA, or otherwise. The provision would be effective upon enactment.

Conference Agreement

The conference agreement increases the composite rate for renal dialysis by 1.6% for 2005.

The prohibition on exceptions contained in BIPA section 422(a)(2) does not apply to pediatric ESRD facilities as of October 1, 2002. Pediatric ESRD facilities are defined as renal facilities with 50% of their patients under 18 years old. The provision is effective upon enactment.

The Inspector General of HHS is required to conduct 2 studies regarding drugs and biologicals (including erythropoietin) furnished to ESRD patients and billed separately to Medicare by ESRD facilities. The first study will address existing drugs and biologicals—those for which a billing code exists prior to January 1, 2004—and is required to be submitted to the Secretary by April 1, 2004. The second study is of new drugs and biologicals—those for which a billing code does not exist prior to January 1, 2004—and is due to the Secretary by April 1, 2006. Each study is required to determine the difference, or spread, between the Medicare payment amount to ESRD facilities for drugs and biologicals, and the facilities' acquisition costs for the drugs and biologicals which are separately billed by the facilities. The studies are also to estimate the rates of growth of expenditures for these drugs and biologicals.

The conference agreement requires the Secretary to establish a basic case-mix adjusted prospective payment system for dialysis services. The basic case-mix adjusted system is required to begin for services furnished on January 1, 2005. The system is required to adjust for a limited number of patient characteristics (the case-mix).

The basic case-mix adjusted system is composed of two components: (1) those services which currently comprise the composite rate (including the 1.6% increase in 2005), and (2) the spread on separately billed drugs and biologicals (including erythropoietin and as determined by the Inspector General reports).

Drugs and biologicals (including erythropoietin) currently billed separately, will continue to be billed separately under the basic case-mix adjusted system at acquisition costs. They cannot be bundled into the new system.

In addition, the Secretary is also required to adjust the basic case-mix adjusted system payment rates by a geographic index. If the geographic index is different from the one used with the composite rate, then the Secretary is required to phase-in the application over a multi-year period.

Overall, spending for ESRD services included under the basic case-mix adjusted system is required to result in the same aggregate amount of expenditures as would occur if the current system continued in 2005

The system would be updated in 2006 for growth in drug spending for the portion of the basic case-mix adjusted payment amount that is represented by what is current spread on separately billed drugs and biologicals. However, the provision does not provide for an update to the composite rate portion of the base rate in 2006 and forward. The increase for drug growth for the spread component would be adjusted downward by its proportionate share (of the spread and composite rate components) and the resulting increase applied to the sum. An adjustment would be made in 2007 for the spread calculated for new drugs and biologicals (those for which a billing code does not exist prior to January 1, 2004) using the 2006 Inspector General study.

Payments for separately billed drugs and biologicals will be 95% of the AWP for 2004 and acquisition costs in 2005, and, beginning in 2006 the Secretary has the authority to apply a payment methodology he determines appropriate which may include the average sales price payment methodology (under the new section 1847A found in section 303(c) of the conference agreement) or acquisition costs.

No administrative or judicial review is permitted of the case-mix system, the relative weights, payment amounts, the geographic adjustment factor, or the update of the basic case-mix adjusted system portion related to drug spending growth applied to spread, or in the determination of the difference between Medicare payment amounts and acquisition costs for separately billed drugs and biologicals.

By October 1, 2005, the Secretary is required to report to Congress on the elements and features for the design and implementation of a fully case-mix adjusted, bundled prospective payment system for services furnished by ESRD facilities, including to the extent feasible, drugs, clinical laboratory tests, and other items that are separately billed by ESRD facilities. The report is required to include a description of the methodology to be used for the establishment of payment rates including the bundle of items and services, case-mix, wage index, rural area payment adjustments, other adjustments, and update framework.

The Secretary is required to establish a 3-year demonstration project of the fully case-mix adjusted payment system for ESRD services, beginning January 1, 2006. The fully case-mix adjusted system is to include a case-mix system for patient characteristics identified in the report and to bundle separately billed drugs and biologicals and related clinical laboratory tests into the payment rates. The Secretary is required to ensure that sufficient numbers of providers of dialysis services and ESRD facilities participate in the demonstration, but not to exceed 500. The Secretary is required to ensure that urban, rural, not-for-profit, for-profit, independent, and specialty providers and facilities are included in the demonstration. During the demonstration, the Secretary is required to increase payment rates that would otherwise apply by 1.6% for dialysis services furnished by demonstration participants. In carrying out the demonstration, the Secretary is required to establish an advisory board comprised of representatives of: patient organizations; individuals with expertise in ESRD services, such as clinicians, economists, and researchers; the Medicare Payment Advisory Commission, the National Institutes of Health, network organizations; Medicare contractors to monitor quality of care; and providers of services and renal dialysis facilities. The advisory panel is required to terminate December 31, 2008. Appropriations are authorized from the Medicare trust funds in the amount of $5 million in FY 2006 to conduct this demonstration.

1-Year Moratorium on Therapy Caps; Provisions Relating to Report (Section 624 of the Conference Agreement and Section 624 of the House Bill).

Present Law

Medicare provides that therapy patients must be under the care of a physician; a plan of treatment must be developed by the physician or therapist; and the plan must be periodically reviewed by the physician.

BBA 97 established annual payment limits per beneficiary for all outpatient therapy services provided by non-hospital providers. The limits applied to services provided by independent therapists as well as to those provided by comprehensive outpatient rehabilitation facilities (CORFs) and other rehabilitation agencies. There are 2 beneficiary limits. The first is a $1,500 per beneficiary annual cap for all outpatient physical therapy services and speech language pathology services. The second is a $1,500 per beneficiary annual cap for all outpatient occupational therapy services. Beginning in 2002, the amount would increase by the Medicare Economic Index (MEI), rounded to the nearest multiple of $10. The limits did not apply to outpatient services provided by hospitals. BBRA 99 suspended application of the therapy limits in 2000 and 2001. BIPA extended the suspension through 2002. The therapy caps became effective in September 2003.

BBA 97 required the Secretary to report to Congress by January 1, 2001, on recommendations on a revised coverage policy of outpatient physical therapy and occupational therapy services based on a classification of individuals by diagnostic category and prior use of services, in both inpatient and outpatient settings, in place of uniform dollar limitations. BIPA required the Secretary to conduct a study on the implications of eliminating the ''in the room'' supervision requirement for Medicare payment for physical therapy assistants who are supervised by physical therapists and the implications of this requirement on the physical therapy cap. A report on the study was due within 18 months of enactment.

House Bill

Application of the therapy caps would be suspended in 2004. The Secretary would be required to submit the reports required by BBA 97 and BIPA by December 31, 2002. The Secretary would be required to request the Institute of Medicine to identify conditions or diseases that should justify conducting an assessment of the need to waive the therapy caps. The Secretary would be required to submit to Congress a preliminary report on the conditions and diseases identified by July 1, 2004. A final report, including recommendations, would be due by October 1, 2004.

Senate Bill

No provision.

Conference Agreement

Application of the therapy caps is suspended as of the date of enactment through calendar year 2005. The implementation of this provision shall not be deemed to have any retroactive impact upon beneficiaries who exceeded their caps prior to the date of enactment. The Secretary is required to submit the reports required by BBA 97 and BIPA by March 31, 2004 relating to the alternatives to a single annual dollar cap on outpatient therapy and the utilization patterns for outpatient therapy. The GAO is required to identify conditions or diseases that may justify waiving the application of the therapy caps and report to Congress by October 1, 2004. The report is required to include a recommendation of criteria, with respect to the conditions and diseases, under which a waiver of the therapy caps would apply.

Waiver of Part B Late Enrollment Penalty for Certain Military Retirees; Special Enrollment Period (Section 625 of the Conference Agreement, Section 627 of the House Bill, and Section 439 of the Senate Bill).

Present Law

A late enrollment penalty is required to be imposed on beneficiaries who do not enroll in Medicare part B upon becoming eligible for Medicare.

House Bill

Congress enacted TRICARE for Life, which re-established TRICARE health care coverage as a wraparound to Medicare for military retirees, age 65 and older. To take advantage of the TRICARE for Life program, military retirees must be enrolled in Medicare Part B. There is a late enrollment penalty for military retirees who do not enroll in Medicare Part B upon becoming eligible for Medicare. This provision would waive the late enrollment penalty for military retirees, 65 and older, who enroll(ed) in the TRICARE for Life program from 2001–2004.

The Secretary would also be required to provide a special Part B enrollment period for these military retirees beginning as soon as possible after enactment and ending December 31, 2004. The provision would apply to premiums for months beginning January 2004. The Secretary would be required to rebate premium penalties paid for months on or after January 2004 for which a penalty does not apply as a result of this provision, but for which a penalty was collected.

Senate Bill

Beginning January 2005, the provision would waive the late enrollment penalty for certain military retirees who enrolled in Part B during 2002, 2003, 2004 or 2005. A special enrollment period, beginning 1 year after enactment and ending December 31, 2005 would be provided.

Conference Agreement

Congress enacted TRICARE for Life, which re-established TRICARE health care coverage as a wraparound to Medicare for military retirees, age 65 and older. To take advantage of the TRICARE for Life program, military retirees must be enrolled in Medicare Part B. The provision waives the late enrollment penalty for military retirees who did not enroll in Medicare Part B upon becoming eligible for Medicare. The waiver applies to the late enrollment penalty for military retirees, 65 and over, who enroll(ed) in the TRICARE for Life program from 2001 to 2004.

The Secretary is required to provide a special Part B enrollment period for these military retirees beginning as soon as possible after enactment and ending December 31, 2004. The provision applies to premiums for months beginning January 2004. The Secretary is required to rebate premium penalties paid for months on or after January 2004 for which a penalty does not apply as a result of this provision, but for which a penalty was collected.

Payments for Services Furnished in Ambulatory Surgical Centers (Section 626 of the Conference Agreement and Section 625 of the House Bill).

Present Law

Medicare uses a fee schedule to pay for the facility services related to a surgery provided in an ambulatory surgery center (ASC). The associated physician services (surgery and anesthesia) are reimbursed under the physician fee schedule. CMS maintains the list of approved ASC procedures which is required to be updated every 2 years. The Secretary is required to update ASC rates based on a survey of the actual audited costs incurred by a representative sample of ASCs every 5 years beginning no later than January 1, 1995. Between revisions, the rates are to be updated annually on a calendar year schedule using the CPI–U. From FY1998 through FY2002, the update was established as the CPI–U minus 2.0 percentage points, but not less than zero.

In June 1998, CMS issued a proposed notice which would have implemented a prospective payment system (PPS) for ASCs. The Balanced Budget Refinement Act of 1999 required that full implementation of the proposed ASC rates be phased in over a 3-year period. The Benefits Improvement and Protection Act of 2000 (BIPA) delayed implementation of the PPS before January 1, 2002. BIPA also required that CMS use 1999 or later cost survey data in the PPS. A final rule implementing the new payment system for ASCs has not yet been issued.

House Bill

The reduction in the update would be extended. ASCs would get an increase calculated as the CPI–U minus 2.0 percentage points (but not less than zero) in each of the fiscal years from 2004 through 2008.

Senate Bill

No provision.

Conference Agreement

In FY2004, starting April 1, 2004, the ASC update will be the CPI–U (estimated as of March 31, 2003 minus 3.0 percentage points. In FY2005, the last quarter of calendar year 2005, and each of the calendar years 2006 through 2009 the update will be 0%. Upon implementation of the new ASC payment system, the Secretary will no longer be required to update ASC rates based on a survey of the actual audited costs incurred by a representative sample of ASCs every 5 years. Subject to GAO's recommendations (discussed subsequently), the Secretary will implement a revised payment system for surgical services furnished in an ASC. This payment system will be designed to be budget neutral in the year it is implemented; the amount of aggregate expenditures for such services under the new system will be the same as would have occurred under the old system. The new system will be implemented so that it is first effective on or after January 1, 2006 and not later than January 1, 2008. There will be no administrative or judicial review of the ASC classification system, relative weights, payment amounts and any geographic adjustment factor. GAO will conduct a comparative study of the relative costs of procedures furnished in ASCs to those furnished in hospital outpatient departments under OPPS. The study will examine the accuracy of the ambulatory payment categories with respect to the procedures furnished in the ASCs. GAO will submit recommendations and consider ASC data with respect to (1) the appropriateness of using groups and relative weights established for the outpatient hospital PPS as the basis of the new ASC payment system; (2) if such weights are appropriate, whether the ASC payments should be based on a uniform percentage of such weights, whether the percentages should vary, or whether the weights should be revised for certain procedures or types of services; and (3) the appropriateness of a geographic adjustment in the ASC payment system and if appropriate, the labor and nonlabor shares of such payment.

Payment for Certain Shoes and Inserts under the Fee Schedule for Orthotics and Prosthetics (Section 627 of the Conference Agreement, and Section 626 of the House Bill).

Present Law

Subject to specified limits and under certain circumstances, Medicare will pay for extra-depth shoes with inserts or custom molded shoes with inserts for an individual with severe diabetic foot disease. Coverage is limited to one of the following within a calendar year: (1) one pair of custom-molded shoes (including inserts provided with such shoes) and two additional pairs of inserts, or (2) one pair of extra-depth shoes (not including inserts provided with such shoes) and three pairs of inserts. An individual may substitute modifications of custom-molded or extra-depth shoes instead of obtaining one pair of inserts, other than the initial pair of inserts. Footwear must be fitted and furnished by a podiatrist or other qualified individual such as a pedorthist, orthotist, or prosthetist. The certifying physician may not furnish the therapeutic shoe unless the physician is the only qualified individual in the area.

Payment is made on a reasonable charge basis, subject to upper limits established by the Secretary. These limits are based on 1988 amounts that were set forth in Section 1833(o) of the Act and then adjusted by the same percentage increases allowed for DME fees except that if the updated limit is not a multiple of $1, it is rounded to the nearest multiple of $1. The Secretary or a carrier may establish lower payment limits than established by statute if shoes and inserts of an appropriate quality are readily available at lower amounts.

Although updates in payment for diabetic shoes are related to that used to increase the DME fee schedule, the shoes are not subject to DME coverage rules or the DME fee schedule. In addition, diabetic shoes are neither considered DME nor orthotics, but a separate category of coverage under Medicare Part B.

House Bill

Payment for diabetic shoes would be limited by the amount that would be paid if they were considered to be a prosthetic or orthotic device. The Secretary would be able to establish lower payment limits than these amounts if shoes and inserts of an appropriate quality are readily available at lower amounts. The Secretary would be required to establish a payment amount for an individual substituting modifications to the covered shoe that would assure that there is no net increase in Medicare expenditures. The provision would apply to items furnished on or after January 1, 2004.

Senate Bill

No provision.

Conference Agreement

Payment for diabetic shoes is limited under the conference agreement by the amount that would be paid if they were considered to be a prosthetic or orthotic device. The Secretary may establish lower payment limits than these amount if shoes and inserts of an appropriate quality are readily available at lower amounts. The Secretary is required to establish a payment amount for an individual substituting modifications to the covered shoe that would assure that there is no net increase in Medicare expenditures. The provision applies to items furnished on or after January 1, 2005.

Payment for Clinical Diagnostic Laboratory Tests (Section 628 of the Conference Agreement, Section 431 of Senate Bill).

Present Law

Medicare payment for clinical diagnostic laboratory test is made using a fee schedule. The fee schedule is updated on a calendar year basis using the CPI–U. BBA 97 froze the fee schedule from 1998 through 2002. The update for 2003 was equal to the full CPI–U increase. No beneficiary cost-sharing is imposed.

House Bill

No provision.

Senate Bill

Medicare would pay all clinical laboratories 80% of the applicable fee schedule amount. Hospital-based and physician office and independent laboratories would be able to charge beneficiaries a 20% coinsurance amount. The Medicare Part B deductible would apply to clinical diagnostic laboratory tests furnished across all settings; except for those tests provided by sole community hospitals (see Senate Section 427). The provision

would apply to tests furnished on or after January 1, 2004.

Conference Agreement

The conference agreement does not provide for any updates to the clinical diagnostic laboratory test fee schedule for 2004 through 2008.

Indexing Part B Deductible to Inflation (Section 629 of the Conference Agreement, Section 628 of the House Bill, Section 433 of the Senate Bill).

Present Law

Under Part B, Medicare generally pays 80 percent of the approved amount for covered services after the beneficiary pays an annual deductible of $100. The Part B deductible has been set at $100 since 1991.

House Bill

Starting for January 1, 2004, the Medicare Part B deductible would be increased by the same percentage as the Part B premium increase. Specifically, the annual percentage increase in the monthly actuarial value of benefits payable from the Federal Supplementary Medical Insurance Trust Fund would be used as the update. The amount would be rounded to the nearest dollar. The provision would be effective upon enactment.

Senate Bill

The Medicare Part B deductible would be set at $100 through 2005 and then increased to $125 in 2006. Effective January 1 of subsequent years, the deductible would be increased annually by the percentage change in the CPI–U for the previous year ending in June. The amount would be rounded to the nearest dollar. The provision would be effective upon enactment.

Conference Agreement

The Medicare Part B deductible will remain $100 through 2004. The deductible will be $110 for 2005, and in subsequent years the deductible will be increased by the same percentage as the Part B premium increase. Specifically, the annual percentage increase in the monthly actuarial value of benefits payable from the Federal Supplementary Medical Insurance Trust Fund will be used as the update. The deductible amount will be rounded to the nearest dollar. The provision is effective upon enactment.

In 1966, Medicare's $50 Part B deductible equaled about 45 percent of Part B charges. Today's $100 deductible equals about three percent of such charges. Indexing the Part B deductible to grow at the same rate as total Part B spending per beneficiary would maintain the deductible at 3 percent of such charges over time.

An unchanged Part B deductible is a benefit increase over time, as costs of medical care rise. Beneficiaries pay about 25 percent of this benefit increase, through increased Part B premiums; taxpayers finance the remaining 75 percent. The Part B deductible has increased only three times since the beginning of Medicare, when it was $50. The deductible has since been increased to $60 in 1973, $75 in 1982, and $100 in 1991. About one-half of beneficiaries are insulated from Part B deductibles through Medigap, Medicaid, or employer-sponsored supplemental insurance that covers the Part B deductible. The Part B deductible has increased only three times since Medicare began in 1965, when it was $50. It was raised to $60 in 1973, $75 in 1982, and $100 in 1991.

5-year Authorization of Reimbursement for All Medicare Part B Services Furnished by Certain Indian Hospitals and Clinics (Section 630 of the Conference Agreement and Section 450C of the Senate Bill).

Present Law

Medicare covers specified Part B services provided by a hospital or ambulatory care clinic (whether provider-based or free-standing) that is operated by the Indian Health Service, by an Indian tribe, or by a tribal organization. These services include physicians' services, health practitioners (physician assistant, nurse practitioner, or clinical nurse specialist; certified registered nurse anesthetist; certified nurse-midwife; clinical social worker; clinical psychologist; and a registered dietitian or nutrition professional) and outpatient physical therapy services provided by a physical or occupational therapists.

House Bill

No provision.

Senate Bill

The provision would expand covered Medicare Part B items and services provided in hospitals or ambulatory care clinics (whether provider-based or freestanding) that are operated by the Indian Health Service or by an Indian tribe or tribal organization. All covered Part B items and services would be paid when provided in a hospital or ambulatory care clinic operated by the Indian Health Service or by an Indian tribe or tribal organization. The provision would apply to items and services furnished on or after October 1, 2004.

Conference Agreement

The conference agreement provides a 5–year expansion of the items and services covered under Medicare Part B when furnished in Indian hospitals and ambulatory care clinics. The conference agreement applies to items and services furnished on or after January 1, 2005.

Conforming Changes Regarding Federally Qualified Health Centers (Section 420 of the Senate Bill).

Present Law

Medicare pays federally qualified health centers (FQHCs) for their services on a reasonable cost basis.

House Bill

No provision.

Senate Bill

Medicare would exclude the costs incurred by a FQHC for providing services and receiving payments through a contract with an eligible entity operating a Medicare prescription drug plan. The provision would be effective upon enactment.

Conference Agreement

No provision.

Reimbursement for Total Body Orthotic Management for Certain Nursing Home Patients (Section 450B of the Senate Bill).

Present Law

Orthotics are rigid devices, often called braces, which are applied to the outside of the body as a means of support for a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. They are categorized into one of three groups of devices: custom fitted, which require alterations to a prefabricated product; custom fabricated, which are made for a specific patient from his/her individual measurements; and molded to patient model, which are created from a cast of the patient's body part. Examples of orthotics include spinal body jackets, hip abductors, and knee braces. Add-ons, such as straps and linings, are billed separately. Suppliers of orthotics include certified orthotists, medical equipment companies, and physicians' offices.

Orthotics (e.g., leg, arm, back, and neck braces) are covered Part B benefits when furnished in an institutional setting, such as in a hospital or skilled nurses facility, while durable medical equipment (DME) is not covered in those settings. Medicare considers a brace as an orthotic device when it can be used independently of DME. On the other hand, if a brace must be used in conjunction with, or is an accessory of, a DME item, then the brace is considered an item of DME. Orthotic devices include braces that are part of a bracing system even if the system depends on attachment to an external structure or frame.

At one point, the Centers for Medicare and Medicaid (CMS) in HCFA Ruling, No. 96–1, declared that bracing systems should be characterized as DME rather than orthotics. That ruling was deemed invalid because it made a substantive change in Medicare coverage rules and was not properly promulgated. Although the braces in a bracing system are attached to an external frame, they perform the functions of braces and the external frame is assistive in nature rather than determinative of the system's classification. Since the patients who need bracing systems typically are cared for in the nursing home environment, the classification of the bracing systems is crucial because orthotics are covered when furnished to nursing home patient, while DME is not. However, under the Benefits Improvement and Protection Act of 2000 (BIPA) (PubLNo 106–554), no payment may be made for prosthetics and certain custom-fabricated orthotics unless they are furnished by a qualified practitioner and fabricated by a qualified practitioner or a qualified supplier at an approved facility. Affected custom-fabricated orthotics are items requiring education, training, and experience to custom-fabricate and that are on a list to be published by the Secretary.

House Bill

No provision.

Senate Bill

The Secretary would be required to issue product codes that qualified practitioners and suppliers may used to receive Medicare reimbursement for qualified total body orthotic management devices no later than 60 days from enactment. These medically prescribed devices would consist of custom fitted individual braces with adjustable points at the hip, knee, ankle, elbow and wrists when the braces are attached to a frame that is integral to the device and the frame serves no purpose without the braces. The device would be designed to improve function, retard the progression of musculoskeletal deformity or restrict, eliminate, or assist in the functioning of the upper or lower extremities for a beneficiary who is in the full time care of a skilled nursing facility who requires such care for medical reasons. The provision would be effective upon enactment.

Conference Agreement

No provision.

Medicare Coverage of Self Injected Biologicals (Section 450E of the Senate Bill).

Although Medicare does not currently provide an outpatient prescription drug benefit, coverage of certain outpatient drugs and biologicals is specifically authorized by statute. For example, under Medicare Part B, outpatient prescription drugs and biologicals are covered if they are usually not self-administered and are provided incident to a physician's services. Generally, Medicare will cover an outpatient drug as usually self-administered if it is delivered by intramuscular injection, but not if it is injected subcutaneously.

House Bill

No provision.

Senate Bill

From January 1, 2004 and before January 1, 2006, Medicare would cover self-injected

biologicals that are approved by the Food and Drug Administration and that are prescribed as complete replacements for drugs or biologicals that are currently covered in physicians' offices or as hospital services provided to outpatients that are usually self-administered and provided incident to a physician's services. Medicare would cover self-injected drugs that are used to treat multiple sclerosis. The provision would apply to drugs and biologicals furnished on or after January 1, 2004 and before January 1, 2006.

Conference Agreement

No provision.

Requiring the Internal Revenue Service to Deposit Installment Agreement and Other Fees in the Treasury as Miscellaneous Receipts (Section 450G of the Senate Bill).

Present Law

The Secretary of the Treasury was granted the authority by Senate Section 3 of the Administrative Provisions of the Internal Revenue Service of Public Law 103–286, the Treasury, Postal Service and General Government Appropriations Act of 1995 to establish new fees (if the fee is authorized by another law) or raise fees for services provided by the Internal Revenue Service to supplement appropriations made available to the Internal Revenue Service. The fees must be based on the costs of providing the specific services (to the persons paying the fees), and the Secretary must report quarterly to the Congress on the collection of such fees and how they are spent.

House Bill

No provision.

Senate Bill

The Secretary of the Treasury must deposit any fees collected under the authority provided by Senate Section 3 of the Administrative Provisions of the Internal Revenue Service of Public Law 103–286, the Treasury, Postal Service and General Government Appropriations Act of 1995 into the Treasury as miscellaneous receipts. The fees collected are only available to the Internal Revenue Service if authority is provided in advance in an appropriations Act. The provision would be effective upon enactment.

Conference Agreement

No provision.

Medicare Coverage of Kidney Disease Education Services (Section 456 of the Senate Bill).

Present Law

No provision.

House Bill

No provision.

Senate Bill

Kidney disease education services would be covered under Medicare. The services covered would be those: furnished to an individual with kidney disease who will require dialysis or a kidney transplant; furnished upon the referral of the physician managing the individual's kidney condition; and designed to provide comprehensive information regarding the management of comorbidities, the prevention of uremic complications, and each option for renal replacement therapy (including peritoneal diaylsis, hemodialysis and transplantation) and to ensure that the individual has the opportunity to actively participate in the choice of therapy. Kidney disease education services would be paid using the physician fee schedule on an assignment-related basis (thus prohibiting balance billing) outside the ESRD composite rate.

The Secretary would be required to ensure (and to monitor implementation to ensure) that each beneficiary who is entitled to kidney disease education services under Medicare receives such services in a timely manner that ensures that the beneficiary receives the maximum benefit of the services.

The Secretary would be required to report to Congress annually on the number of Medicare beneficiaries who are entitled to these education services and who received these services. In addition, the report would include any recommendations for legislative and administrative action as the Secretary determines appropriate. The first report would be due April 1, 2004. The provision would apply to services furnished on or after January 1, 2004.

Conference Agreement

No provision.

Subtitle D—Additional Demonstrations, Studies and Other Provisions

Demonstration Project for Coverage of Certain Prescription Drugs and Biologics (Section 641 of the Conference Agreement and Section 631 of the House Bill).

Present Law

No provision.

House Bill

The Secretary would be required to conduct a 2-year demonstration project in 3 states covering more than 10,000 patients under Part B of the Medicare program that would pay for drugs and biologicals that are prescribed as replacements for existing covered drugs that are furnished incident to a physician's professional service which are not usually self-administered including oral anticancer chemotherapeutic agents. The project would not extend beyond December 31, 2005 and would not cost more than $100 million. The Secretary would be required to submit an evaluation to Congress concerning patient access and outcomes as well as the project's cost effectiveness. The Secretary would also be required to examine any cost savings attributed to reduced physicians' services and hospital outpatient department services for the administration of the biological. The demonstration project would begin 90 days from enactment and would end no later than December 31, 2005.

Senate Bill

No provision.

Conference Agreement

The conference agreement requires the Secretary to conduct a 2–year demonstration project in 6 states covering more than 50,000 patients under Medicare Part B that pays for drugs and biologics that are prescribed as replacements for existing covered drugs that are furnished incident to a physician's professional service which are not usually self-administered, including oral anticancer chemotherapeutic agents. The project is required to provide for cost-sharing applicable with respect to the drugs or biologics in the same manner as the cost-sharing applicable under part D for standard prescription drug coverage. The project is not permitted to cost more than $500 million. No less than 40 percent of the funding shall be for oral cancer. The Secretary is required to submit an evaluation to Congress concerning patient access and outcomes as well as the project's cost effectiveness. The Secretary is also required to examine any cost savings attributed to reduced physicians' services and hospital outpatient department services for the administration of the biological. The demonstration project is required to begin 90 days following enactment and end no later than December 31, 2005.

The managers intend that this provision of the demonstration will provide immediate Part B coverage for all immunomodulating drugs and biologicals used when treating multiple sclerosis. Coverage will be extended without regard to whether there is medical or other supervision with respect to the administration of such drug or biological, and include the biological administered via intramuscular injection currently covered under Section 1861(s)(2)(A) or (B) of the Social Security Act.

Extension of Coverage of Intravenous Immune Globulin (IVIG) for the Treatment of Primary Immune Deficiency Diseases in the Home (Section 642 of the Conference Agreement and Section 629 of the House Bill).

Present Law

Intravenous immune globulin (IVIG) is a blood product prepared from the pooled plasma of donors. It has been used to treat a variety of autoimmune diseases, including mucocutaneous blistering diseases. It has fewer side effects than steroids or immunosuppressive agents. Effective October 1, 2002, IVIG is covered for the treatment of certain conditions including pemphigus vulgaris, pemphigus foliaceus, and epidermolysis bullosa acquisita for the following specific patient subpopulations: (1) patients who have failed conventional therapy; (2) patients in whom conventional therapy is otherwise contraindicated; and (3) patients with rapidly progressive disease in whom a clinical response could not be affected quickly enough using conventional agents. IVIG for the treatment of autoimmune mucocutaneous blistering diseases must be used only for short term therapy and not as a maintenance therapy. Contractors have discretion to define what constitutes a failure of conventional therapy and what constitutes short-term therapy.

House Bill

Intravenous immune globulin for the treatment of primary immune deficiency diseases in the home would be included as a covered medical service. Intravenous immune globulin would be defined as an approved pooled plasma derivative for the treatment in the patient's home of a patient with a diagnosed primary immune deficiency disease, if a physician determines administration of the derivative in the patient's home is medically appropriate. This would not include items or services related to the administration of the derivative. Intravenous immune globulin would be paid at 80 percent of the lesser of actual charge or the payment amount. This provision would apply to items furnished on or after January 1, 2004.

Senate Bill

No provision.

Conference Agreement

The conference agreement includes intravenous immune globulin for the treatment in the home of primary immune deficiency diseases as a covered medical service under Medicare. Intravenous immune globulin is defined as an approved pooled plasma derivative for the treatment, in the patient's home, of a patient with a diagnosed primary immune deficiency disease, if a physician determines administration of the derivative in the patient's home is medically appropriate. Items or services related to the administration of the derivative are not included in the definition. Intravenous immune globulin is to be paid at 80 percent of the lesser of actual charge or the payment amount. This provision applies to items furnished on or after January 1, 2004.

MedPAC Study of Coverage of Surgical First Assisting Services of Certified Registered Nurse First Assistants (Section 643 of the Conference Agreement and Section 450I of the Senate Bill).

Present Law

Surgical first assisting services are not separately covered services of Medicare and certified registered nurse first assistants are

not able to bill the Medicare program directly for their services. Their services are paid by surgeons who are paid under the Medicare physician fee schedule.

House Bill

No provision.

Senate Bill

The Secretary would be required to conduct a 3–year demonstration in 5 states that would pay for ''surgical first assisting services'' to Medicare beneficiaries furnished by a certified registered nurse first assistant. These services would consist of assisting a physician with surgery and related preoperative, intraoperative, and postoperative care furnished by a certified registered nurse first assistant. Payment would be 80% of the lesser of: the actual charge for the services or 85% of the physician fee schedule amount. Aggregate payments for the demonstration would be required not to exceed the amount that would have been paid if this demonstration project had not been implemented. The Secretary would be required to report to Congress on the evaluation of patient outcomes and on the cost-effectiveness of the demonstration by January 1, 2007. The demonstration is required to begin 90 days after enactment.

Conference Agreement

The conference agreement requires that MedPAC study the feasibility and advisability of Medicare Part B payment for surgical first assisting services furnished to Medicare beneficiaries by a certified registered nurse first assistant. MedPAC is required to submit the report by January 1, 2005 and to include recommendations for legislation or administrative action.

MedPAC Study of Payment for Cardio-Thoracic Surgeons (Section 644 of the Conference Agreement).

Present Law

Cardio-thoracic surgeons are paid under the Medicare physician fee schedule for their services.

House Bill

No provision.

Senate Bill

No provision.

Conference Agreement

The conference agreement requires the MedPAC to study the practice expense relative values in the Medicare physician fee schedule for the specialty of thoracic surgery to determine whether such values adequately take into account the attendant costs of nurse assistants at surgery. The study is required to be submitted to Congress by January 1, 2005 and to include recommendations for legislative or administrative action.

Study on Coverage of Outpatient Vision Services Furnished by Vision Rehabilitation Professionals Under Part B (Section 645 of the Conference Agreement and Section 446 of the Senate Bill).

Present Law

Medicare does not cover routine eye care or related services and will not pay for eyeglasses; most contact lenses; eye examinations for the purpose of prescribing, fitting, or changing eyeglasses or contact lenses; and most procedures performed to determine the refractive state of the eyes.

Medicare pays for prosthetic devices (other than dental) which replace all or part of an internal body organ (including contiguous tissue) when furnished incident to physicians' services or on a physician's order. The law specifically provides coverage for one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens.

The Rehabilitation Act of 1973 as amended prohibits discrimination in programs conducted by federal agencies, in programs receiving federal financial assistance, in federal employment and employment practices of federal contractors. The act provides much of the basis for the Americans with Disabilities Act including its standards for determining employment discrimination.

House Bill

No provision.

Senate Bill

Medicare Part B would cover vision rehabilitation services furnished to a beneficiary who is diagnosed with certain vision impairments. These vision impairments would be vision loss that constitutes a significant limitation of visual capability that cannot be corrected by conventional means and that is manifested by one or more of the following conditions: (1) best corrected visual acuity of less than 20/60 or significant central field defect; (2) significant peripheral field defect including homonymous or heteronymous bilateral visual field defect or generalized contraction or constriction of field; (3) reduced peak contrast sensitivity; and (4) other appropriate diagnoses or indications. Covered services would be established by a plan of care developed by a qualified physician or qualified occupational therapist whose plan of care is periodically reviewed by a qualified physician. These services would be provided in an appropriate setting by a qualified physician, qualified occupational therapist, or vision rehabilitation professional under the general supervision of a qualified physician using a plan of care established and reviewed by the qualified physician. A qualified physician would be an ophthalmologist or a doctor of optometry. A vision rehabilitation professional would include an orientation and mobility specialist, a rehabilitation teacher, or a low vision therapist who is appropriately licensed and certified under prevailing state laws with appropriate education and training.

Medicare would pay for the services under the physician fee schedule. These services would not be paid under the hospital outpatient department prospective payment system. Payment would be made to the qualified physician or the facility (such as a rehabilitation agency, a clinic, or other facility) through which services are furnished under the plan care if there is a contractual arrangement between the vision rehabilitation specialist and the facility where the facility submits the bill for the services. Medicare's coverage of vision rehabilitation services would not be taken into account for any purpose under the Rehabilitation Act of 1973.

The Secretary would be required to publish a interim final rule in the Federal Register no later than 180 days from the date of enactment; the regulation, although effective immediately, would be subject to at least a 60–day public comment period. The Secretary would be required to consult with qualified professional and consumer groups including the National Vision Rehabilitation Cooperative, the Association for Education and Rehabilitation of the Blind and Visually Impaired, the Academy for Certification of Vision Rehabilitation and Education Professionals, the American Academy of Ophthalmology, the American Occupational Therapy Association, and the American Optometric Association.

Conference Agreement

The conference agreement requires the Secretary to study the feasibility and advisability of: (1) providing for payment for vision rehabilitation services furnished by vision rehabilitation professionals, and (2) implementing a demonstration project for vision care PPO networks to furnish and pay for conventional eyeglasses subsequent to each cataract surgery with the insertion of intra ocular lens. The Secretary is urged to examine any licensure or certification difficulties faced by vision rehabilitation professionals. The report is due to Congress by January 1, 2005 and is to include recommendations for legislation or administrative action. In reviewing reimbursement for vision rehabilitation professionals, the report shall examine payments through qualified physicians to vision rehabilitation professionals for either directly supervised services or services delivered under generalized supervision.

Medicare Health Care Quality Demonstration Programs (Section 646 of the Conference Agreement and Section 441 of the Senate Bill).

Present Law

No provision.

House Bill

No provision.

Senate Bill

The Secretary would be required to establish a 5-year demonstration program that examines the health delivery factors which encourage the delivery of improved patient care quality including: (1) incentives to improve the safety of care provided to beneficiaries; (2) appropriate use of best practice guidelines; (3) reduction of scientific uncertainty through examination of service variation and outcomes measurement; (4) encouragement of shared decision making between providers and patients; (5) the provision of incentives to improve safety, quality, and efficiency; (6) appropriate use of culturally and ethnically sensitive care; and (7) related financial effects associated with these changes. The participants would include appropriate health care groups including physician groups, integrated health care delivery systems, or regional coalitions. These health care groups may implement alternative payment systems that encourage the delivery of high quality care and streamline documentation and reporting requirements. They may also offer benefit packages distinct from those that are currently available under Medicare Parts A and B and under the Part C Medicare Advantage plan. To qualify for this demonstration, health care groups must meet Secretary-established quality standards; implement quality improvement mechanisms that integrate community-based support, primary care, and referral care; encourage patient participation in decisions; among other requirements.

The Secretary may waive Medicare and Peer Review and Administrative Simplification (Title XI) requirements as necessary and may direct agencies within Health and Human Services (HHS) to evaluate, analyze, support, and assist in the demonstration project. The demonstration program would be subject to budget-neutrality requirements. The Secretary would not be permitted to implement the program before October 1, 2004.

Conference Agreement

The conference agreement requires the Secretary to establish a 5-year demonstration program that examines the health delivery factors which encourage the delivery of improved patient care quality including: (1) incentives to improve the safety of care provided to beneficiaries; (2) appropriate use of best practice guidelines; (3) reduction of scientific uncertainty through examination of service variation and outcomes measurement; (4) encouragement of shared decision making between providers and patients; (5) the provision of incentives to improve safety, quality, and efficiency; (6) appropriate use of culturally and ethnically sensitive care; and (7) related financial effects associated with these changes. Health care groups

that may participate are physician groups, integrated health care delivery systems, and regional coalitions. These health care groups may implement alternative payment systems that encourage the delivery of high quality care and streamline documentation and reporting requirements. They may also offer benefit packages distinct from those that are currently available under Medicare Parts A and B and under the Part C Medicare Advantage plan.

To qualify for this demonstration, health care groups must meet Secretary-established quality standards; implement quality improvement mechanisms that integrate community-based support, primary care, and referral care; encourage patient participation in decisions; among other requirements. The Secretary may waive Medicare and Peer Review and Administrative Simplification (Title XI) requirements as necessary and may direct agencies within Health and Human Services (HHS) to evaluate, analyze, support, and assist in the demonstration project. The demonstration program is subject to budget-neutrality requirements.

GAO Study on Coverage of Marriage and Family Therapist Services and Mental Health Counselor Services Under Part B of the Medicare Program (Section 647 of the Conference Agreement and Section 448 of the Senate Bill).

Present Law

Medicare's Part B payment for outpatient mental health services is limited to 62.5% of covered expenses incurred in any calendar year in connection with the treatment of a mental, psychoneurotic, or personality disorder of an individual who is not an inpatient of a hospital at the time such expenses are incurred. The term ''treatment'' does not include brief office visits for the sole purpose of monitoring or changing drug prescriptions used in the treatment of such disorders or partial hospitalization services that are not directly provided by the physician. This 62.5% payment limitation applies to outpatient mental health treatments furnished by physicians, comprehensive outpatient rehabilitation facilities (CORFs), physician assistants, clinical psychologists, and clinical social workers. Items and supplies furnished by physicians or other mental health practitioners in connection with treatment are also subject to the limitation. The limitation is applied only to therapeutic services (e.g., psychotherapy) and to follow-up diagnostic services performed to evaluate the progress of a course of treatment. Charges for initial diagnostic services (i.e., psychiatric testing and evaluation used to diagnose the patient's illness) are not subject to this limitation. The 62.5% limitation is subject to Part B deductible and coinsurance requirements.

Medicare covers outpatient hospital partial hospitalization services connected with the treatment of mental illness. Partial hospitalization services are covered only if the individual would otherwise require inpatient psychiatric care. The 62.5% payment limitation does not apply to partial hospitalization services, except for services that are directly provided by a physician. Under this benefit, Medicare covers: (A) individual and group therapy with physicians or psychologists (or other authorized mental health professionals); (B) occupational therapy; (C) services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric patients; (D) drugs and biologicals furnished for therapeutic purposes that cannot be self-administered; (E) individualized activity therapies that are not primarily recreational or diversionary; (F) family counseling (for treatment of the patient's condition); (G) patient training and education; and (H) diagnostic services. Partial hospitalization services are also covered in community mental health centers. Family counseling services with members of the household are covered only where the primary purpose of such counseling is the treatment of the patient's condition.

House Bill

No provision.

Senate Bill

Medicare would cover marriage and family therapist services and mental health counselor services for the diagnosis and treatment of mental illness. The therapists would be legally authorized to provide such services under State law and would provide services that would be otherwise covered if furnished by a physician or furnished incident to a physician's professional service. No facility or other provider would charge or be paid for these services. The amount of payment would be 80% of the lesser of the actual charge or 75% of the amount paid to a psychologist. These services would be subject to assignment. These services would be excluded from the skilled nursing facility prospective payment system. Rural health clinics, federally qualified health centers, hospice programs would be authorized to provide such services. Marriage and family therapists would be authorized to develop post hospital discharge plans for patients. The provisions would apply to services furnished on or after January 1, 2004.

Conference Agreement

The conference agreement requires the GAO to study the feasibility and advisability of providing Medicare Part B coverage of marriage and family therapist services and mental health counselors and of the appropriate settings and payment methodologies of such services. Recommendations for legislation or administrative actions are also required to be included in the study. The report is required to be submitted to Congress no later than January 1, 2005.

MedPAC Study on Direct Access to Physical Therapy Services (Section 648 of the Conference Agreement, Section 624 of the House bill and Section 449 of the Senate bill).

Present Law

No provision.

House Bill

GAO would be required to conduct a study on access to physical therapist services in States authorizing access to such services without a physician referral compared to States that require such a physician referral. The study would: (1) examine the use of and referral patterns for physical therapist services for patients age 50 and older in states that authorize such services without a physician referral and in states that require such a referral; (2) examine the use of and referral patterns for physical therapist services for patients who are Medicare beneficiaries; (3) examine the physical therapist services within the facilities of the Department of Defense; and (4) analyze the potential impact on beneficiaries and on Medicare expenditures of eliminating the need for a physician referral for physical therapist services under the Medicare program. GAO would be required to submit a report to Congress on the study within one year of enactment.

Senate Bill

The Secretary would be required to establish a 3-year demonstration project in at least 5 states to examine the costs and patient satisfaction associated with allowing Medicare fee-for-service beneficiaries direct access to outpatient physical therapy services and comprehensive outpatient rehabilitation facility (CORF) services. In this instance, the beneficiary would not be required to be under the care of or referred by a physician to receive physical therapy services. Also, a physician or qualified physical therapist would be permitted to certify, recertify, establish and periodically review the beneficiary's plan of care. To the extent possible, the demonstration project would be conducted on a statewide basis. The project would be required to be established not later than 1 year after the date of enactment. The Secretary would be allowed to terminate the operation of a project at a site if, based on actual data, Medicare expenditures are greater than they otherwise would be without implementation of the demonstration project. The Secretary would be able to waive Medicare requirements as necessary and appropriate. The Secretary would be required to conduct interim and final evaluations of the project which would be submitted to the Congressional committees of jurisdiction no later than the end of the second year of operation and no later than 180 days after the end of the project. This provision would be effective upon enactment.

Conference Agreement

The conference agreement requires MedPAC to study the feasibility and advisability of allowing Medicare beneficiaries in fee-for-service direct access to outpatient physical therapy services and those physical therapy services that are furnished as comprehensive rehabilitation facility services. For the purposes of the study, direct access is defined as access to physical therapy services without the requirement that beneficiaries be under the care of, or referred by, a physician. Further, the services provided are not required to be under the supervision of a physician. Finally, either a physician or a qualified physical therapist could satisfy any requirement for certification, recertification and establishment and review of a plan of care. This study, together with recommendations for legislation or administrative actions, must be submitted to Congress no later than January 1, 2005.

Demonstration Project for Consumer Directed Chronic Outpatient Services (Section 648 of the Conference Report and Section 736 of the House bill)

Present Law

No provision. Medicare coverage requires that a beneficiary need medically necessary care. In general, Medicare pays the provider that delivers skilled health care services.

House Bill

The Secretary would be required to establish no fewer than 3 demonstration projects that evaluate methods to improve the quality of care provided to Medicare beneficiaries with chronic conditions and that reduce expenditures that would otherwise be made on their behalf by Medicare. The methods would be required to include permitting beneficiaries to direct their own health care needs and services. In designing the demonstrations, the Secretary would be required to evaluate practices used by group health plans and practices under State Medicaid programs that permit patients to self-direct the provision of personal care services and to determine the appropriate scope of personal care services that would apply under the demonstration projects.

The Secretary would be required to establish the demonstrations within 2 years of enactment. Demonstrations would be required to be located in an urban area, a rural area, and an area that has a Medicare population with a diabetes rate that significantly exceeds the national average rate. The Secretary would be required to evaluate the clinical and cost effectiveness of the demonstrations. Reports to Congress would be required biannually beginning 2 years after the demonstrations begin.

Senate Bill

No provision.

Conference Agreement

The conference agreement requires the Secretary to establish no fewer than 3 demonstration projects that evaluate methods to improve the quality of care provided to Medicare beneficiaries with chronic conditions and that reduce expenditures that would otherwise be made on their behalf by Medicare. The methods are required to include permitting beneficiaries to direct their own health care needs and services. In designing the demonstrations, the Secretary is required to evaluate practices used by group health plans and practices under State Medicaid programs that permit patients to self-direct the provision of personal care services and to determine the appropriate scope of personal care services that apply under the demonstration projects.

The Secretary is required to establish the demonstrations within 2 years of enactment. Demonstrations are required to be located in an urban area, a rural area, and an area that has a Medicare population with a diabetes rate that significantly exceeds the national average rate. The Secretary is required to evaluate the clinical and cost effectiveness of the demonstrations. Reports to Congress are required biannually beginning 2 years after the demonstrations begin.

Medicare Care Management Performance Demonstration (Section 649 of the Conference Report and Section 736 of the House Bill).

Current Law

No provision.

House Bill

No provision.

Senate Bill

The Secretary would be required to establish a 3-year demonstration program to promote continuity of care, help stabilize medical conditions, prevent or minimize acute exacerbations of chronic conditions, and reduce adverse health outcomes before October 1, 2004. Six sites would be designated for the demonstration, 3 in urban areas and at least 1 in a rural area. One site would be required to be located in Arkansas. Any Medicare beneficiary enrolled in part B who has at least 4 complex medical conditions and is unable to manage their own care or has a functional limitation and resides in a demonstration area may participate in the program if the beneficiary identifies a principal care physician who agrees to manage the complex clinical care of the beneficiary under the demonstration.

Each principal care physician who agrees to manage the complex clinical care of a beneficiary eligible to participate would be required to agree to: (1) serve as the primary contact of the beneficiary in accessing items and services under Medicare; (2) maintain medical information related to care and services furnished by other health care providers including clinical reports, medication and treatments prescribed by other physicians, hospital and hospital outpatient services, skilled nursing home care, home health care, and medical equipment services; (3) monitor and advocate for the continuity of care of the beneficiary and the use of evidence-based guidelines; (4) promote self-care and family care giver involvement where appropriate; (5) have appropriate staffing arrangements to conduct patient self-management and other care coordination activities as specified by the Secretary; refer the beneficiary to community service organizations and coordinate the services of such organizations with the care provided by health care providers; and (7) meet such other complex care management requirements as the Secretary may specify.

The Secretary would pay each principal care physician a monthly complex care management fee developed by the Secretary. The fee would be the full payment for all the functions performed by the principal care physician including any functions performed by other qualified practitioners acting on behalf of the physician, appropriate staff under the supervision of the physician, and any other person under a contract with the physician, including any person who conducts patient self-management and caregiver education. Aggregate payments by Medicare could not exceed the amount that would otherwise have been paid if the demonstration program had not been implemented. The Secretary would be required to report to Congress on the demonstration program 6 months after its completion.

Conference Agreement

The Secretary would be required to establish a 3-year demonstration program to promote continuity of care, help stabilize medical conditions, prevent or minimize acute exacerbations of chronic conditions, and reduce adverse health outcomes. Four sites would be designated for the demonstration: with at least two in urban areas and one in a rural area. One of the demonstration sites would be in a state with a medical school with a geriatrics department that manages rural outreach sites and is capable of managing patients with multiple chronic conditions, one of which is dementia. Any Medicare beneficiary enrolled in part A and B who has one or more chronic medical conditions specified by the Secretary (one of which may be a cognitive impairment) and is unable to manage their own care or has a functional limitation and resides in a demonstration area may participate in the program if the beneficiary identifies a principal care physician who agrees to manage the complex clinical care of the beneficiary under the demonstration.

The conferees encourage CMS to work with Agency for Healthcare Research and Quality (AHRQ) to provide grants to assist physicians in carrying out the health information technology aspect of the demonstration. In particular, the grants should focus on issues involving clinical decision support tools, clinical reminders, and improved communication between patients, providers and payors. AHRQ is currently working to provide grant programs in this area.

Demonstration of Coverage of Chiropractic Services under Medicare (Section 440 of the Senate Bill).

Present Law

No specific provision with respect to a demonstration project. Medicare covers limited chiropractic services, specifically manual manipulation for correction of a dislocated or misaligned vertebra or subluxation.

House Bill

No provision.

Senate Bill

The Secretary would be required to establish a 3-year demonstration program at 6 sites to evaluate the feasibility and desirability of covering additional chiropractic services under Medicare. These projects may not be implemented before October 1, 2004. The chiropractic services included in the demonstration shall include, at a minimum, care for neuromusculoskeletal conditions typical among eligible beneficiaries as well as diagnostic and other services that a chiropractor is legally authorized to perform. An eligible beneficiary participating in the demonstration project, including those enrolled in Medicare +Choice or Medicare Advantage plans, would not be required to receive approval by physician or other practitioner in order to receive chiropractic services under the demonstration project.

The Secretary would be required to consult with chiropractors, organizations representing chiropractors, beneficiaries and organizations representing beneficiaries in establishing the demonstration projects. Participation by eligible beneficiaries would be on a voluntary basis. The 6 sites would be equally split between rural and urban areas; at least one of the sites would be in a health professional shortage area. The Secretary would be required to evaluate the demonstration projects to determine (1) whether the participating beneficiaries used fewer Medicare covered services than those who did not participate; (2) the cost of providing such chiropractic services under Medicare; (3) the quality of care and satisfaction of participating beneficiaries; and (4) other appropriate matters.

The Secretary would be required to submit a report, including recommendations, to Congress on the evaluation no later than 1 year after the demonstration projects conclude. The Secretary would waive Medicare requirements as necessary. The demonstration program would be subject to a budget-neutrality requirement. Appropriations from the Federal Supplementary Insurance Trust Fund are authorized as necessary to conduct this demonstration. The provision would be effective upon enactment.

Conference Agreement

The Secretary would be required to establish a 2–year demonstration program at 4 sites to evaluate the feasibility and desirability of covering additional chiropractic services under Medicare. These projects may not be implemented before October 1, 2004. The chiropractic services included in the demonstration shall include, at a minimum, care for neuromusculoskeletal conditions typical among eligible beneficiaries as well as diagnostic and other services that a chiropractor is legally authorized to perform by the State or jurisdiction where treatment occurs. An eligible beneficiary participating in the demonstration project, including those enrolled in Medicare +Choice or Medicare Advantage plans, would not be required to receive approval by physician or other practitioner in order to receive chiropractic services under the demonstration project.

The Secretary would be required to consult with chiropractors, organizations representing chiropractors, beneficiaries and organizations representing beneficiaries in establishing the demonstration projects. Participation by eligible beneficiaries would be on a voluntary basis. The 4 sites would be equally split between rural and urban areas; at least one of the sites would be in a health professional shortage area. The Secretary would be required to evaluate the demonstration projects to determine (1) whether the participating beneficiaries used fewer Medicare covered services than those who did not participate; (2) the cost of providing such chiropractic services under Medicare; (3) the quality of care and satisfaction of participating beneficiaries; and (4) other appropriate matters.

The Secretary would be required to submit a report, including recommendations, to Congress on the evaluation no later than 1 year after the demonstration projects conclude. The Secretary would waive Medicare requirements as necessary. The demonstration program would be subject to a budget-neutrality requirement. Appropriations from the Federal Supplementary Insurance Trust Fund are authorized as necessary to conduct this demonstration.

Demonstration Project to Examine What Weight Loss Weight Management Services

Can Cost-Effectively Reach the Same Result as the NIH Diabetes Primary Prevention Trial Study: A 50 Percent Reduction in the Risk for Type 2 Diabetes for Individuals Who Have Impaired Glucose Tolerance and Are Obese (Section 450I of the Senate Bill).

Present Law

No provision regarding the demonstration. Medicare covers medical nutrition therapy services for beneficiaries with diabetes or a renal disease who (1) have not received diabetes outpatient self-management training services within a time period to be determined by the Secretary, (2) are not receiving maintenance dialysis, and (3) meet other criteria to be established by the Secretary. Nutrition therapy services are nutritional diagnostic, therapy, and counseling services for the purpose of disease management. The services must be provided by a registered dietitian or nutritional professional pursuant to a referral by a physician. Payment is based on the lower of actual charges or 85% of the physician fee schedule on an assignment-related basis.

House Bill

No provision.

Senate Bill

The Secretary would be required to establish a demonstration project that would examine the cost effectiveness and health benefits of providing group weight loss management services for Medicare beneficiaries who are obese and have impaired glucose tolerance. Group weight loss management services are those furnished to beneficiaries who have been diagnosed and referred by a physician for assessment and treatment based on individual needs or a specific program or method that has demonstrated efficacy to produce and maintain weight loss through results published in peer-reviewed scientific journals. The program would be required to provide assessment of current body weight and recording of weight status at each meeting session; provision of a healthy eating plan; provision of an activity plan; provision of a behavior modification plan; and a weekly group support meeting.

Expenditures would be constrained by 2 limitations: the costs of group weight loss management services could not exceed the annual cost per recipient of the medical nutritional therapy benefit and the total amount of payments made under the demonstration could not exceed $2.5 million for each fiscal year of the project. Medical nutrition therapy services that would be furnished under the demonstration project would be covered under part B of Medicare and payment would be 80% of the lesser of the actual charge for the services or 85% of the applicable physician fee schedule amount. Group weight loss management professionals would be paid by Medicare on an assignment-related basis and balance billing would not be permitted.

The demonstration project would be conducted for 2 years at sites designated by the Secretary. The Secretary would be required to give preference to sites located in rural areas or areas that have a high concentration of Native Americans with type 2 diabetes. The Secretary would be required to submit interim reports on this demonstration project to the Committee on Ways and Means and the Committee on Finance. A final report to both Committees would be due 6 months after the date the demonstration project concludes. The provision would be effective upon enactment.

Conference Agreement

No provision.

TITLE VII—PROVISIONS RELATING TO PARTS A AND B

Subtitle A—Home Health Services

Update in Home Health Services (Section 701 of the Conference Agreement and Section 701 of the House Bill).

Present Law

Home health service payments are increased on a federal fiscal year basis that begins in October. The FY 2004 statutory update will be the full increase in the market basket index. The prospective payment system provides for outlier payment B payments for extraordinarily costly cases B with the total amount of outlier payment (the outlier pool) not exceeding 5 percent of estimated total home health prospective payments.

House Bill

This provision would increase home health agency payments by the home health market basket percentage increase minus 0.4 percentage points for 2004 through 2006. The update for subsequent years would be the full market basket percentage increase. The provision would also change the time frame for the update from the federal fiscal year to a calendar year basis. The home health prospective payment rates would not increase for the October 1 through December 31, 2003 period.

Senate Bill

No provision.

Conference Agreement

The conference agreement changes the time frame for the home health update from the federal fiscal year to a calendar year basis beginning with 2004. Home health agency payments are increased by the full market basket percentage for the last quarter of 2003 (October, November, and December) and for the first quarter of 2004 (January, February, and March). The update for the remainder of 2004 and for 2005 and 2006 is the home health market basket percentage increase minus 0.8 percentage points. The size of the outlier pool for home health prospective payment may not exceed 3 percent of the total payment projected under the payment system beginning January 1, 2004, total payments are not increased to account for the difference.

Demonstration Project to Clarify the Definition of Homebound (Section 702 of the Conference Agreement, Section 704 of the House Bill, and Section 450 of the Senate Bill).

Present Law

Home health services are covered only if the Medicare beneficiary is confined to the home, needs skilled nursing care on an intermittent basis or needs physical or occupational therapy or speech-language pathology services, has had a plan of care established that is periodically reviewed by a physician, and is under a physician's care. Any absence of a beneficiary from the home for purposes of receiving health care treatment, including regular absences for participating in therapeutic, psychosocial, or medical treatment in an adult daycare program does not disqualify an individual from being considered confined to the home (or homebound). Further, any other absence of a beneficiary from the home cannot disqualify an individual from being considered homebound if the absence is of infrequent or of relatively short duration.

Absence from the home to attend a religious service is considered an absence of infrequent or short duration.

House Bill

The Secretary would be required to conduct a 2-year demonstration project where beneficiaries with chronic conditions would be deemed to be homebound in order to receive home health services under Medicare. A beneficiary would have to have been certified by a physician to have a permanent and severe condition that will not improve; to permanently need assistance with at least 3 out of the 5 activities of daily living (eating, toileting, transferring, bathing, and dressing); to permanently require skilled nursing services (not including medication management); to need either an attendant during the day to monitor and treat the beneficiary's medical condition or daily skilled nursing; and to require technological assistance or the assistance of another person to leave the home.

The Secretary would be required to select 3 states in which to conduct the demonstration in the northeast, midwest and western regions of the United States. Up to 15,000 beneficiaries would be permitted to participate. Data would be required to be collected regarding the quality of care, patient outcomes, and additional costs, if any to Medicare. The demonstration would be required to begin within 6 months of enactment. Within 1 year of completing the demonstration, the Secretary would be required to report to Congress on whether the subject of the demonstration adversely affected the provision of home health services under Medicare or directly caused an unreasonable increase of expenditures under Medicare; specific data showing any increase in expenditures directly attributable to the demonstration project; and specific recommendations to exempt permanently and severely disabled homebound beneficiaries from restrictions on the length, frequency, and purpose of their absences from the home to qualify for home health services without incurring additional unreasonable costs to Medicare. The provision would be effective upon enactment.

Senate Bill

The Secretary would be required to conduct a 2-year demonstration project where beneficiaries with chronic conditions would be deemed to be homebound in order to receive home health services under Medicare. A beneficiary would have to have been certified by a physician to have a permanent and severe condition that will not improve; to permanently need assistance with at least 3 out of the 5 activities of daily living (eating, toileting, transferring, bathing, and dressing); to permanently require skilled nursing services (not including medication management); to need either an attendant during the day to monitor and treat the beneficiary's medical condition or daily skilled nursing; and to require technological assistance or the assistance of another person to leave the home.

The Secretary would be required to select 3 states in which to conduct the demonstration in the northeast, midwest and western regions of the United States. Up to 15,000 beneficiaries would be permitted to participate. Data would be required to be collected regarding the quality of care, patient outcomes, and additional costs, if any to Medicare. The demonstration would be required to begin within 6 months of enactment. Within 1 year of completing the demonstration, the Secretary would be required to report to Congress on whether the subject of the demonstration adversely effected the provision of home health services under Medicare or directly caused an unreasonable increase of expenditures under Medicare; specific data showing any increase in expenditures directly attributable to the demonstration project; and specific recommendations to exempt permanently and severely disabled homebound beneficiaries from restrictions on the length, frequency, and purpose of their absences from the home to

qualify for home health services without incurring additional unreasonable costs to Medicare. The provision would be effective upon enactment.

Conference Agreement

The Secretary is required to conduct a 2-year demonstration project where beneficiaries enrolled in Medicare Part B with specified chronic conditions would be deemed to be homebound in order to receive home health services under Medicare. A beneficiary is eligible to be deemed to be homebound if the beneficiary: (1) has been certified by a physician to have a permanent and severe condition that is not expected to improve; (2) permanently needs assistance with at least 3 out of the 5 activities of daily living (eating, toileting, transferring, bathing, and dressing); (3) permanently requires skilled nursing services (not including medication management); (4) needs either an attendant during each day to monitor and treat the beneficiary's medical condition or to assist the beneficiary with activities of daily living; (5) requires technological assistance or the assistance of another person to leave the home; and (6) does not regularly work in a paid position full-time or part-time outside the home.

The Secretary is required to select 3 states in the northeast, midwest and western regions of the United States in which to conduct the demonstration. Up to 15,000 beneficiaries can participate. Data must be collected regarding the quality of care, patient outcomes, and additional costs, if any to Medicare. The demonstration is required to begin within 6 months of enactment. Within 1 year of completing the demonstration, the Secretary is required to report to Congress on: whether the subject of the demonstration adversely effected the provision of home health services under Medicare or has directly caused an unreasonable increase of expenditures under Medicare; specific data showing any increase in expenditures directly attributable to the demonstration project; and specific recommendations to exempt permanently and severely disabled homebound beneficiaries from restrictions on the length, frequency, and purpose of their absences from the home to qualify for home health services without incurring additional unreasonable costs to Medicare. Payment for the costs of carrying out the demonstration project will be made from the Part B Trust Fund. The provision is effective upon enactment.

Demonstration Project for Medical Adult Day Care Services (Section 703 of the Conference Agreement, Section 732 of the House Bill, Section 454 of the Senate Bill).

Present Law

No provision

House Bill

Subject to earlier provisions, the Secretary would be required to establish a demonstration project under which a home health agency, directly or under arrangement with a medical adult day care facility, provide medical adult day care services as a substitute for a portion of home health services otherwise provided in a beneficiary's home. Such services would have to be provided as part of a plan for an episode of care for home health services established for a beneficiary. Payment for the episode would equal 95% of the amount that would otherwise apply. In no case would the agency or facility be able to charge the beneficiary separately for the medical adult day care services. The Secretary would reduce payments made under the home health prospective payment system to offset any amounts spent on the demonstration project. The 3-year demonstration project would be conducted in not more than 5 sites (which can include multiple facilities) in states that license or certify providers of medical adult day care services, as selected by the Secretary. Participation of up to 15,000 Medicare beneficiaries would be on a voluntary basis.

When selecting participants, the Secretary would give preference to home health agencies that are currently licensed to furnish medical adult day care services and have furnished such services to Medicare beneficiaries on a continuous basis for a prior 2–year period. A medical adult day care facility would (1) have been licensed or certified by a State to furnish medical adult day care services for a continuous 2–year period; (2) have been engaged in providing skilled nursing services or other therapeutic services directly or under arrangement with a home health agency; and (3) would meet quality standards and other requirements as established by the Secretary. The Secretary would be able to waive necessary Medicare requirements except that beneficiaries must be homebound in order to be eligible for home health services.

The Secretary would be required to evaluate the project's clinical and cost effectiveness and submit a report to Congress no later than 30 months after its commencement. The report would include: (1) an analysis of patient outcomes and comparative costs relative to beneficiaries who receive only home health services for the same health conditions and (2) recommendations concerning the extension, expansion, or termination of the project. The provision would be effective upon enactment.

Senate Bill

Subject to earlier provisions, the Secretary would be required to establish a demonstration project under which a home health agency, directly or under arrangement with a medical adult day care facility, provide medical adult day care services as a substitute for a portion of home health services otherwise provided in a beneficiary's home. Such services would have to be provided as part of a plan for an episode of care for home health services established for a beneficiary. Payment for the episode would equal 95% of the amount that would otherwise apply. In no case would the agency or facility be able to charge the beneficiary separately for the medical adult day care services. The Secretary would reduce payments made under the home health prospective payment system to offset any amounts spent on the demonstration project. The 3- year demonstration project would be conducted in not more than 5 sites in states that license or certify providers of medical adult day care services, as selected by the Secretary. Participation of up to 15,000 Medicare beneficiaries would be on a voluntary basis.

When selecting participants, the Secretary would give preference to home health agencies that are currently licensed to furnish medical adult day care services and have furnished such services to Medicare beneficiaries on a continuous basis for a prior 2–year period. A medical adult day care facility would (1) have been licensed or certified by a State to furnish medical adult day care services for a continuous 2–year period; (2) have been engaged in providing skilled nursing services or other therapeutic services directly or under arrangement with a home health agency; and (3) would meet quality standards and other requirements as established by the Secretary. The Secretary would be able to waive necessary Medicare requirements except that beneficiaries must be homebound in order to be eligible for home health services.

The Secretary would be required to evaluate the project's clinical and cost effectiveness and submit a report to Congress no later than 30 months after its commencement. The report would include: (1) an analysis of patient outcomes and comparative costs relative to beneficiaries who receive only home health services for the same health conditions and (2) recommendations concerning the extension, expansion, or termination of the project. The provision would be effective upon enactment.

Conference Agreement

Subject to earlier provisions in the conference agreement, the conference agreement requires the Secretary to establish a demonstration project under which a home health agency, directly or under arrangement with a medical adult day care facility, provides medical adult day care services as a substitute for a portion of home health services otherwise provided in a beneficiary's home. Such services would be provided as part of a plan for an episode of care for home health services established for a beneficiary. Payment for the episode will equal 95% of the amount that would otherwise apply subject to budget neutrality provisions. The agency or facility is prohibited from charging the beneficiary separately for the medical adult day care services. The Secretary is required to reduce payments made to medical adult day care facilities under the demonstration to offset excess spending. The 3–year demonstration project is to be conducted in not more than 5 sites in states that license or certify providers of medical adult day care services, as selected by the Secretary. Participation of up to 15,000 Medicare beneficiaries is on a voluntary basis.

When selecting participants, the Secretary is required to give preference to home health agencies that are currently licensed to furnish medical adult day care services and have furnished such services to Medicare beneficiaries on a continuous basis for a prior 2–year period. A medical adult day care facility is one that: (1) has been licensed or certified by a State to furnish medical adult day care services for a continuous 2–year period; (2) has been engaged in providing skilled nursing services or other therapeutic services directly or under arrangement with a home health agency; and (3) would meet quality standards and other requirements as established by the Secretary. The Secretary is able to waive necessary Medicare requirements except that beneficiaries must be homebound in order to be eligible for home health services.

The Secretary is required to evaluate the project's clinical and cost effectiveness and submit a report to Congress no later than 6 months after completion of the demonstration. The report is required to include: (1) an analysis of patient outcomes and comparative costs relative to beneficiaries who receive only home health services for the same health conditions, and (2) recommendations concerning the extension, expansion, or termination of the project. The provision is effective upon enactment.

Temporary Suspension of OASIS Requirement for Collection of Data on Non-Medicare and Non-Medicaid Patients (Section 704 of the Conference Agreement, Section 954 in the House Bill, Section 630 in the Senate Bill).

Present Law

Medicare is required to monitor the quality of home health care and services for all patients as part of the survey process with a standardized, reproducible assessment instrument. The purpose of the monitoring is to determine whether the agency is helping all patients achieve and maintain the highest functional capacity that is possible as is reflected in the care plan the home health agency has developed for the patient. Medicare has implemented this requirement

using the Outcomes and Assessment Information Set (OASIS). The OASIS data are used for Medicare payment (under home health prospective payment) and for quality improvement purposes for all patients.

House Bill

The requirement that home health agencies must collect OASIS data on private pay (non-Medicare, non-Medicaid) patients would be suspended until after the Secretary (1) reported to Congress on the benefits of these data, the value of the data compared to the administrative burden of data collection in small agencies, and the use of the OASIS information by both large and small agencies and then (2) published final regulations regarding the collection and use of non-Medicare/non-Medicaid OASIS data. The provision would not prohibit home health agencies from collecting OASIS data on private pay patients for the agencies' own use.

Senate Bill

Same provision.

Conference Agreement

The conference agreement suspends the requirement that home health agencies must collect OASIS data on private pay (non-Medicare, non-Medicaid) until the Secretary (1) reports to Congress on the benefits of these data, the value of the data compared to the administrative burden of data collection in small agencies, and the use of the OASIS information by both large and small agencies, and then (2) publishes final regulations regarding the collection and use of OASIS. The provision does not prohibit home health agencies from collecting OASIS data on private pay patients for the agencies' own use.

MedPAC Study of Medicare Margins of Home Health Agencies (Section 705 of the Conference Agreement and Section 703 of the House Bill).

Present Law

No provision.

House Bill

The provision would require MedPAC to study payment margins of home health agencies paid under the Medicare home health prospective payment system. The study would examine whether systematic differences in payment margins were related to differences in case mix, as measured by home health resource groups (HHRGs). MedPAC would be required to submit a report to Congress on the study within 2 years of enactment.

Senate Bill

No provision.

Conference Agreement

The conference agreement requires MedPAC to study payment margins of home health agencies paid under the Medicare home health prospective payment system, using cost reports filed by agencies. The study is required to examine whether systematic differences in payment margins are related to differences in case mix, as measured by home health resource groups (HHRGs), among agencies. MedPAC is required to submit a report to Congress on the study within 2 years of enactment.

Coverage of Religious Nonmedical Health Care Institution Services Furnished In the Home. (Section 706 of the Conference Report).

Present Law

No provision

House Bill

No provision

Conference Report

A religious nonmedical health care institution can provide home health services to individuals that meet the criteria laid out in 1821.

Increase in Medicare Payment for Certain Home Health Services (Section 451/Duplicative Provisions 459 and 463 of the Senate Bill).

Present Law

Home health PPS provides payment for a 60–day episode of care furnished to a Medicare beneficiary. Medicare's payment is adjusted to reflect the type and intensity of care furnished and area wages as measured by the hospital wage index. BIPA increased PPS payments by 10% for home health services furnished in the home of beneficiaries living in rural areas during the 2-year period beginning April 1, 2001, through March 31, 2003, without regard to certain budget- neutrality provisions applying to home health PPS. The temporary additional payment was not included in the base for determination of payment updates.

Home health PPS is required to make payments for extraordinarily costly cases. The total amount of the outlier payment may not exceed 5% of the total payment estimated to be made for the fiscal year.

House Bill

No provision.

Senate Bill

A 10% additional payment for home health care services furnished in a rural area during FY 2005 and FY 2006 would be provided without regard to certain budget-neutrality requirements. The total amount of outlier payments would be reduced to no more than 3% of total payments in FY 2004 and 4% for FYs 2005 and 2006. The provision would be effective for services furnished on or after October 1, 2003.

Conference Agreement

No provision.

Limitation on Reduction in Area Wage Adjustment Factors under the Prospective Payment System for Home Health Services (Section 452 of the Senate Bill).

Present Law

Home health agencies are paid under Medicare using the prospective payment system. In calculating payment, the portion of the base payment amount that is attributable to wages and wage related costs is required to be adjusted for those costs. The Secretary is required to calculate an area wage adjustment factor that is actually used to adjust the base payment amount. The factors change annually as new wage data are reported and areas change in relative costliness.

House Bill

No provision.

Senate Bill

The provision would limit any reduction in the home health area wage adjustment factor for fiscal years 2005 and 2006. Any reduction could be no more than 3% less than the area wage adjustment factor applicable to home health services for the area in the previous year. The provision would be effective upon enactment.

Conference Agreement

No provision.

Subtitle B—Graduate Medical Education

Extension of Update Limitation on High Cost Programs (Section 711 of the Conference Agreement and Section 711 of the House Bill).

Present Law

Medicare pays hospitals for its share of direct graduate medical education (DGME) costs in approved programs using a count of the hospital's number of full-time equivalent residents and a hospital-specific historic cost per resident, updated for inflation. BBRA changed Medicare's methodology for calculating DGME payments to teaching hospitals to incorporate a national average amount based on FY1997 hospital specific per resident amounts. Starting in FY2001, hospitals received no less than 70% of a geographically adjusted national average amount. BIPA increased this floor to 85% of the locality adjusted, updated, and weighted national PRA starting for cost report periods beginning during FY2002. Hospitals with per resident amounts above 140% of the geographically adjusted national average amount had payments frozen at current levels for FY2001 and FY2002, and in FY2003–FY2005 would receive an update equal to the Consumer Price Index (CPI) increase minus 2 percentage points. Currently, hospitals with per resident amounts between 85% and 140% of the geographically adjusted national average would continue to receive payments based on their hospital-specific per resident amounts updated for inflation.

House Bill

The hospitals with per resident amounts above 140% of the geographically adjusted national average amount would not get an update from FY2004 through FY2013.

Senate Bill

No provision.

Conference Agreement

Hospitals with per resident amounts about 140% of the geographically adjusted national average amount would not get an update from FY2004 through FY20013.

Exception to the Initial Residency Period for Geriatric Residency or Fellowship Programs (Section 712 of the Conference Agreement and Section 410 of the Senate Bill).

Present Law

Medicare counts residents in their initial residency period (the lesser of the minimum number of years required for board eligibility in the physician's specialty or 5 years) as 1.0 FTE. Residents whose training has extended beyond their initial residency period count as 0.5 FTE. Residents in certain specialties are allowed additional years in their initial residency period.

Geriatrics is a subspecialty of family practice, internal medicine and psychiatry. A 1-year fellowship is required for certification in geriatrics, following an initial residency in one of those three areas. The certifying boards agreed to reduce the minimum fellowship requirement from 2 years to 1 year, beginning with the 1998 exam. Those physicians interested in an academic career in geriatrics are encouraged to pursue 2-year and 3-year fellowships.

House Bill

No provision.

Senate Bill

The Secretary would be required to promulgate interim final regulations after notice and comment that establish a 2-year exception to the initial residency program for certain geriatric training programs. The regulations would be effective for cost reporting periods on or after October 1, 2003. The provision would be effective upon enactment.

Conference Agreement

The conference agreement clarifies that Congress intended to provide an exception to the initial residency period for geriatric fellowship programs to accommodate programs that require 2 years of training to initially become board eligible in the geriatric specialty. The Secretary is required to promulgate interim final regulations after notice and comment consistent with this intent after notice and subject to public comment. The regulations will be effective for cost reporting periods on or after October 1, 2003. The conferees also clarify that under section

1886(h) (5)(F), the initial residency period for any residency for which the ACGME requires a preliminary or general clinical year of training is to be determined in the resident's second year of training.

The Conference Committee is pleased that the Secretary has published a proposed rule, on January 12 2001, to provide Medicare payment for clinical psychology internship training programs. The Committee notes that Congress has consistently urged the Secretary to initiate payment for the training of clinical psychologists since 1997 and still awaits a final rule.

The Committee is concerned that delay in the rules will mean that hospitals and institutions will continue to reduce or eliminate psychology training programs as has been occurring in recent years to the detriment of Medicare beneficiaries. The Committee directs implementation of the rule within six months of the date of enactment of the law to which this report is attached. The Committee notes that clinical psychologists provide valuable and unique services to Medicare beneficiaries during their training. Regarding their training, clinical psychologists are distinguishable from other health care professionals in that they are the only doctoral level mental health professionals fully participating in Medicare whose clinical training is not currently reimbursed. In addition, their clinical internship training is entirely controlled, administered, supervised, evaluated, and certified by the hospital or institution, separately accredited, and distinct from any university training they receive. Clinical psychologists are hospital-based in the final stages of their training function in a parallel status to medical interns and residents, not medical nursing or health professional students. Where a clinical psychologist has clearly finished his or her educational curriculum and is training solely in the hospital setting, it is the intention of Congress that the hospital be reimbursed if that training is hospital-based.

Authority to Include Costs of Training of Psychologists in Payments to Hospitals Under Medicare (Section 408 of the Senate).

Present Law

Medicare pays hospitals for its share of direct costs associated with approved hospital-based training programs for nurses and certain other allied health professionals including inhalation therapists, nurse anesthetists, occupational and physical therapists. Medicare will not pay for such costs associated with psychologists' training.

House Bill

No provision.

Senate Bill

Medicare would reimburse its share of the reasonable costs of approved education activities of psychologists under the allied health professional training provisions. The provision would apply for cost reporting periods beginning on or after October 1, 2004.

Conference Agreement

No provision.

Clarification of Congressional Intent Regarding the Counting of Residents in a Non-provider Setting and a Technical Amendment Regarding the 3-year Rolling Ratio and the IME Ratio (Section 411 of the Senate Bill).

Present Law

Medicare has different resident limits for counting residents its indirect medical education (IME) adjustment and for reimbursement for a teaching hospital's direct medical education (DGME) costs. Generally, a hospital's IME adjustment depends on a hospital's teaching intensity as measured by the ratio of the number of interns and residents per bed (the IRB ratio). Prior to BBA 1997, the number of residents that could be counted for IME purposes included only those in the hospital inpatient and outpatient departments. Effective October 1, 1997, under certain circumstances, a hospital may now count residents in non-hospital sites for the purposes of IME. Medicare's DGME payment to teaching hospital is based on its updated cost per resident (subject to a locality adjustment and certain payment corridors), the weighted number of approved full-time-equivalent (FTE) residents, and Medicare's share of inpatient days in the hospital. Medicare counts residents in their initial residency period (the lesser of the minimum number of years required for board eligibility in the physician's specialty or 5 years) as 1.0 FTE. Residents whose training has extended beyond their initial residency period count as 0.5 FTE. Residents in certain specialties are allowed additional years in their initial residency period. Residents who are graduates from foreign medical schools do not count unless they pass certain exams.

Generally, the resident counts for both IME and DGME payments are based on the number of residents in approved allopathic and osteopathic teaching programs that were reported by the hospital for the cost reporting period ending in calendar year 1996. The DGME resident limit is based on the unweighted resident counts. It may differ from the IME limit because in 1996 residents training in non-hospital sites were eligible for DGME payments but not for IME payments. Hospitals that established new training programs before August 5, 1997 are partially exempt from the cap. Other exceptions apply to certain hospitals including those with new programs established after that date. Hospitals in rural areas (and non-rural hospitals operating training programs in rural areas) can be reimbursed for 130% of the number of residents allowed by their cap. Under certain conditions, an affiliated group of hospitals under a specific arrangement may combine their resident limits into an aggregate limit.

Subject to these resident limits, a teaching hospital's IME and DGME payments are based on a 3-year rolling average of resident counts, that is, the resident count will be based on the average of the resident count in the current year and the 2 preceding years. The rolling average calculation includes podiatry and dental residents. If a hospital is above its limit, the count for the purposes of the rolling average is the FTE cap. In addition to the resident limit, BBA 1997 also places a limit on the IRB ratio itself. A hospital's IRB ratio used to calculate its IME adjustment for the current payment year cannot exceed its IRB ratio from the immediately preceding cost reporting period.

CMS has published regulations that limit Medicare's graduate medical payments when existing residents are transferred from a non-hospital entity to a teaching hospital, particularly when the non-hospital entity has historically paid for the training costs without hospital funding. CMS seeks to limit reimbursement to those residents that rotate from a hospital setting to non-hospital sites in order to (1) encourage hospitals to broaden physician training in ways that will encompass different primary care settings; and (2) prevent cost shifting from existing support within the community to Medicare.

House Bill

No provision.

Senate Bill

The Secretary would be required to reimburse teaching hospitals for residents in non-hospital locations, when hospitals incur all, or substantially all, the costs of the training in that site starting from the effective date of a written agreement between the hospital and the entity owning or operating the non-hospital site. The effective date of the written agreement would be determined according to generally accepted accounting principles. The Secretary would not be able to take into account the fact that the hospital costs incurred are lower than actual Medicare reimbursement. Starting for FY2004, dental and podiatric residents would be removed from the 3-year rolling average calculation for IME and DGME reimbursements. The provision would be effective upon enactment.

Conference Agreement

For 12 months as of January 1, teaching hospitals can count residents in non-hospital locations regardless of the financial arrangement between the hospital and the teaching physician at the nonhospital clinic site participating in a family practice program. Provisions regarding the payment of IME and DME for training in non-hospital sites that were included in the Balanced Budget Act of 1997 Congress were intended to encourage placement of residents in rural and other underserved areas and in ambulatory sites that are more in alignment with the types of practice they would have upon practice. The purpose was two-fold: to increase access to care by increasing the numbers of residents training in those settings, and to increase the likelihood of physicians placing themselves in practice in rural and underserved areas.

For programs established after January 1, 2002, the Secretary shall clarify in future regulation its definition of reasonableness of payment for supervisory physicians.

The Secretary shall initiate a study on the training of residents in non-hospital settings, and the use of volunteer faculty in those settings. The study is due within six months of enactment. The study shall include the following:

Examination of the effect of the change in the BBA that allowed payment by Medicare for graduate medical education in non-hospital settings, to include whether access and numbers of physicians placing in rural and underserved areas has increased.

Examination of programs on a national level regarding evidence of possible misuse of federal money with respect to volunteering supervisory physicians.

A determination whether supervisory physicians are freely volunteering their time.

A description of what incentives are available in each state that are offered to physicians who volunteer their time as supervisory physicians (eg. CME credit hours, hospital privileges, etc.)

Subtitle C—Chronic Care Improvement

Voluntary Chronic Care Improvement Under Traditional Fee-For-Service (Section 721 of the Conference Agreement, Section 721 of the House Bill, and Section 442 of the Senate Bill).

Present Law

No provision.

A hearing was held by the Ways and Means Committee, Health Subcommittee on February 25, 2003 on the importance of providing chronic care management in fee-for-service Medicare. Statistics from the Robert Wood Johnson Foundation state 84% of Medicare beneficiaries have one or more chronic conditions and account for 95% of Medicare spending. With Americans living longer due to advances in medical procedures and increased availability to medications, Medicare costs will continue to escalate. Thus, chronic care programs should be implemented in both traditional fee-for-service and private plans to target these individuals, improve health outcomes and save money.

The Centers for Medicare & Medicaid Services (CMS) has run demonstration programs in the Medicare program targeting high cost seniors. Currently, CMS is managing more than a dozen disease management demonstration projects. The BBA allowed for the continuation of demonstration projects that were cost-effective, improved quality of care and patient/beneficiary satisfaction. These demonstration sites enrolled more than 7,600 Medicare beneficiaries. CMS has also started on disease management demonstrations authorized by BIPA of 2000, to provide disease management services to Medicare beneficiaries with congestive heart failure, diabetes, or coronary heart disease. CMS estimates that enrollment will include around 30,000 Medicare beneficiaries. BIPA also required a physician group demonstration to encourage coordination and reward physicians for improving beneficiary health outcomes. CMS has demonstrated significant progress in integrating chronic care management programs into fee-for-service Medicare and HMOs. The following provision would increase the number of chronic care management programs (also known as disease management programs) in fee-for-service Medicare, with the intention of expanding these programs nationwide if health outcomes improve and Medicare costs decrease.

Additionally, a 1999 survey showed 56% of employers offer disease management services to their employees, along with 67% of HMOs and 64% of POS plans. Private plans continue to offer disease management programs to reduce costs, improve health outcomes, and increase patient and provider satisfaction. Because many of these health plans offer chronic care management programs already, it is important to require Medicare Advantage to offer these programs, as well.

House Bill

The Secretary would be required to establish a process for providing chronic care improvement programs for Medicare beneficiaries in fee-for-service Medicare (Parts A and B) who have certain chronic conditions such as congestive heart failure, diabetes, chronic obstructive pulmonary disease (COPD), stroke or other diseases identified by the Secretary for inclusion in the program. The Secretary would establish administrative regions (called CCMA regions) within the United States for the chronic care improvement programs. Within each region, the Secretary would select at least two contractors under a competitive bidding process on the basis of the ability of each bidder to achieve improved health outcomes of beneficiaries and improved financial outcomes of the Medicare program. A contractor could be a disease improvement organization, health insurer, provider organization, a group of physicians, or any other legal entity that the Secretary determines appropriate. Contractors would be required to meet certain clinical, quality improvement, financial, and other requirements specified by the Secretary. Subcontractors could be used by the contractors. The Secretary would be able to phase-in implementation of the program beginning one year after enactment.

Each program would be required to have a method for identifying targeted Medicare beneficiaries who would be offered participation in the program. The Secretary would be required to assist the program in identifying beneficiaries. Each beneficiary would be assigned to only one contractor that would be responsible for guiding beneficiaries in managing their health, including all co-morbidities. Initial contact with a Medicare beneficiary would be from the Secretary who would provide information about the program, a description of advantages in participating, notification that the contractor could contact the beneficiary directly concerning participation, the voluntary nature of program participation, and a means to decline participation or decline being contacted by the program. Each program would be required to develop an individualized, goal-oriented chronic care improvement plan with the beneficiary. The chronic care improvement plan would be required to contain: a single point of contact to coordinate care; self-improvement education for the individual and support education for health care providers, primary caregivers, and family members; coordination between prescription drug benefits, home health, and other health care services; collaboration with physicians and other providers to enhance communication of relevant clinical information; the use of monitoring technologies, where appropriate; and information about hospice care, pain and palliative care, and end-of-life care, as appropriate. In developing the chronic care improvement plan, programs would be required to use decision support tools such as evidence-based practice guidelines to track and monitor each beneficiary across care settings and evaluate outcomes using a clinical information database. The program would be required to meet any additional requirements that the Secretary finds appropriate. Programs that have been accredited by qualified organizations would be deemed to have met such requirements as specified by the Secretary.

Contractor payments for each chronic care improvement program would be required to result in Medicare program outlays that would otherwise have been incurred in the absence of the program for the three-year contract period. The Secretary would be required to assure that there would be no net aggregate increase in Medicare payments, in entering into a contract for the program over the 3-year period, including program outlays, administrative expenses (that would not have been paid under Medicare without this demonstration), and contractor fees. Contracts for chronic care improvement programs would be treated as a risk-sharing arrangement. In addition, payment to contractors would be subject to the contractor meeting clinical and financial performance standards established by the Secretary.

Program contractors would be required to report to the Secretary on the quality of care and efficacy of the program in terms of process measures (such as reductions in errors of treatment and rehospitalization rates), beneficiary and provider satisfaction, health outcomes, and financial outcomes. The Secretary would be required to submit to Congress annual reports on the program including information on progress made toward national coverage, common delivery models, and information on improvements in health outcomes as well as financial efficiencies resulting from the program. The Secretary would also be required to conduct a randomized clinical trial to assess the potential for cost reductions under Medicare by comparing costs of beneficiaries enrolled in chronic care improvement programs and beneficiaries who are eligible to participate but are not enrolled.

Appropriations of such sums as necessary to provide for contracts with chronic care improvement programs would be authorized from the Medicare Trust Funds, but in no case would the funding be permitted to exceed $100 million over 3 years.

The provision would be effective upon enactment and the Secretary would be required to begin implementing the chronic care improvement programs no later than 1 year after enactment.

Senate Bill

No provision.

Conference Agreement

The conference agreement requires the Secretary to establish and implement chronic care improvement programs. If the programs are established, they are required to improve clinical quality and beneficiary satisfaction and achieve spending targets for Medicare for beneficiaries with certain chronic health conditions.

The chronic care improvement (CCI) program is required to (1) have a process to screen each targeted beneficiary for conditions other than the specified chronic conditions, such as impaired cognitive ability and co-morbidities, in order to develop an individualized, goal-oriented care management plan; (2) provide each targeted beneficiary participating in the program with the care management plan; and (3) carry out the plan and other chronic care improvement activities. The care management plan is required to be developed with the beneficiary and, to the extent appropriate, include: (1) a designated point of contact responsible for communications with the beneficiary and for facilitating communications with other health care providers; (2) self-care education for the beneficiary (through approaches such as disease management or medical nutrition therapy) and education for primary caregivers and family members; (3) education for physicians and other providers and collaboration to enhance communication of relevant clinical information; (4) the use of monitoring technologies that enable patient guidance through the exchange of pertinent clinical information, such as vital signs, symptomatic information, and health self-assessment; and (5) the provision of information about hospice care, pain and palliative care, and end-of-life care. To the extent that a care management plan includes medical nutrition therapy, such services should be delivered by a registered dietician or nutrition professional as defined in Section 1861 of the Social Security Act (42 U.S.C. 1395x.)

The Secretary is required to develop a method for identifying targeted beneficiaries who may benefit from participation in a chronic care improvement program and to communicate with the targeted beneficiary regarding the opportunity to participate. Targeted beneficiaries who are eligible to participate cannot be enrolled in a plan under Medicare Part C and must have one or more of the threshold conditions including: congestive heart failure, diabetes, chronic obstructive pulmonary disease (COPD), or other diseases or conditions specified by the Secretary. Beneficiary participation is voluntary.

In carrying out the care management plan, the chronic care improvement organization is required to: (1) guide the participant in managing the participant's health (including all co-morbidities, relevant health care services, and pharmaceutical needs) and in performing activities as specified under the elements of the care management plan of the participant; (2) use decision-support tools such as evidence-based practice guidelines or other criteria as determined by the Secretary; and (3) develop a clinical information database to track and monitor each participant across settings and to evaluate outcomes.

The establishment of the chronic care improvement program is conducted in 2 parts. In phase I, the developmental phase, the Secretary is required to enter into contracts with chronic care improvement organizations for the development, testing, and evaluation of chronic care improvement programs using randomized controlled trials. The first contract is required 12 months after enactment for a 3-year period. The Secretary is required to enter into contracts to ensure

that chronic care improvement programs cover geographic areas in which at least 10 percent of Medicare beneficiaries reside. The Secretary is further required to ensure that each chronic care improvement program includes at least 10,000 targeted beneficiaries along with a sufficient number of Medicare beneficiaries to serve as a control group. The Secretary is required to contract for an independent evaluation of each chronic care improvement program. The evaluation is required to include quality improvement measures, such as adherence to evidence-based guidelines and rehospitalization rates; beneficiary and provider satisfaction; health outcomes; and financial outcomes, including any cost savings to Medicare.

If the Secretary finds that the chronic care improvement programs have improved the clinical quality of care, improved beneficiary satisfaction, and achieved specified spending targets, then the Secretary is required to expand the program to additional geographic areas not covered during phase I. Phase II may include national expansion of the program and is required to begin no later than 6 months after the completion of phase I (nor earlier than 2 years after phase I began). The Secretary is also required to evaluate phase II programs using the same criteria used in the phase I evaluation.

Chronic care improvement organizations are required to monitor and report to the Secretary on health care quality, cost, and outcomes, in a time and manner specified by the Secretary. The organizations are also required to comply with any additional requirements the Secretary may specify. The Secretary may deem chronic care improvement organizations which are accredited by qualified organizations to have met requirements that the Secretary may specify.

The Secretary is not permitted to contract with an organization to operate a chronic care improvement program unless the organization meets the requirements for a chronic care improvement program and such clinical, quality improvement, financial, and other requirements as the Secretary deems to be appropriate for the target beneficiaries to be served; and the organization demonstrates (to the satisfaction of the Secretary) that it is able to assume financial risk for performance under the contract. Each contract is required to specify performance standards for each of the specified evaluation factors including clinical quality and Medicare spending targets, against which the performance of the chronic care improvement organization under the contract is measured. Contractual adjustments are required if the contractor fails to meet specified performance standards. Further, the contract is required to provide for full recovery by the government of any amount by which the fees paid to the contractor exceed the estimated savings to Medicare that are attributable to the implementation of the contract. The Secretary is required to ensure that aggregate Medicare benefit expenditures for targeted beneficiaries participating in the chronic care improvement program do not exceed estimated Medicare expenditures for a comparable population in the absence of such a program.

Appropriations of such sums as necessary to provide for contracts with chronic care improvement programs would be authorized from the Medicare Trust Funds, but in no case would the funding be permitted to exceed $100 million over 3 years, beginning October 1, 2003.

The Secretary is required to submit an interim report to Congress on the scope of implementation of the program, the design of the programs, and the preliminary cost and quality findings based on the evaluation criteria no later than 2 years after implementation. No later than 3½ years after implementation, the Secretary is required to submit an update to the interim report to Congress. The Secretary is further required to submit to Congress 2 additional biennial reports on the chronic care improvement programs. The first is due no later than 2 years after the update report.

Medicare Advantage Quality Improvement Programs (Section 722 of the House Bill and Sections 202 and 442 of the Senate Bill)

Present Law

Under the Medicare+Choice program, organizations are required to have quality assurance programs that include measuring outcomes, monitoring and evaluating high volume and high risk services and the care of acute and chronic conditions, and evaluating the effectiveness of the efforts.

House Bill

Each Medicare Advantage plan offered would be required to have a chronic care improvement program for enrollees with multiple or sufficiently severe chronic conditions such as congestive heart failure, diabetes, chronic obstructive pulmonary disease (COPD), stroke, prostate and colon cancer, hypertension, or other disease identified by the Secretary. The program would be required to have a method for monitoring and identifying enrollees with multiple or sufficiently severe chronic conditions and to develop with an enrollee's consent an individualized, goal-oriented chronic care improvement plan.

The chronic care improvement plan would be required to include: a single point of contact to coordinate care; self-improvement education for the individual and support education for health care providers, primary caregivers, and family members; coordination between prescription drug benefits, home health, and other health care services; collaboration with physicians and other providers to enhance communication of relevant clinical information; the use of monitoring technologies, where appropriate; and information about hospice care, pain and palliative care, and end-of-life care, as appropriate. In developing the chronic care improvement plan, programs would be required to use decision support tools such as evidence-based practice guidelines track and monitor each beneficiary across care settings and evaluate outcomes using a clinical information database. The program would be required to meet any additional requirements that the Secretary finds appropriate. Programs that have been accredited by qualified organizations would be deemed to have met such requirements as specified by the Secretary.

Each Medicare Advantage organization would be required to report to the Secretary on the quality of care and efficacy of the chronic care improvement program in terms of process measures (such as reductions in errors of treatment and rehospitalization rates), beneficiary and provider satisfaction, health outcomes, and financial outcomes. The provision would apply for contract years beginning on or after one year after enactment.

Senate Bill

The quality assurance program for Medicare Advantage plans would be required to provide access to disease management and chronic care services and to provide access to preventive benefits and information for enrollees on the benefits in addition to current quality assurance requirements.

The Secretary would be required to establish a demonstration program that uses qualified care management organizations to provide health risk assessment and care management services to Medicare beneficiaries that are at high-risk (as defined by the Secretary but including beneficiaries with multiple sclerosis or other disabling chronic conditions, nursing home residents or beneficiaries at risk for nursing home placement, or beneficiaries that are also eligible for Medicaid). The Secretary would select 6 sites, giving preference to sites located in rural areas. The demonstration program would last 5 years but would not be implemented before October 1, 2004.

Any high-risk beneficiary residing in a designated area who is not a member of a Medicare+Choice plan may participate if the beneficiary identifies a care management organization that agrees to furnish care management services to the beneficiary under the demonstration program. The Secretary would be required to contract with care management organizations to provide care management services to beneficiaries eligible to participate in the demonstration. The Secretary may contract with more than one care management organization in a geographic area.

The Secretary would pay the care management organization a fee that is based on bids submitted by care management organizations. The fee would be required to place the care management organization partially at risk. Payment of the full fee would depend upon the care management organization meeting benchmarks for quality and cost. The Secretary may cancel a contract with a care management organization if the organization does not meet negotiated savings or quality outcome targets for the year. Aggregate payments by Medicare could not exceed the amount that would otherwise have been paid if the demonstration program had not been implemented. The Secretary would be required to report to Congress six months after the completion of the demonstration on the program. The provision would be effective upon enactment.

Conference Agreement

The conference agreement requires each Medicare Advantage organization to have an on-going quality improvement program for improving the quality of care provided to enrollees (except for private fee-for-service plans or MSA plans) effective for contract years beginning January 1, 2006. As part of the quality improvement program, each MA organization is required to have a chronic care improvement program. Each chronic care improvement program is required to have a method for monitoring and identifying enrollees with multiple or sufficiently severe chronic conditions that meet criteria established by the organization for participation under the program.

Each MA organization is required to provide for the collection, analysis and reporting of data that permit measurement of health outcomes and other indicators of quality. The Secretary will establish through regulation appropriate reporting requirements for regional PPOs. The Secretary is permitted to change the types of data that are required of plans only after submitting to Congress a report on the reasons for the changes that was prepared in consultation with MA plans and private accrediting bodies. The Secretary is not permitted to collect data on quality, outcomes, and beneficiary satisfaction for the purposes of consumer choice and program administration if the data were not already being collected as of November 1, 2003. However, these provision regarding data are not to be construed as restricting the ability of the Secretary to carry out the comparative information dissemination provisions regarding plan quality and performance that are contained in section 1851(d)(4)(D).

The conference agreement also provides that MA organizations are deemed to meet

the quality improvement program requirements as the Secretary determines to be appropriate if the MA organization is accredited (and periodically reaccredited) by a private accrediting organization under a process that the Secretary has determined ensures that the accrediting organization applies and enforces standards that meet or exceed the standards established by the Secretary.

Chronically Ill Medicare Beneficiary Research, Data, Demonstration Strategy (Section 723 of the Conference Agreement).

Present Law

No provision.

House Bill

No provision.

Senate Bill

No provision.

Conference Agreement

The conference agreement requires the Secretary to develop a plan to improve quality of care and to reduce the cost of care for chronically ill Medicare beneficiaries within 6 months after enactment. The plan is required to use existing data and identify data gaps, develop research initiatives, and propose intervention demonstration programs to provide better health care for chronically ill Medicare beneficiaries. The plan is required to: (1) integrate existing datasets including the Medicare Current Beneficiary Survey, the Minimum Data Set, the Outcome and Assessment Information Set, data from the Quality Improvement Organizations, and claims data; (2) identify any new data needs and a methodology to address new data needs; (3) plan for the collection of such data in a data warehouse; and (4) develop a research agenda using the data. In developing the plan, the Secretary is required to consult with experts in the fields of care for the chronically ill (including clinicians) and is required to enter into contracts with appropriate entities for the development of the plan. The Secretary is required to implement the plan no later than 2 years after enactment. Appropriations are authorized from amounts in the Treasury not otherwise appropriated, such sums as may be necessary in fiscal years 2004 and 2005 to carry out this provision.

Subtitle D—Other Provisions

Improvements in the National and Local Coverage Determination Process to Respond to Changes in Technology (Section 731 of the Conference Agreement, Section 733 of the House Bill, and Sections 458 and 554 of the Senate Bill).

Present Law

Coverage Determinations. Under administrative authorities, CMS announced in March 2003 the establishment of a technology council charged with improving Medicare coverage, coding and payment for emerging technologies. Council membership includes senior CMS staff.

Clinical Trials. No explicit statutory authorization regarding category A clinical trials. Under existing authorities, Medicare covers the routine costs of qualifying clinical trials which includes items or services typically provided absent a clinical trial and items or services needed for the diagnosis or treatment of complications. Medicare does not pay for certain aspects of the clinical trial including: the investigational item or service, items and services not used in the direct clinical management of the patient, and items and services customarily provided by the research sponsor free of charge for any enrollee in the trial.

Coding. The Secretary issues temporary national Health care Common Procedure Coding System (HCPCS) codes under Medicare Part B that are used until permanent codes are established.

House Bill

Coverage. The Secretary would be required to make available to the public the factors considered in making national coverage determinations of whether an item or service is reasonable and necessary. The Secretary would be required to develop guidance documents similar to those required by the Federal Food, Drug and Cosmetic Act (21 U.S.C. 371(h)). The provision would establish a time frame for decisions regarding national coverage determinations of 6 months after a request when a technology assessment is not required and 9 months when a technology assessment is required and in which a clinical trial is not requested.

Following the 6- or 9-month period, the Secretary would be required to make a draft of the proposed decision available in the HHS website or by other means; to provide a 30-day public comment period; to make a final decision on the request within 60 days following the conclusion of the public comment period; make the clinical evidence and data used in making the decision available to the public when the decision differs from the recommendations of the Medicare Coverage Advisory Committee; and in the case of a decision to grant the coverage determination, assign a temporary or permanent code and implement the coding change. In instances where a request for a national coverage determination is not reviewed by the Medicare Coverage Advisory Committee, the Secretary would be required to consult with appropriate outside clinical experts.

The Secretary would also be required to develop a plan to evaluate new local coverage determinations to decide which local decisions should be adopted nationally and to decide to what extent greater consistency can be achieved among local coverage decisions, to require the Medicare contractors within an area to consult on new local coverage policies, and to disseminate information on local coverage determination among Medicare contractors to reduce duplication of effort. The provision would be effective for determinations as of January 1, 2004.

Clinical Trials. Medicare would cover the routine costs of care for beneficiaries participating in clinical trials that are conducted in accordance with an investigational device exemption approved under section 530(g) of the Federal Food, Drug, and Cosmetic Act. The provision would be effective for clinical trials begun before, on, or after the date of enactment and to items and services furnished on or after enactment.

Coding. The Secretary would be required to implement revised procedures for the issuance of temporary national HCPCS codes by January 1, 2004. The provision would further require the Secretary to use data reflecting prices and costs of products in the United States in setting payment rates. The provision would be effective upon enactment.

Senate Bill

Coverage. The provision would establish a time frame for decisions regarding national coverage determinations of 6 months after a request when a technology assessment is not required and 9 months when a technology assessment is required and in which a clinical trial is not requested. Following the 6- or 9-month period, the Secretary would be required to make a draft of the proposed decision available in the HHS website or by other means; to provide a 30-day public comment period; to make a final decision on the request within 60 days following the conclusion of the public comment period; make the clinical evidence and data used in making the decision available to the public when the decision differs from the recommendations of the Medicare Coverage Advisory Committee; and in the case of a decision to grant the coverage determination, assign a temporary or permanent code and implement the coverage decision at the end of the 60-day period. The provision would apply to national coverage determinations as of January 1, 2004.

The Secretary would be required to establish a Council for Technology and Innovation composed of senior CMS staff and clinicians to coordinate coverage, coding, and payment processes under Title XVIII and the exchange of information on new technologies between CMS and other entities that make similar decisions. The provision would be effective upon enactment.

Clinical Trials. The routine costs of care for Medicare beneficiaries participating in clinical trials that are conducted in accordance with an investigational device exemption approved under Senate Section 530(g) of the Federal Food, Drug, and Cosmetic Act would be covered. This provision would not require the Secretary to modify the existing regulations and cover the cost of a medical device that is the subject of an investigational device exemption by the Food and Drug Administration. The Secretary would be required to ensure that total Medicare expenditures associated with this provision do not exceed: $32 million in 2005; $34 million in 2006; $36 million in 2007; $38 million in 2008; $40 million in 2009; $42 million in 2010; $44 million in 2011; $48 million in 2012; and $50 million in 2013. The Secretary would be required to take appropriate steps to stay within these funding limitations, including limiting the number of clinical trials covered and paying for only a portion of the associated routine costs. The provision would be effective for clinical trials begun before, on, or after the date of enactment and to items and services furnished on or after January 1, 2005.

Coding. No provision.

Conference Agreement

Coverage. The conference agreement requires the Secretary to make available to the public the factors considered in making national coverage determinations of whether an item or service is reasonable and necessary. The Secretary is required to develop guidance documents similar to those required by the Federal Food, Drug and Cosmetic Act (21 U.S.C. 371(h)). The provision establishes a timeframe for decisions regarding national coverage determinations of 6 months after a request when a technology assessment is not required and 9 months when a technology assessment is required and in which a clinical trial is not requested.

Following the 6- or 9-month period, the Secretary is required to make a draft of the proposed decision available in the HHS website or by other means; to provide a 30-day public comment period; to make a final decision on the request with 60 days following the conclusion of the public comment period; make the clinical evidence and data used in making the decision available to the public when the decision differs from the recommendations of the Medicare Coverage Advisory Committee; and in the case of a decision to grant the coverage determination, assign a temporary or permanent code and implement the coding change. In instances where a request for a national coverage determination is not reviewed by the Medicare Coverage Advisory Committee, the Secretary is required to consult with appropriate outside clinical experts.

The Secretary is also required to develop a plan to evaluate new local coverage determinations to decide which local decisions should be adopted nationally and to decide to what extent greater consistency can be achieved among local coverage decisions, to

require the Medicare contractors within an area to consult on new local coverage policies, and to disseminate information on local coverage determination among Medicare contractors to reduce duplication of effort. The provision is effective for national determinations as of January 1, 2004 and for local coverage determinations made on or after July 1, 2004.

Clinical Trials. The conference agreement prohibits the Secretary from excluding from Medicare coverage the routine costs of care incurred by a Medicare beneficiary participating in a category A clinical trial, beginning with routine costs incurred on and after January 1, 2005. The conference agreement makes clear that this provision does not apply to, or affect, Medicare coverage or payment for a non-experimental/investigational (category B) device.

Coding. The conference agreement requires the Secretary to implement revised procedures for issuing temporary national HCPCS codes under Medicare Part B no later than July 1, 2004.

Extension of Treatment for Certain Physician Pathology Services Under Medicare (Section 732 of the Conference Agreement, Section 734 of the House Bill, and Section 435 of the Senate Bill).

Present Law

In general, independent laboratories cannot directly bill for the technical component of pathology services provided to Medicare beneficiaries who are inpatients or outpatients of acute care hospitals. BIPA permitted independent laboratories with existing arrangements with acute care hospitals to bill Medicare separately for the technical component of pathology services provided to the hospitals' inpatients and outpatients. The arrangement between the hospital and the independent laboratory had to be in effect as of July 22, 1999. The direct payments for these services apply to services furnished during a 2-year period starting on January 1, 2001 and ending December 31, 2002.

House Bill

Medicare would make direct payments for the technical component of pathology services furnished to beneficiaries who are inpatients or outpatients of acute care hospitals on or after January 1, 2004 until December 31, 2008. A change in hospital ownership would not affect these direct billing arrangements. The provision would be effective as if it had been included in BIPA.

Senate Bill

Direct payments for the technical component for these pathology services would be made for services furnished during 2005. The provision would be effective upon enactment.

Conference Agreement

Direct payments for the technical component for these pathology services will be made for services furnished during 2005 and 2006.

Payment for Pancreatic Islet Cell Investigational Transplants for Medicare Beneficiaries in Clinical Trials (Section 733 of the Conference Agreement, Section 735 of the House Bill, and Section 462 of the Senate Bill).

Present Law

No explicit statutory authorization. Under existing authorities, Medicare covers the routine costs of qualifying clinical trials which includes items or services typically provided absent a clinical trial and items or services needed for the diagnosis or treatment of complications. Medicare does not pay for certain aspects of the clinical trial including: the investigational item or service, items and services not used in the direct clinical management of the patient, and items and services customarily provided by the research sponsor free of charge for any enrollee in the trial.

House Bill

Medicare would be required to pay for the routine costs for items and services that beneficiaries receive as part of a clinical investigation of pancreatic islet cell transplants conducted by the National Institute of Health. The provision would be effective upon enactment.

Senate Bill

The Secretary would be required to establish a 5-year demonstration project to pay for pancreatic islet cell transplantation and related items and services for Medicare beneficiaries who have type 1 diabetes and end-stage renal disease. The Secretary would be required to establish an appropriate methodology to pay for the items and services furnished under the demonstration. A report to Congress would be required on the project 4 months after the demonstration ends. The provision would be effective upon enactment.

Conference Agreement

The conference agreement requires the Secretary, acting through the National Institute of Diabetes and Digestive and Kidney Disorders, to conduct a clinical investigation of pancreatic islet cell transplantation which includes Medicare beneficiaries. Beginning no earlier than October 1, 2004, the Secretary is required to pay for the routine costs as well as transplantation and appropriate related items and services for Medicare beneficiaries who are participating in such a trial.

In implementing the clinical investigation of pancreatic islet cell transplantations, CMS, in working with NIH, should ensure that a sufficient number of Medicare beneficiaries participate so that the results are applicable to the broader Medicare population with Type 1 diabetes and Medicare is able to make an informed decision regarding coverage of pancreatic islet transplantation.

Restoration of Trust Funds (Section 734 of the Conference Agreement and Section 623 of the Senate Bill).

Present Law

The Federal Hospital Insurance (HI) Trust Fund was established on July 30, 1965 as a separate account in the U.S. Treasury. All of the HI financial operations are handled through this fund. The trust fund's primary source of income consists of amounts appropriated to it, under permanent authority, on the basis of taxes paid by workers, their employers, and individuals with self-employment income. Up to 85% of an individual or a couples Old Age and Survivors, Disability Insurance (OASDI) benefits may be subject to federal income taxation if their income exceeds certain thresholds. The income tax revenue attributable to the first 50% of the OASDI benefits is allocated to the OAS and DI trust funds. The revenue associated with the amount between 50% and 85% is allocated to the HI trust funds. An incorrect amount of income from the taxation of OASDI benefits was transferred into the HI Trust Fund in April 2001, because of clerical error. An additional amount was transferred into the HI Trust Fund in December, 2001 to correct for the principal component of the error. Correction of the interest component associated with the clerical error requires legislation.

House Bill

No provision.

Senate Bill

After consultation with the Secretary of HHS, the Secretary of the Treasury would be required to transfer into the HI Trust fund an amount that would have been held by that fund if the clerical error had not occurred within 120 days of enactment.

Conference Agreement

The conference agreement requires the Secretary of the Treasury to transfer into the HI Trust Fund an amount that would have been held by that fund if the clerical error had not occurred. Such money is appropriated to the HI Trust Fund. The appropriation is made and transfer is required within 120 days of enactment of this Act. In the case of a clerical error that occurs after April 15, 2001, the Secretary of the Treasury is required to notify the appropriate committees of Congress about the error and the actions to be taken, before such action is taken.

Modifications to Medicare Payment Advisory Commission (MedPAC) (Section 735 of the Conference Agreement and Section 731 of the House Bill).

Present Law

The Medicare Payment Advisory Commission is a 17-member body that reports and makes recommendations to Congress regarding Medicare payment policies. The Comptroller General is required to establish a public disclosure system for Commissioners to disclose financial and other potential conflicts of interest.

House Bill

MedPAC would be required to examine the budgetary consequences of a recommendation before making the recommendation and to review the factors affecting the efficient provision of expenditures for services in different health care sectors under Medicare fee-for-service. MedPAC would be required to submit 2 additional reports no later than June 1, 2004. The first report would study the need for current data, and the sources of current data available, to determine the solvency and financial circumstances of hospitals and other Medicare providers. MedPAC would be required to examine data on uncompensated care, as well as the share of uncompensated care accounted for by the expenses for treating illegal aliens. The second report would address investments and capital financing of hospitals participating under Medicare and access to capital financing for private and not-for-profit hospitals. The provision would also require that members of the Commission be treated as employees of Congress for purposes of financial disclosure requirements.

Senate Bill

No provision.

Conference Agreement

The conference agreement requires that MedPAC is to examine the budgetary consequences of a recommendation before making the recommendation and to review the factors affecting the efficient provision of expenditures for services in different health care sectors under Medicare fee-for-service. MedPAC is required to submit 2 additional reports no later than June 1, 2004. The first report is to study the need for current data and the sources of current data available, to determine the solvency and financial circumstances of hospitals and other Medicare providers. The second report is to address investments and capital financing of hospitals participating under Medicare and access to capital financing for private and not-for-profit hospitals.

The conference agreement requires that the Comptroller General appoint experts in the area of pharmaco-economics or prescription drug benefit programs to MedPAC. In addition, members of the Commission are required to be treated as employees of Congress for purposes of financial disclosure requirements and the Comptroller General is required to ensure compliance with this requirement.

Technical Amendments (Section 736 of the Conference Agreement).

Present Law

The Medicare, Medicaid, and SCHIP Benefit Improvement and Protection Act of 2000 (BIPA) contains certain grammatical omissions.

House Bill

No provision.

Senate Bill

No provision.

Conference Agreement

The conference agreement corrects the grammatical omissions.

Institute of Medicine Report (Section 723 of the House Bill).

Present Law

No provision.

House Bill

No provision.

Senate Bill

No provision.

Conference Agreement

No provision.

MedPAC Report (Section 724 of the House Report).

Present Law

No provision.

House Bill

MedPAC would be required to evaluate the chronic care improvement program. The evaluation would be required to include a description of the status of the implementation of the programs, the quality of health care services provided to individuals participating in the program, and the cost savings attributed to the implementation of the program. The report of the evaluation would be required to be submitted to Congress not later than two years after the implementation of the programs. The provision would be effective upon enactment.

Senate Bill

No provision.

Conference Agreement

No provision.

MedPAC Study on Medicare Payments and Efficiencies in the Health Care System (Section 455 of the Senate Bill).

Present Law

No provision.

House Bill

No provision.

Senate Bill

MedPAC would be required to make recommendations to Congress regarding ways to recognize and reward efficiencies and lower utilization of services created by the practice of medicine in historically efficient and low-cost areas. The recommendations would be required to be made within established Medicare payment methodologies for hospitals and physicians. The measures of efficiency would include: shorter than average hospital stays; fewer than average physician visits; fewer than average laboratory tests; greater than average utilization of hospice services; and the efficacy of disease management and preventive health services. The recommendations would be due 18 months after enactment.

Conference Agreement

No provision.

TITLE VIII—COST CONTAINMENT

Subtitle A: Cost Containment

Inclusion in Annual Report of Medicare Trustees of Information on Status of Medicare Trust Funds (Section 801 of the Conference Agreement, Section 131 of House Bill; Sections 131 and 132 of Senate Bill).

Current Law

The Medicare Board of Trustees was established under the Social Security Act to oversee the financial operations of the Medicare Hospital Insurance (HI) trust fund and the Medicare Supplementary Medical Insurance (SMI) trust fund. The Trustees are required to submit annual reports to the Congress.

The HI trust fund revenues come primarily from payroll taxes. Employers and employees each pay 1.45% of their earnings, while self-employed workers pay 2.9% of their net income. Other HI revenue sources include interest on the investments of the trust fund, federal income taxes on Social Security benefits, premiums from voluntary enrollees into Part A, railroad retirement account transfers and reimbursement for certain uninsured persons. Medicare Part A pays for beneficiaries medical expenses incurred in hospitals, skilled nursing facilities, hospices, and a portion of home health care services.

The SMI trust fund revenues are composed of beneficiary premiums to purchase Part B and general revenues. The Part B premium is set at an amount so that aggregate premiums are estimated to equal 25% of program costs and the monthly premium for 2003 is $58.70. General revenues comprise the remaining 75% of Part B program costs. Medicare Part B pays for the following: physician and other health care practitioner services; other medical and health services, including laboratory and diagnostic tests; outpatient hospital services and clinic services; and therapy and ambulance services; durable medical equipment, and home health services not covered under Part A.

House Bill

The provision would require the trustees to submit a combined report on the status of the two trust funds and the Prescription Drug Trust Fund. The report would include a statement of the total amounts obligated during the preceding fiscal year from the General Revenues of the Treasury for payment of benefits and the percentage such amount bore to all other general revenue obligations of the Treasury in that year. This information would be provided for each year beginning with the inception of Medicare. Ten-year and 75-year projections would also be required. The report would also provide a comparison to the rate of growth in the gross domestic product. Each report would be published by the Committees on Ways and Means and Energy and Commerce and be made available on the Internet.

Senate Bill

Section 131 would require the trustees to submit a combined report on the status of the two trust funds including the Prescription Drug Account. The report would include a statement of the total amounts obligated during the preceding fiscal year from the General Revenues of the Treasury and the percentage such amount bore to all other obligations of the Treasury in that year. This calculation would be made separately for Medicare benefits and for administrative and other expenses. This information would be provided for each year beginning with the inception of Medicare. Ten-year and 50-year projections would also be required. The report would also provide a comparison of the rates of growth for both benefits and administrative costs to the rates of growth in the gross domestic product, health insurance costs in the private sector, employment-based health insurance costs in the public and private sectors, and other areas as determined appropriate by the Board of Trustees.

The section would express the sense of the Congress that the committees of jurisdiction would hold hearings on these reports.

Section 132 would require the 2004 reports to include an analysis of the total amount of unfunded obligation of Medicare. The analysis would compare long-term obligations, including the combined obligations of the HI and SMI trust funds, to the dedicated funding sources for the program (not including transfers of general revenue)

Conference Agreement

Beginning with their report in 2005, the Trustees' annual report is required to include information on: (1) projections of growth of general revenue Medicare spending as a percentage of the total Medicare outlays for the fiscal year and each of the succeeding 6 fiscal years, 10, 50, and 75 years after the fiscal year, and previous fiscal years; (2) comparisons with the growth trends for the gross domestic product, private health costs, national health expenditures, and other appropriate measures; (3) expenditures and trends in expenditures under Part D; and (4) a financial analysis of the combined Medicare trust funds if general revenue funding for Medicare is limited to 45 percent of total Medicare outlays. The trust fund reports are also required to include a determination as to whether there is projected to be ''excess general revenue Medicare funding'' (as defined in the paragraph below) for any of the succeeding 6 fiscal years in its annual reports of Medicare's trust funds.

''Excess general revenue Medicare funding'' is defined as general revenue Medicare funding expressed as a percentage of total Medicare outlays in excess of 45 percent. This measure is calculated by dividing total Medicare outlays minus dedicated Medicare financing sources by total Medicare outlays.

An affirmative determination of excess general revenue funding of Medicare for 2 consecutive annual reports will be treated as funding warning for Medicare in the second year for the purposes of requiring Presidential submission of legislation to Congress. Whenever any Trustees report includes a determination that within the 7-fiscal-year period there will be excess general revenue Medicare funding, Congress and the President are advised to address the matter under existing rules and procedures.

Dedicated Medicare financing sources include amounts appropriated to the HI trust fund for payroll taxes, transfers from the Railroad Retirement accounts, reimbursements for uninsured persons, and reimbursement for transitional insured coverage; taxation of certain OASDI benefits and tier II railroad retirement taxes, state transfers for Medicare coverage of eligible individuals who receive public assistance; premiums for Parts A, B, and D paid by non-Federal sources including amounts from voluntary enrollees (Part A), adjustments (Part B) and the MA monthly prescription drug beneficiary premiums paid under Part C that are attributable to basic prescription drug coverage (Part D); and gifts received by the Medicare trust funds. The premium amounts are determined without regard to any reduction in the Part B premiums attributable to the beneficiary rebate under the MA program and Part D premium amounts are deemed to include any penalties for late enrollment.

Medicare outlays means total outlays from the Medicare trust funds and include payments made to plans under part C that are attributable to any rebates under the Medicare Advantage program and Medicare administrative expenditures. These outlays are required to be offset by the amount of fraud and abuse collection when applied to or deposited into a Medicare trust fund.

The Medicare trust funds are defined as the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund which includes the Medicare Prescription Drug Account.

Presidential Submission of Legislation (Section 802 of the Conference Agreement).

House Bill

No provision.

Senate Bill

No provision.

Conference Agreement

In the event that a Medicare funding warning is made, the President is required to submit to Congress proposed legislation to respond to the warning. This must be completed within the 15-day period beginning on the date of the budget submission to Congress for the succeeding year it is made. If during the year in which the warning is made, legislation is enacted which eliminates excess general revenue Medicare funding for the 7-fiscal year period, then the President is not required to make a legislative proposal. The conference agreement expresses a sense of Congress that legislation submitted in this regard should be designed to eliminate excess general revenue Medicare funding for the 7-fiscal year period that begins in such year, as certified by the Board of Trustees not later than 30 days after the date of enactment.

Procedures in the House of Representatives (Section 803 of the Conference Agreement).

House Bill

No provision.

Senate Bill

No provision.

Conference Agreement

The conference agreement sets out the procedures for House consideration of the President's legislative proposal. Within 3 days of receiving the President's legislative proposal, the Majority Leader and Minority Leader of the House, or their designees, are required to introduce the proposal. Any legislation introduced is required to be referred to the appropriate committees which are required to report Medicare funding legislation no later than June 30. The chairman of the Committee on the Budget is required to certify whether or not Medicare funding legislation eliminates excess general revenue Medicare funding for any year within the 7-fiscal year period and whether the legislation would eliminate excess general revenue Medicare funding within the 7-fiscal year period.

If the House fails to vote on final passage of the legislation by July 30, fallback procedures are provided for under the conference agreement. After 30 calendar days (and concurrently 5 legislative days) after the introduction of the legislation, a move to discharge any committee to which the legislation has been referred is in order, under specified circumstances, and debate on the motion to discharge is limited to one hour.

The conference agreement provides for floor consideration in the House of the discharged legislation by the Committee of the Whole no later than 3 legislative days after discharge.

House Bill

No provision.

Senate Bill

No provision.

Conference Agreement

Section 804 provides for some limited special procedures in the Senate for consideration of legislation arising from the Medicare Trustees determination that there will be ''excess general revenue Medicare funding'' under section 801.

If the Medicare Trustees report, pursuant to section 801, includes a ''medicare funding warning'' and if the President submits the legislation described in section 802 in response to such warning, that legislation (along with any other qualifying legislation otherwise introduced in the Senate or received from the House) will be entitled to the special procedures set out in section 804.

Section 804(a) requires the Majority Leader and the Minority Leader (or their designees) to introduce the President's legislation. Such legislation must be entitled ''A bill to respond to a medicare funding warning.'' This bill, regardless of the subject matter and notwithstanding any jurisdictional precedents of the Senate, shall be referred to the Committee on Finance. Any other legislation introduced by any member of the Senate, bearing this same title, shall also be referred to the Committee on Finance. Such referrals shall not be considered to create any jurisdictional precedents for the Senate.

Section 804(c) provides that this ''medicare funding legislation'' will be entitled to the special rules set out in subsections (d) and (e) only if: (1) it was passed by the House or (2) it is limited to matters within the jurisdiction of the Committee on Finance. This subsection ensures that a measure is subject to the special rules (whether it be the President's bill or one introduced by a member of the Senate) only if its contents are limited to matters solely within the jurisdiction of Finance. Thus the President or any member of the Senate may propose any type of legislation in the name of eradicating the ''excess general revenue Medicare funding'', but only those measures which conform with the jurisdictional constraints of the Committee on Finance, shall be entitled to the special procedures set out in this section.

Clearly however, the Senate can not dictate the content of the House-passed measure. Thus subsection (c) explicitly states that a bill coming over from the House would still be entitled to these special procedures. The conferees intend that these procedures apply to the House-passed bill regardless of any jurisdictional issues, but limit the application of the procedures to a Senate-originated matter that is within the jurisdiction of Finance. If a measure does not qualify for these special procedures, then it shall be considered under the regular order in the Senate.

Section 804(d) provides a unique mechanism in the Senate: a motion to discharge a specific piece of legislation. Subsection (d) states that if the Committee on Finance has not reported any ''medicare funding legislation'' by June 30 then it is in order for any Senator to move to discharge the committee from any one of the pieces of ''medicare funding legislation'' that has been referred to that committee. Only one motion may be made in any session of Congress and such motion may only refer to a single piece of legislation. This motion is not amendable and debate of the motion and any related appeals is limited to 2 hours. The 2 hours is to be equally divided and controlled between the maker of the motion and the Majority Leader (or their designees). If the Majority Leader supports the motion, then the time in opposition will be controlled by the Minority Leader (or the Minority Leader's designee).

Unlike other instances of limited debate, in this case, a point of order may be made at any time during the 2 hours—a Senator need not await the expiration or yielding back of time to do so. Any appeal made within the 2 hours, may be debated for whatever time remains if any Senator desires to debate the appeal. Any motion or appeal made after the 2 hours shall be decided without debate. It is not in order to move to proceed to the consideration of any other measure or matter while the motion to discharge (or the motion to reconsider the vote with respect to the motion to discharge) is pending. The only motions in order during the 2 hours (or at the conclusion of the 2 hours) of debate are as follows: to postpone to a day certain, to postpone indefinitely, to lay on the table, to take a recess, to adjourn to a day certain, to adjourn. These motions shall have the same precedence as described in Rule XXII of the Standing Rules of the Senate. Note that pursuant to subsection (d)(2), the motion to proceed to executive business (which is listed in Rule XXII) as well as the motion to proceed to any other legislative matter is explicitly precluded.

Pursuant to subsection (d)(4), this special motion to discharge is no longer available if the Chairman of the Committee on the Budget certifies that ''medicare funding legislation'' which eliminates the ''excess general revenue medicare funding'' described in section 801(c) has been enacted in that session.

Subsection (e) reiterates the fact that under existing Senate procedures once ''medicare funding legislation'' has been placed on the Calendar (having been either reported or discharged from the committee) it is in order for any member of the Senate to make a motion to proceed to the consideration of that measure. Such motion and all subsequent actions in the Senate shall be considered under the Standing Rules of the Senate and the precedents thereto or pursuant to any unanimous consent agreements reached, as the case may be. This section should not be interpreted as creating a ''privileged'' measure in the Senate. Consequently, it is the intent of the Conferees that there will be no further special procedures (such as a waiver or alteration of the procedures with respect to reports set out in Rule XVII or any other rule of the Standing Rules of the Senate) available to such measures as a result of this Act.

Subtitle B: Income-Related Reduction in Part B Premium Subsidy

Present Law

The Medicare Part B premium is currently set each year to cover 25 percent of Medicare's benefits under Part B. When Medicare was created in 1965, the Part B premium was set to cover 50 percent of the costs of the Part B benefits. The share of Part B spending covered by the premium declined between 1975 and 1983 to less than 25 percent of spending, because during that time premium increases were limited by the cost-of-living adjustment for Social Security benefits. During the late 1980s and early 1990s, Congress routinely voted to set the Part B premium at 25 percent of Part B costs, and that percentage was codified in the Balanced Budget Act of 1997 (BBA 97).

All seniors over age 65 who elect Part B during their initial enrollment period pay the same Part B premium, regardless of income.

House Bill

No provision.

Senate Amendment

No provision.

Conference Agreement

In order to begin to address the fiscal challenges facing the Medicare program, beginning in 2007, Medicare beneficiaries with incomes over $80,000 for an individual or $160,000 for a married couple will be asked to contribute more to the cost of their Medicare benefits through payment of a higher premium. Approximately 4 percent of Medicare beneficiaries have incomes above these levels. All beneficiaries will continue to receive some level of premium assistance, and all beneficiaries will continue to be eligible for the full range of Medicare benefits. This proposal will target taxpayer dollars at those who need it the most by reducing the government subsidy for those who have the resources to cover more of their own costs.

Beneficiaries with incomes under $80,000 for an individual and $160,000 for a married couple will continue to receive a government subsidy at 75 percent and pay premiums at the 25 percent rate. Those with incomes between $80,000 and $100,000 ($160,000 and $200,000 for a married couple) will receive a 65 percent subsidy and pay 35 percent as a premium. Those with incomes between $100,000 and $150,000 ($200,000 and $300,000 for a couple) will receive a 50 percent subsidy and pay a premium at 50 percent. Those with incomes between $150,000 and $200,000 ($300,000 and $400,000 for a married couple) will receive a 35 percent subsidy and pay a premium at a 65 percent rate. Those with incomes above $200,000 ($400,000 for a married couple) will receive a 20 percent subsidy and pay a premium at an 80 percent rate.

Beneficiaries who are affected will be notified of their premium levels at the start of the year. They may appeal their premium level based on major changes in life circumstances, such as divorce, marriage, or death of a spouse. Although this policy affects only a small number of beneficiaries, it will have a significant impact in controlling the growth of Medicare spending in the future.

To facilitate the income-related reduction in Part B premium subsidy, the conference agreement authorizes the disclosure of certain return information to employees and contractors of the Social Security Administration. Upon written request from the Commissioner of Social Security, the IRS may disclose certain items of return information with respect to a taxpayer whose premium may be subject to adjustment. With respect to such taxpayers, the IRS may disclose (1) taxpayer identity information; (2) filing status; (3) adjusted gross income; (4) the amounts excluded from such taxpayer's gross income under sections 135 and 911 of the Internal Revenue Code (relating to income from United States Savings bonds used to pay higher education tuition and fees, and foreign earned income); (5) tax-exempt interest received or accrued during the taxable year to the extent such information is available; (6) amounts excluded from such taxpayer's gross income by sections 931 and 933 of the Internal Revenue Code (relating to income from sources within Guam, American Samoa, the Northern Mariana Islands, or Puerto Rico); (7) for nonfilers only, such other information relating to the liability of the taxpayer as the Secretary may prescribe by regulation, as might indicate that the amount of the premium of the taxpayer may be subject to adjustment (including estimated tax payments and income information derived from Form W–2, Form 1099, or similar information returns); and (8) the taxable year with respect to which the preceding information relates. Return information disclosed under this authority may be used by employees and contractors of the Social Security Administration only for purposes of, and to the extent necessary in, establishing the appropriate amount of any Part B premium adjustment. Employees and contractors of the Social Security Administration are subject to the penalties for unauthorized disclosure and inspection, as well as the applicable safeguard requirements.

TITLE IX—REGULATORY REDUCTION AND CONTRACTING REFORM

Administrative Improvements within the Centers for Medicare & Medicaid Services (CMS) (Section 900 of the Conference Agreement, Sections 801 and 802 of the House Bill, Sections 301 and 302 of the Senate Bill).

Present Law

The authority for administering the Medicare program resides with the Secretary of Health and Human Services. The Secretary originally created the agency that administers the Medicare and Medicaid programs in 1977 under his administrative authority. Regulations regarding Medicare are required to be promulgated by the Secretary. The Medicare statute requires that the Administrator of the Centers for Medicare & Medicaid Services (CMS formerly known as the Health Care Financing Administration) be appointed by the President with the advice and consent of the Senate. Title 5 of the U.S. Code sets the Administrator's salary at level IV of the Executive Schedule. The Medicare statute requires that the HCFA administrator appoint a Chief Actuary who reports directly to such administrator and is paid at the highest rate of basic pay for the Senior Executive Service.

House Bill

The section would amend title XVIII to add new section 1809 which, under subsection (a), would establish a new Medicare Benefits Administration (MBA) within the Department of Health and Human Services.

Subsection (b) would provide for an Administrator and Deputy Administrator of the MBA. Both would be appointed by the President with the advice and consent of the Senate for 4-year terms. If a successor did not take office at the end of the term, the Administrator would continue in office until the successor enters the office. In that event, the confirmed successor's term would be the balance of the 4-year period. The Administrator would be paid at level III of the Executive Schedule and the Deputy Administrator at level IV of the Executive Schedule. The Administrator would be responsible for the exercise of all powers and the discharge of duties of the MBA and has authority and control over all personnel. The provision would permit the Administrator to prescribe such rules and regulations as the Administrator determined necessary or appropriate to carry out the functions of MBA, subject to the Administrative Procedure Act. The Administrator would be able to establish different organizational units within the MBA except for any unit, component, or provision specifically provided for by section 1809. The Administrator may assign duties, delegate, or authorize redelegations of authority to MBA officers and employees as needed. The Secretary of Health and Human Services shall ensure appropriate coordination between the Administrator of MBA and the Administrator of the Centers for Medicare & Medicaid Services (CMS) in administering the Medicare program. The provision also would establish a position of Chief Actuary within the MBA who would be appointed by the Administrator and paid at the highest rate of basic pay for the Senior Executive Service. The Chief Actuary would exercise such duties as are appropriate for the office of Chief Actuary and in accordance with professional standards of actuarial independence.

Subsection (c) would prescribe the duties of the Administrator and administrative provisions relating to the MBA. In administering parts C, D, and E of Medicare, the Administrator would be required to negotiate, enter into and enforce contracts with Medicare Advantage plans and enhanced fee-for-service plans and with prescription drug plan sponsors for Medicare prescription drug plans. The Administrator would be required to carry out any duty provided for under part C, D, or E of Medicare including implementing the prescription drug discount card endorsement program and demonstration programs (that are carried out in whole or in part under part C, D, or E). The provision specifically prohibits the Administrator from requiring a particular formulary or instituting a price structure for the reimbursement of covered drugs, from interfering in any way with negotiations between prescription drug plan sponsors and Medicare Advantage organizations and enhanced fee-for-service organizations and drug manufacturers, wholesalers, or other suppliers of covered drugs; and otherwise interfering with the competitive nature of providing prescription drug coverage through such entities and organizations. These negotiations would be carried out by private plans, eager to capture market share through lower premiums, and manufacturers, willing to negotiate discounts for volume assurance. Such private sector entities are far better suited to achieve maximum discounts and lower premiums for plan participants than a disinterested Administrator.

The Administrator would be required to submit a report to Congress and the President on the administration of parts C, D, and E during the previous year by not later than March 31 of each year.

The Administrator, with the approval of the Secretary, would be permitted to hire staff to administer the activities of MBA without regard to chapter 31 of title 5 of the U.S. Code, except for 12 sections. The Administrator would be required to employ staff with appropriate and necessary experience in negotiating contracts in the private sector. The staff of MBA would be paid without regard to chapter 51 (other than section 5101 requiring classification of positions according to certain principles) and chapter 53 (other than section 5301 relating to the principles of pay systems) of title 5 of the U.S. Code. The rate of compensation for staff of MBA would not be able to exceed level IV of the Executive Schedule. The Administrator would be limited in the number of full-time-equivalent (FTEs) employees for the MBA to the number of FTEs within CMS performing the functions being transferred at the time of enactment. The Secretary, the Administrator of MBA and the Administrator of CMS would be required to establish an appropriate transition of responsibility to redelegate the administration of Medicare part C from CMS to MBA. The provision would require the Secretary to ensure that the Administrator of CMS transfers such information and data as the Administrator of MBA requires to carry out the duties of MBA.

Subsection (d) would require the Secretary to establish an Office of Beneficiary Assistance within MBA to coordinate Medicare beneficiary outreach and education activities, and provide Medicare benefit and appeals information to Medicare beneficiaries under parts C, D, and E.

Subsection (e) would establish the Medicare Policy Advisory Board (the Board) within the MBA to advise, consult with, and make recommendations to the Administrator regarding the administration and payment policies of parts C, D, and E. The Board would be required to report to Congress and to the Administrator of MBA such reports as the Board determines appropriate and may contain recommendations that the Board considers appropriate regarding legislative or administrative changes to improve the administration of parts C, D, and E including: increasing competition under part C, D, or E for services furnished to beneficiaries; improving efforts to provide beneficiaries information and education about Medicare, parts C, D, and E, and Medicare enrollment; evaluating implementation of risk adjustment under parts C and E; and improving competition and access to plans under parts C, D, and E. The reports would be required to be published in the Federal Register. The reports would be submitted directly to Congress and no officer or agency of the government would be allowed to require the Board to submit a report for approval, comments,

or review prior to submission to Congress. Not later than 90 days after a report is submitted to the Administrator, the Administrator would be required to submit to Congress and the President an analysis of the recommendations made by the Board. The analysis would be required to be published in the Federal Register.

The Board would be made up of 7 members serving three-year terms, with 3 members appointed by the President, 2 appointed by the Speaker of the House of Representatives, and 2 appointed by the President pro tempore of the Senate. Board members may be reappointed but may not serve for more than 8 years. The Board shall elect the Chair to serve for 3 years. The Board is required to meet at least three times a year and at the call of the Chair.

The Board would be required to have a director who, with the approval of the Board, may appoint staff without regard to chapter 31 of title 5 of the United States Code (which addresses authority for employment). In addition, the director and staff could be paid without regard to the provisions of chapter 51 and 53 of title 5 which are related to classification and pay rates and pay systems—although the rate of compensation is capped at level IV of the Executive Schedule. The Board could contract with and compensate government and private agencies or persons to carry out its duties without regard to section 3709 of the Revised Statutes (41 U.S.C. 5).

Subsection (f) would authorize an appropriation of such sums as are necessary from the Federal Hospital Insurance Trust Fund and from the Federal Supplementary Medical Insurance Trust Fund (including the Prescription Drug Account) to carry out section 1808.

The provision would be effective upon enactment, however, the enrollment and eligibility functions and implementation of parts C and E would be effective January 1, 2006.

Senate Bill

The section would amend title XVIII to add new section 1808, which, under subsection (a), would establish a new Center for Medicare Choices (CMC) within the Department of Health and Human Services by no later than March 1, 2004, to administer parts C and D of Medicare.

Subsection (b) would provide for an Administrator of CMC who would be appointed by the President with the advice and consent of the Senate for 5-year terms. The Administrator would be able to appoint a Deputy Administrator. If a successor did not take office at the end of the term, the Administrator would continue in office until the successor enters the office. In that event, the confirmed successor's term would be the balance of the 5-year period. The Administrator would be paid at level III of the Executive Schedule and the Deputy Administrator at level IV of the Executive Schedule. The Administrator would be responsible for the exercise of all powers and the discharge of duties of CMC and has authority and control over all personnel. The provision would permit the Administrator to prescribe such rules and regulations as the Administrator determined necessary or appropriate to carry out the functions of CMC, subject to the Administrative Procedure Act. The Administrator would be able to establish different organizational units within the CMC except for any unit, component, or provision provided by section 1808. The Administrator may assign duties, delegate, or authorize redelegations of authority to CMC officers and employees as needed. The Secretary of Health and Human Services shall ensure appropriate coordination between the Administrator of CMC and the Administrator of the Centers for Medicare & Medicaid Services in administering the Medicare program.

Subsection (c) would prescribe the duties of the Administrator and administrative provisions relating to the CMC. In administering parts C and D of Medicare, the Administrator would be required to negotiate, enter into and enforce contracts with MedicareAdvantage plans and with eligible entities for Medicare prescription drug plans. The Administrator would be required to carry out any duty provided for under part C or D of Medicare including demonstration programs (that are carried out in whole or in part under parts C or D). The Administrator of the agency, to the extent possible, would not be able interfere in any way with negotiations between eligible entities, MedicareAdvantage organizations, hospitals, physicians, other entities or individuals furnishing items and services under this title (including contractors for such items and services), and drug manufacturers, wholesalers, or other suppliers of covered drugs. The Administrator would be required to submit a report to Congress and the President on the administration of the voluntary prescription drug delivery program not later than March 31 of each year.

The Administrator, with the approval of the Secretary, would be able to employ management staff as determined appropriate. The Administrator would be able to compensate such managers up to the highest rate of basic pay for the Senior Executive Service. Any such manager would be required to have demonstrated, by their education and experience (either in the public or private sectors) superior expertise in the review, negotiation, and administration of health care contracts, the design of health care benefit plans, actuarial sciences, compliance and health plan contracts, consumer education and decision-making.

Subsection (d) would require the Secretary to establish an Office of Beneficiary Assistance within CMC to make Medicare eligibility determinations, enroll beneficiaries into Medicare, provide Medicare benefit and appeals information, and carry out any other activities relating to Medicare beneficiaries under title XVIII. Within the Office of Beneficiary Assistance, a Beneficiary Ombudsman would be established who is appointed by the Secretary. The Ombudsman would be required to receive complaints, grievances, and requests for information submitted by a Medicare beneficiary regarding any aspect of the Medicare program; to provide assistance with the complaints, grievances and requests including assisting beneficiaries with appeals; and with problems arising from disenrolling from a MedicareAdvantage plan or a prescription drug plan. The Ombudsman would be required to submit annual reports to Congress, the Secretary, and the Medicare Competitive Policy Advisory Board describing the activities of the Ombudsman's office and including any recommendations for improvement in the administration of title XVIII. The Ombudsman would also be required to coordinate with state medical ombudsmen programs, and with state- and community-based consumer organizations to provide information about the Medicare program and to conduct education outreach regarding resolution or avoidance of disputes and problems under the Medicare program.

Subsection (e) would establish the Medicare Competitive Policy Advisory Board (the Board) within the CMC to advise, consult with, and make recommendations to the Administrator regarding the administration and payment policies of parts C and D. The Board would be required to report to Congress and to the Administrator of CMC such reports as the Board determines appropriate and may contain recommendations that the Board considers appropriate regarding legislative or administrative changes to improve the administration of parts C and D including: stability and solvency of the program, increasing competition, improving the quality of benefits, incorporating disease management, improving competition and access to plans in rural areas, and improving beneficiary information and education for the entire Medicare program. The reports would be required to be published in the Federal Register. The reports would be submitted directly to Congress and no officer or agency of the government would be allowed to require the Board to submit a report for approval, comments, or review prior to submission to Congress. Not later than 90 days after a report is submitted to the Administrator, the Administrator would be required to submit to Congress and the President an analysis of the recommendations made by the Board. The analysis would be required to be published in the Federal Register. The Administrator of CMC is required to provide information and assistance to the Board as is requested to carry out its functions.

The Board would be made up of 7 members serving three-year terms, with three members appointed by the President, two appointed by the Speaker of the House of Representatives, and two appointed by the President pro tempore of the Senate. Board members may be reappointed but may not serve for more than 8 years. The Board shall elect the Chair to serve for three years. The Board is required to meet at least three times a year and at the call of the Chair. The Board is required to have an executive director who, with the approval of the Board, may appoint staff as appropriate.

Subsection (f) would authorize an appropriation of such sums as are necessary from the Federal Hospital Insurance Trust Fund and from the Federal Supplementary Medical Insurance Trust Fund (including the Prescription Drug Account) to carry out section 1808.

The provision would also require that the Secretary provide 1–800–Medicare as a means by which individuals seeking information about or assistance with Medicare can receive assistance. The Secretary would be required to route calls to the appropriate entity to provide the assistance or information. The 1–800–Medicare number would be included in the Medicare handbook in place of the listing of phone numbers of individual contractors.

The Administrator of CMC would be added as Co-Secretary of the Board of Trustees of the Medicare Trust Funds. In addition, the pay level for the Administrator of CMS would be increased from level IV of the Executive Schedule to level III.

The CMC would be required to be established by the Secretary no later than March 1, 2004.

Conference Agreement

The conference agreement creates a new section 1808 of the Social Security Act establishing a center within the Centers for Medicare & Medicaid Services to administer Parts C and D of Medicare, provide notice and information to beneficiaries (as required under section 1804 of the Social Security Act), and other such duties as specified by the Secretary. The person heading the Center is required to report to the Administrator of CMS. The Secretary is required to ensure that the Center is carrying out these duties by no later than January 1, 2008.

The conference agreement permits the Secretary to employ management staff as he determines to be appropriate. If such staff are employed, the staff must have demonstrated superior expertise in at least one of the following areas: (1) the review, negotiation, and

administration of health care contracts; (2) the design of health care benefit plans; (3) actuarial sciences; (4) consumer education and decision making; (5) any other area specified by the Secretary that requires specialized management or other expertise. The Secretary is required to establish the rate of pay taking into account expertise, experience, and performance. The pay rate cannot exceed the highest rate of basic pay for the Senior Executive Service under section 5382(b) of title 5, United States Code (currently ES–6). Such flexibility ensures those with private sector, real world experience managing benefit plans are hired and utilized to ensure the success of the new Medicare plans. This expertise will help mitigate against potential failure in coaxing integrated plans that promote coordinated care and modern health delivery into the Medicare program.

The conference agreement requires that an actuary within the office of the Chief Actuary of CMS have duties exclusively related to Parts C and D of Medicare and related provisions. The pay grade for the Administrator of CMS is increased to Executive Level III beginning January 1, 2004. The conferees strongly encourage the hiring of a separate actuary within the office of the actuary to assist the functions of the center. Because the analysis of the fee-for-service actuary can effect payment rates in private plan reimbursement, the two should be kept independent and answer directly to the Secretary.

In addition, the conference agreement changes statutory references from the Health Care Financing Administration to the Centers for Medicare & Medicaid Services.

Construction; Definition of Supplier (Section 901 of the Conference Agreement, Section 901 of the House Bill).

Present Law

Section 1861 of the Social Security Act contains definitions of services, institutions, and so forth under Medicare. Supplier is not explicitly defined.

House Bill

Nothing in this title would be construed as compromising or affecting existing legal remedies for addressing fraud or abuse, whether it be criminal prosecution, civil enforcement or administrative remedies (including the False Claims Act) or to prevent or impede HHS from its efforts to eliminate waste, fraud, or abuse in Medicare. The provision also would clarify that consolidation of the Medicare administrative contractors does not consolidate the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund. The provision would also clarify that the term ''supplier'' means a physician or other practitioner, a facility or other entity (other than a provider of services) furnishing items or services under Medicare. The provision would be effective upon enactment.

Senate Bill

No provision.

Conference Agreement

The conference agreement provides that nothing in this title shall be construed as compromising or affecting existing legal remedies for addressing fraud or abuse, whether it be criminal prosecution, civil enforcement or administrative remedies (including the False Claims Act) or to prevent or impede HHS from its efforts to eliminate waste, fraud, or abuse in Medicare. The conference agreement also clarifies that consolidating the Medicare administrative contractors does not consolidate the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund. The agreement also clarifies that the term ''supplier'' means a physician or other practitioner, a facility or other entity (other than a provider of services) furnishing items or services under Medicare. The provision is effective upon enactment.

Issuance of Regulations (Section 902 of the Conference Agreement, Section 902 of the House Bill, Section 501 of the Senate Bill).

Present Law

The Secretary is required to prescribe regulations that are necessary to administer the Medicare program. The Secretary must publish proposed regulations in the Federal Register, with at least 30 days to solicit public comment before issuing the final regulation except in the following circumstances: (1) the statute permits the regulation to be issued in interim final form or provides for a shorter public comment period; (2) the statutory deadline for implementing a provision is less than 150 days after the date of enactment of the statute containing the provision; (3) under the good cause exception contained in the rule-making provision of title 5 of the United States Code, notice and public comment procedures are deemed impracticable, unnecessary or contrary to the public interest. The Secretary must publish a list of all manual instructions, interpretative rules, statements of policy, and guidelines, which are promulgated to carry out Medicare law in the Federal Register no less frequently than every 3 months.

There is no explicit statutory instruction on logical outgrowth. The courts have repeatedly held that new matter in final regulations must be a ''logical outgrowth of the proposed rule'' and is an inherent aspect of notice and comment rulemaking.

House Bill

The provision would require the Secretary, in consultation with the Director of the Office of Management and Budget, to establish and publish a regular timeline for the publication of final regulations based on the previous publication of a proposed rule or an interim final regulation. The timeframe established would not be permitted to be longer than three years, except under extraordinary circumstances. If the Secretary were to vary the timeline he established, the provision would require him to publish a notice in the Federal Register with the new timeline and an explanation of the variation. In the case of interim final regulations, the provision would require that if the Secretary did not meet his established timeframe, then the interim final regulation would not be able to continue in effect unless the Secretary published a notice of continuation of the regulation that included an explanation of why the regular time line had not been complied with. This provision regarding timelines would be effective upon enactment.

The provision also would require that a measure in a final regulation that is not a logical outgrowth of the proposed regulation or interim final regulation would be treated as a proposed regulation. The measure would not be able to take effect until public comment occurred and the measure was published as a final regulation. This provision would apply to final regulations published on or after the date of enactment.

Senate Bill

The Secretary would be required to publish a final regulation within 12 months of the publication of an interim final regulation or the interim final regulation would no longer be effective. Subject to appropriate notice, the Secretary would be able to extend this deadline for up to 12 additional months. The Secretary would be required to publish a notice in the Federal Register 6 months after the date of enactment providing the status of each interim final regulation for which no final regulation has been published and providing the date by which the final regulation is planned to be published. This provision would be effective upon enactment.

Conference Agreement

The conference agreement requires the Secretary, in consultation with the Director of the Office of Management and Budget, to establish and publish a regular timeline for the publication of final regulations based on the previous publication of a proposed rule or an interim final regulation. The timeframe established is not be permitted to be longer than 3 years, except under extraordinary circumstances. If the Secretary varies the timeline he established, he is required to publish a notice in the Federal Register with the new timeline and an explanation of the variation. In the case of interim final regulations, if the Secretary does not meet his established timeframe, then the interim final regulation cannot continue in effect unless the Secretary publishes a notice of continuation of the regulation that includes an explanation of why the regular timeline was not complied with. This agreement regarding timelines is effective upon enactment.

The conference agreement also requires that a measure in a final regulation that is not a logical outgrowth of the proposed regulation or interim final regulation is to be treated as a proposed regulation. The measure could not take effect until public comment occurred and the measure is published as a final regulation. This agreement applies to final regulations published on or after enactment.

Compliance with Changes in Regulation and Policies. (Section 903 of the Conference Agreement, Section 903 of the House Bill, Sections 502 and 533 of the Senate Bill).

Present Law

No explicit statutory instruction. As a result of case law, there is a strong presumption against retroactive rulemaking. In *Bowen* v. *Georgetown University Hospital*, the Supreme Court ruled that there must be explicit statutory authority to engage in retroactive rulemaking.

House Bill

The provision would bar retroactive application of any substantive changes in regulation, manual instructions, interpretative rules, statements of policy, or guidelines unless the Secretary determines retroactive application is needed to comply with the statute or is in the public interest, effective upon enactment. No substantive change would go into effect until 30 days after the change is issued or published unless it would be needed to comply with statutory changes or was in the public interest. Compliance actions would be able to be taken for items and services furnished only on or after the effective date of the change, effective upon enactment. If a provider or supplier follows written guidance provided by the Secretary or a Medicare contractor when furnishing items or services or submitting a claim and the guidance is inaccurate, the provider or supplier would not be subject to penalty or repayment of overpayment (unless the inaccurate information was due to a clerical or technical operational error).

Senate Bill

Same provisions.

Conference Agreement

The conference agreement bars retroactive application of any substantive changes in regulation, manual instructions, interpretative rules, statements of policy, or guidelines unless the Secretary determines retroactive application is needed to comply with the

statute or is in the public interest. No substantive change could go into effect until 30 days after the change is issued or published unless it is needed to comply with statutory changes or in the public interest. Compliance actions could be taken for items and services furnished only on or after the effective date of the change, effective upon enactment. If a provider or supplier follows written guidance provided by the Secretary or a Medicare contractor when furnishing items or services or submitting a claim and the guidance is inaccurate, the provider or supplier is not subject to penalty or interest (unless the inaccurate information was due to a clerical or technical operational error).

The conference agreement also makes clear that a provider or supplier is not subject to any penalty or interest on a repayment plan (including under section 1893 of the Social Security Act, relating to the Medicare Integrity Program, or otherwise) relating to the provision of such items or services or a claim if the provider or supplier reasonably relied on the guidance. The conference agreement applies to a sanction imposed with respect to guidance provided on or after July 24, 2003.

Reports and Studies Relating to Regulatory Reform. (Section 904 of the Conference Agreement, Section 904 of the House Bill, Section 503 of the Senate Bill).

Present Law

No provision.

House Bill

The GAO would be required to study the feasibility and appropriateness of the Secretary providing legally binding advisory opinions on appropriate interpretation and application of Medicare regulations. The report would be due to Congress 1 year after enactment.

The Secretary would be required to report to Congress every 2 years on the administration of Medicare and areas of inconsistency or conflict among various provisions under law and regulation. The report would include recommendations for legislation or administrative action that the Secretary determines appropriate to further reduce such inconsistency or conflicts. The first report would be due to Congress 2 years after enactment.

Senate Bill

Requires the Secretary to report to Congress in 2 years, and every 3 years thereafter, on the administration of Medicare and areas of inconsistency or conflict among various provisions under law and regulation and recommendations for legislation or administrative action that the Secretary determines appropriate to further reduce such inconsistency or conflicts.

Conference Agreement

The conference agreement requires the GAO to study the feasibility and appropriateness of the Secretary providing legally binding advisory opinions on appropriate interpretation and application of Medicare regulations. The report is due to Congress 1 year after enactment.

The Secretary is required to report to Congress in 2 years and every 3 years thereafter on the administration of Medicare and areas of inconsistency or conflict among various provisions under law and regulation. The report is to include recommendations for legislation or administrative action that the Secretary determines appropriate to further reduce such inconsistency or conflicts.

Increased Flexibility in Medicare Administration. (Section 911 of the Conference Agreement, Section 911 of the House Bill, Section 521 of the Senate Bill).

Present Law

The Secretary is authorized to enter into agreements with fiscal intermediaries nominated by different provider associations to make Medicare payments for health care services furnished by institutional providers. For Medicare Part B claims, the Secretary is authorized to enter into contracts only with health insurers (or carriers) to make Medicare payments to physicians, practitioners and other health care suppliers. Section 1834(a)(12) of the Act authorizes separate regional carriers for the payment of durable medical equipment (DME) claims. The Secretary is also authorized to contract for certain program safeguard activities under the Medicare Integrity Program (MIP).

Certain terms and conditions of the contracting agreements for fiscal intermediaries and carriers are specified in the Medicare statute. Medicare regulations coupled with long-standing agency practices have further limited the way that contracts for claims administration services can be established.

Certain functions and responsibilities of the fiscal intermediaries and carriers are specified in the statute as well. The Secretary may not require that carriers or intermediaries match data obtained in its other activities with Medicare data in order to identify beneficiaries who have other insurance coverage as part of the Medicare Secondary Payer (MSP) program. With the exception of prior authorization of DME claims, an entity may not perform activities (or receive related payments) under a claims processing contract to the extent that the activities are carried out pursuant to a MIP contract. Performance standards with respect to the timeliness of reviews, fair hearings, reconsiderations and exemption decisions are established as well.

A Medicare contract with an intermediary or carrier may require any of its employees certifying or making payments provide a surety bond to the United States in an amount established by the Secretary. Neither the contractor nor the contractor's employee who certifies the amount of Medicare payments is liable for erroneous payments in the absence of gross negligence or intent to defraud the United States. Neither the contractor nor the contractor's employee who disburses payments is liable for erroneous payments in the absence of gross negligence or intent to defraud the United States, if such payments are based upon a voucher signed by the certifying employee.

House Bill

This provision would add a new Section 1874A to the Social Security Act and would permit the Secretary to competitively contract with any eligible entity to serve as a Medicare contractor. The provision would eliminate the distinction between Part A contractors (fiscal intermediaries) and Part B contractors (carriers) and take the separate authorities for fiscal intermediaries and carriers and merge them into a single authority for the new contractor. These new contractors would be called Medicare Administrative Contractors (MACs) and would assume all the functions of the current fiscal intermediaries and carriers: determining the amount of Medicare payments required to be made to providers and suppliers, making the payments, providing education and outreach to beneficiaries, providers and suppliers, communicating with providers and suppliers, and additional functions as are necessary.

The Secretary would be permitted to renew the MAC contracts annually for up to 5 years. All contracts would be required to be re-competed at least every 5 years using competitive processes. Federal Acquisition Regulations (FAR) would apply to these contracts except to the extent any provisions are inconsistent with a specific Medicare requirement, including incentive contracts. The contracts would be required to contain performance requirements that would be developed by the Secretary who could consult with beneficiary, provider, and supplier organizations, would be consistent with written statements of work and would be used for evaluating contractor performance. MAC would be required to furnish the Secretary such timely information as he may require and to maintain and provide access to records the Secretary finds necessary. The Secretary could require a surety bond from the MAC or certain officers or employees as the Secretary finds appropriate. The Secretary would be prohibited from requiring that the MAC match data from other activities for Medicare secondary payer purposes.

The provision would limit liability of certifying and disbursing officers and the Medicare Administrative Contractors except in cases of reckless disregard or the intent to defraud the United States. This limitation on liability would not limit liability under the False Claims Act. The provision also establishes circumstances where contractors and their employees would be indemnified, both in the contract and as the Secretary determines appropriate.

The provision would make numerous conforming amendments as the authorities for the fiscal intermediaries and carriers are stricken. After enactment of the bill, but before October 1, 2005, the Secretary would be permitted to enter into new fiscal intermediary agreements without regard to any of the provider nomination provisions.

The Secretary would be required to submit a report to Congress and the GAO by no later than October 1, 2004, that describes the plan for implementing these provisions. The GAO is required to evaluate the Secretary's plan and, within six months of receiving the plan, report on the evaluation to Congress and make any recommendations the Comptroller General believes appropriate. The Secretary is also required to report to Congress by October 1, 2008 on the status of implementing the contracting reform provisions including the number of contracts that have been competitively bid, the distribution of functions among contracts and contractors, a timeline for complete transition to full competition, and a detailed description of how the Secretary has modified oversight and management of Medicare contractors to adapt to full competition.

Competitive bidding for the MACs would be required to begin for annual contract periods that begin on or after October 1, 2005.

Senate Bill

Same provision, containing three main differences: First, contracts would be required to be recompeted every 6 years. Second, a MAC with a contract to perform local coverage determinations would be required to designate at least 1 different individual to serve as a medical director for each state for which local coverage determinations are made; use the medical director in making the local coverage determinations; and appoint a contractor advisory committee for each state for which local coverage determinations are made to participate in an advisory capacity in the development of the local determinations. Finally, competitive bidding for the MACs would be required to begin for annual contract periods that begin on or after October 1, 2011.

Conference Agreement

The conference agreement adds a new Section 1874A to the Social Security Act into which the Medicare contractor authority is consolidated. The conference agreement permits the Secretary to competitively contract with any eligible entity to serve as a Medicare Administrative Contractor (MAC). The conference agreement eliminates the distinction between Part A contractors (fiscal intermediaries) and Part B contractors

(carriers) and takes the separate authorities for fiscal intermediaries and carriers and merges them into a single authority for the new contractor. All the functions of the current fiscal intermediaries and carriers are assumed by the new MACs: determining the amount of Medicare payments required to be made to providers and suppliers, making the payments, providing education and outreach to beneficiaries, providers and suppliers, communicating with providers and suppliers, and additional functions as are necessary.

The Secretary is permitted to renew the MAC contracts annually for up to 5 years. All contracts must be re-competed at least every 5 years using competitive processes. Federal Acquisition Regulations (FAR) apply to MAC contracts except to the extent any provisions are inconsistent with a specific Medicare requirement, including incentive contracts. (The conference agreement does not extend FAR provision to other contractors under title XVIII.) The Secretary is required to develop contract performance requirements to carry out the functions described in the provision and to develop standards for measuring the extent to which a contractor has met the requirements. The Secretary is required to consult with beneficiary and provider organizations, and organizations and agencies performing other Medicare functions. The Secretary is required to make the performance requirements and measurement standards available to the public and must include provider and beneficiary satisfaction levels as one of the requirements.

MAC performance requirements are required to be included in the contract and consistent with written statements of work and used for evaluating contractor performance. MACs are required to furnish the Secretary such timely information as he may require and to maintain and provide access to records the Secretary finds necessary. The Secretary may require a surety bond from the MAC or certain officers or employees as the Secretary finds appropriate. The Secretary is prohibited from requiring that the MAC match data from other activities for Medicare secondary payer purposes.

The conference agreement limits the liability of certifying and disbursing officers and the Medicare Administrative Contractors except in cases of reckless disregard or the intent to defraud the United States. The standard does not limit liability for conduct that constitutes a violation of the False Claims Act. The conference agreement also establishes circumstances where contractors and their employees are indemnified, both in the contract and as the Secretary determines appropriate.

The conference agreement makes numerous conforming amendments as the statutory authorities for the fiscal intermediaries and carriers are stricken. After enactment of the bill, but before October 1, 2005, the Secretary is authorized to enter into new fiscal intermediary agreements without regard to any of the provider nomination provisions under section 1816 of the Social Security Act and may enter into new carrier contracts. The Secretary is required to take such steps as are necessary to provide for an appropriate transition from the fiscal intermediary agreements and carrier contracts to the MAC contracts. In addition, the Secretary is explicitly authorized to continue Medicare Integrity Program fiscal intermediary agreements and carrier contracts from the enactment of this provision through October 1, 2011.

The Secretary is required to submit a legislative proposal providing technical and conforming amendments to this provision to the appropriate committees of Congress within 6 weeks of enactment. The Secretary is required to submit a report to Congress and the GAO by no later than October 1, 2004, that describes the plan for implementing these provisions. The GAO is required to evaluate the Secretary's plan and, within 6 months of receiving the plan, report on the evaluation to Congress and make any recommendations the Comptroller General believes appropriate. The Secretary is also required to report to Congress by October 1, 2008, on the status of implementing the contracting reform provisions including the number of contracts that have been competitively bid, the distribution of functions among contracts and contractors, a timeline for complete transition to full competition, and a detailed description of how the Secretary has modified oversight and management of Medicare contractors to adapt to full competition.

Competitive bidding for the MACs would be required to begin October 1, 2005 and all contracts should have been bid under the new structure by September 30, 2011.

Requirements for Information Security for Medicare Administrative Contractors (Section 912 of the Conference Agreement, Section 912 of the House Bill).

Present Law

No provision.

House Bill

Medicare administrative contractors (as well as fiscal intermediaries and carriers until the MACs are established) would be required to implement a contractor-wide information security program to provide information security for the operation and assets of the contractor for Medicare functions. The information security program would be required to meet certain requirements for information security programs imposed on Federal agencies under title 44 of the United States Code. Medicare administrative contractors would be required to undergo an annual independent evaluation of their information security programs. Existing contractors would be required to undergo the first independent evaluation within one year after the date of enactment and new contractors would be required to have such a program in place before beginning the claim determination and payment activities. The results of the independent evaluations would be submitted to the Secretary and the HHS Inspector General. The Inspector General of HHS would be required to report to Congress annually on the results of the evaluations. The Secretary would be required to address the results of the evaluations in required management reports.

Senate Bill

No comparable provision.

Conference Agreement

The conference agreement requires Medicare administrative contractors (as well as fiscal intermediaries and carriers until the MACs are established) to implement a contractor-wide information security program to provide information security for the operation and assets of the contractor for Medicare functions. The information security program is required to meet certain requirements for information security programs imposed on Federal agencies under title 44 of the United States Code. Medicare administrative contractors are required to undergo an annual independent evaluation of their information security programs. Current fiscal intermediaries and carriers are required to undergo the first independent evaluation within one year after the date of enactment and new contractors would be required to have such a program in place before beginning the claim determination and payment activities. The MACs are required to submit the results of the independent evaluations to the Secretary and the HHS Inspector General. The Inspector General of HHS is required to report to Congress annually on the results of the evaluations. The Secretary is required to address the results of the evaluations in required management reports.

Provider Education and Technical Assistance. (Section 921 of the Conference Agreement, Section 921 of the House Bill, Sections 531 and 532 of the Senate Bill).

Present Law

(a) Coordination of Education Funding.

Present Law

Medicare's provider education activities are funded through the program management appropriation and through Education and Training component of the Medicare Integrity Program (MIP). Both claims processing contractors (fiscal intermediaries and carriers) and MIP contractors may undertake provider education activities.

House Bill

The provision would add Section 1889 to the Social Security Act, which would require the Secretary to coordinate educational activities through the Medicare contractors to maximize the effectiveness of education efforts for providers and suppliers and to report to Congress with a description and evaluation of the steps taken to coordinate provider education funding. The provision would be effective upon enactment. The Secretary would be required to report to Congress on the steps taken to coordinate the funding of provider education under the provision by October 1, 2004.

Senate Bill

The provision would require the Secretary to coordinate educational activities through the Medicare contractors to maximize the effectiveness of education efforts for providers and suppliers. The provision would be effective upon enactment.

Conference Agreement

The conference agreement adds section 1889 to the Social Security Act requiring the Secretary to coordinate educational activities through the Medicare contractors to maximize the effectiveness of education efforts for providers and suppliers and to report to Congress with a description and evaluation of the steps taken to coordinate provider education funding. The agreement is effective upon enactment. The Secretary is required to report to Congress on the steps taken to coordinate the funding of provider education under the provision by October 1, 2004.

(b) Incentives to Improve Contractor Performance.

Present Law

No specific statutory provision. Since FY1996, as part of the audit required by the Chief Financial Officers Act, an estimate of improper payments in Medicare fee-for-service has been established annually. As a recent initiative, CMS is implementing a comprehensive error rate-testing program to produce national, contractor specific, benefit category specific and provider specific paid claim error rates.

House Bill

The Secretary would be required to use specific claims payment error rates (or similar methodology) to provide incentives for contractors to implement effective education and outreach programs for providers and suppliers. The provision would require the Comptroller General to submit to Congress and the Secretary a study and to make recommendations on the adequacy of the Secretary's methodology by October 1, 2004. The Secretary would be required to report to Congress by October 1, 2004 regarding how he intends to use the methodology in assessing Medicare contractor performance.

Senate Bill

The provision would require the Secretary to use specific claims payment error rates (or similar methodology) to provide incentives for contractors to implement effective education and outreach programs for providers and suppliers by October 1, 2004. The Conferees agree that any such methodology shall include non-responses in the measurement of the error rate. The Comptroller General would be required to study the adequacy of the methodology and make recommendations to the Secretary. The Secretary would be required to report to Congress regarding how he intends to use the methodology in assessing Medicare contractor performance.

Conference Agreement

The conference agreement requires the Secretary to use specific claims payment error rates (or similar methodology) to provide incentives for contractors to implement effective education and outreach programs for providers and suppliers. The Comptroller General is required to submit to Congress and the Secretary a study the adequacy of the methodology and to make recommendations. The Secretary is required to report to Congress by October 1, 2004 regarding how he intends to use the methodology in assessing Medicare contractor performance.

(c) Provision of Access to and Prompt Responses from Medicare Administrative Contractors.

Present Law

No specific statutory provision. Statutory provisions generally instruct carriers to assist providers and others who furnish services in developing procedures relating to utilization practices and to serve as a channel of communication relating information on program administration. Fiscal intermediaries are generally instructed to (1) provide consultative services to institutions and other agencies to enable them to establish and maintain fiscal records necessary for program participation and payment and (2) serve as a center for any information as well as a channel for communication with providers.

House Bill

The Secretary would be required to develop a strategy for communicating with beneficiaries, providers and suppliers. Medicare contractors would be required to provide responses to written inquiries that are clear, concise and accurate within 45 business days of the receipt of the written inquiry. The Secretary would be required to ensure that Medicare contractors have a toll-free telephone number where beneficiaries, providers and suppliers may obtain information regarding billing, coding, claims, coverage, and other appropriate Medicare information. Medicare contractors would be required to maintain a system for identifying the person supplying information to beneficiaries, providers, and suppliers and to monitor the accuracy, consistency, and timeliness of the information provided. The Secretary would be required to establish and make public standards to monitor the accuracy, consistency, and timeliness of written and telephone responses of Medicare contractors as well as to evaluate the contractors against these standards. The provision would be effective October 1, 2004.

Senate Bill

Identical provision.

Conference Agreement

The conference agreement requires the Secretary to develop a strategy for communicating with beneficiaries, providers and suppliers, beginning October 1, 2004. Medicare contractors are required to provide responses to written inquiries that are clear, concise and accurate within 45 business days of the receipt of the written inquiry. The Secretary is required to ensure that Medicare contractors have a toll-free telephone number where beneficiaries, providers and suppliers may obtain information regarding billing, coding, claims, coverage, and other appropriate Medicare information. Medicare contractors would be required to maintain a system for identifying the person supplying information to beneficiaries, providers, and suppliers and to monitor the accuracy, consistency, and timeliness of the information provided. The Secretary is required to establish and make public standards to monitor the accuracy, consistency, and timeliness of written and telephone responses of Medicare contractors as well as to evaluate the contractors against these standards. The conference agreement authorizes to be appropriated such sums as are necessary to carry out this subsection.

(d) Improved Provider Education and Training.

Present Law

In FY 2003, approximately $122 million was budget by CMS for provider education and training.

House Bill

The provision would authorize $25 million to be appropriated from the Medicare Trust Funds for fiscal years 2005 and 2006, and such sums as necessary for succeeding fiscal years for Medicare contractors to increase education and training activities for providers and suppliers. Medicare contractors would be required to tailor education and training activities to meet the special needs of small providers or suppliers. The provision defines a small provider as an institution with fewer than 25 full-time equivalents (FTEs) and a small supplier as one with fewer than 10 FTEs.

Senate Bill

The provision would provide increased funding for the Medicare Integrity Program of $35 million beginning with FY2004 for increased provider and supplier education. Also would require Medicare contractors to take into consideration the special needs of small providers or suppliers when conducting education and training activities and permits provision of technical assistance beginning January 1, 2004.

Conference agreement

The conference agreement authorizes such sums as necessary to be appropriated for fiscal years beginning with FY 2005 to be used to increase education and training activities for providers and suppliers regarding billing, coding, and other appropriate items and may be used to improve the accuracy, consistency, and timeliness of contractor responses. Beginning October 1, 2004, Medicare contractors are required to tailor education and training activities to meet the special needs of small providers or suppliers. Technical assistance is permitted to be included in the education and training activities. The provision defines a small provider as an institution with fewer than 25 full-time equivalents (FTEs) and a small supplier as one with fewer than 10 FTEs.

(e) Requirement to Maintain Internet Sites.

Present Law

No statutory provision. CMS and the Medicare contractors currently maintain internet sites.

House Bill

The provision would require that the Secretary and the Medicare contractors maintain Internet sites to answer frequently asked questions and provide published materials of the contractors beginning October 1, 2004.

Senate Bill

No provision.

Conference agreement

Beginning October 1, 2004, the conference agreement requires the Secretary and the Medicare contractors to maintain Internet sites to answer frequently asked questions and provide published materials of the contractors.

(f) Additional Provider Education Provisions.

Present Law

No provision.

House Bill

The provision would bar Medicare contractors from using a record of attendance (or non-attendance) at educational activities to select or track providers or suppliers in conducting any type of audit or prepayment review. The provision would not require Medicare contractors to disclose information that would compromise law enforcement activities or reveal findings of law enforcement-related audits. This provision would be effective upon enactment.

Senate Bill

The provision would bar Medicare contractors from using a record of attendance (or non-attendance) at educational activities to select or track providers or suppliers in conducting any type of audit or prepayment review. The provision would not require Medicare contractors to disclose the screens used for identifying claims that will be subject to medical review or information that would compromise pending law enforcement activities or reveal findings of law enforcement-related audits. This provision would be effective upon enactment.

Conference agreement

The conference agreements bars Medicare contractors from using a record of attendance (or non-attendance) at educational activities to select or track providers or suppliers in conducting any type of audit or prepayment review. Nothing in section 1889 or 1893(g) shall be construed as providing for disclosure by a Medicare contractor of the screens used for identifying claims that will be subject to medical review or of information that would compromise pending law enforcement activities or reveal findings of law enforcement-related audits. The agreement is effective upon enactment.

Small Provider Technical Assistance Demonstration Program. (Section 922 of the Conference Agreement, Section 922 of the House Bill).

Present Law

No provision.

House Bill

The Secretary would be required to establish a demonstration program to provide technical assistance to small providers and suppliers, when they have requested the assistance, to improve compliance with Medicare requirements. If errors are found, the Secretary would be barred from recovering any overpayments barring evidence of fraud and if the problem that is the subject of the compliance review has been satisfactorily corrected within 30 days and the problem remains corrected. Providers participating would be expected to pay 25 percent of the cost of the technical assistance. A GAO study would be required not later than 2 years after the demonstration program begins. Appropriations would be authorized for $1 million for FY 2005 and $6 million for FY 2006 to carry out the demonstration.

Senate Bill

No provision.

Conference Agreement

The conference agreement requires the Secretary to establish a demonstration program to provide technical assistance to

small providers and suppliers, when they have requested the assistance, in order to improve compliance with Medicare requirements. Technical assistance includes direct and in-person examination of billing systems and internal controls to determine program compliance and to suggest more efficient or effective means of achieving compliance. Providers participating are expected to pay 25 percent of the cost of the technical assistance. Appropriations of such sums as may be necessary to carry out this demonstration program are authorized from amounts not otherwise appropriated in the Treasury. The GAO is required to evaluate the demonstration no later than 2 years after it begins and submit a report to the Congress and the Secretary. The GAO is required to include in the report recommendations regarding the continuation or extension of the demonstration.

Medicare Provider Ombudsman; Medicare Beneficiary Ombudsman. (Section 923 of the Conference Agreement, Section 923 of the House Bill, Sections 301 and 534 of the Senate Bill).

Present Law

No provision.

House Bill

A Medicare Provider Ombudsman would be required to be appointed by the Secretary and located within the Department of Health and Human Services. The Provider Ombudsman would be required to provide confidential assistance to providers and suppliers regarding complaints, grievances, requests for information, and resolution of unclear or conflicting guidance about Medicare. The Ombudsman would submit recommendations to the Secretary regarding improving the administration of Medicare, addressing recurring patterns of confusion under Medicare, and ways to provide for an appropriate and consistent response in cases of self-identified overpayments by providers and suppliers. Such sums, as necessary, would be authorized and be appropriated for FY 2004 and subsequent years.

A Medicare Beneficiary Ombudsman would be required to be appointed by the Secretary and located within HHS. The Secretary would be required to appoint both ombudsmen not later than one year from the date of enactment. The Beneficiary Ombudsman would be required to have expertise and experience in health care, education of, and assistance to Medicare beneficiaries. The Beneficiary Ombudsman would be required to receive complaints, grievances, and requests for information submitted by Medicare beneficiaries. The Beneficiary Ombudsman would also be required to assist beneficiaries in collecting relevant information to seek an appeal of a decision or determination made by the Secretary, a Medicare contractor, or a Medicare+Choice organization and assisting a beneficiary with any problems arising from disenrolling in a Medicare+Choice plan and with presenting income information for purposes relating to the prescription drug benefit. The Beneficiary Ombudsman would be required to work with state Health Insurance Counseling Programs, to the extent possible.

Such sums as are necessary are authorized to be appropriated for FY 2004 and each succeeding fiscal year to carry out the ombudsmen provisions.

This provision would also require the use of 1–800–MEDICARE for all individuals seeking information about, or assistance with Medicare. Rather than listing individual telephone numbers for Medicare contractors in the Medicare handbook, only 1–800–MEDICARE would be shown. The Comptroller General would be required to study the accuracy and consistency of information provided by the 1–800–MEDICARE line and to assess whether the information sufficiently answers the questions of beneficiaries. The report on the study would be required to be submitted to Congress not later than one year after enactment.

Senate Bill

Same provisions.

Conference Agreement

The conference agreement creates a new section 1810 establishing a Medicare Beneficiary Ombudsman. The Secretary is required to appoint an Ombudsman with expertise and experience in the fields of health care and education of (and assistance to) Medicare beneficiaries not later than 1 year after the date of enactment. The Ombudsman will receive complaints, grievances, and requests for information from Medicare beneficiaries, and provide assistance in these matters and matters relating to appeals decisions made by Medicare contractors, Medicare+Choice organizations or the Secretary, as well as assistance to beneficiaries with any problems disenrolling from a Medicare+Choice plan. In addition, the Ombudsman will assist beneficiaries in presenting information relating to the income-related premium adjustment. The Beneficiary Ombudsman is required to work with State Health Insurance Counseling Programs, to the extent possible. The Ombudsman is prohibited from advocating for any increases in payment or new coverage of services, but may identify issues and problems in payment or coverage policies.

Appropriations are authorized to be appropriated in such sums as are necessary for FY 2004 and each succeeding fiscal year to carry out the Beneficiary Ombudsman provision.

The conference agreement also requires making 1–800–MEDICARE available to all individuals seeking information about, or assistance with, Medicare. Rather than listing individual telephone numbers for Medicare contractors in the Medicare handbook, only 1–800–MEDICARE would be shown. The Comptroller General is required to study the accuracy and consistency of information provided on the 1–800–MEDICARE line and to assess whether the information sufficiently answers the questions of beneficiaries. The report on the study is due to Congress not later than one year after enactment.

It is the intent of the Conferees that Medicare beneficiaries have access to prescription drugs for the treatment of mental illness and neurological diseases resulting in severe epileptic episodes under the new provisions of Part D. To fulfill this purpose the Administrator of the Center for Medicare Choices shall take the appropriate steps before the first open enrollment period to ensure that Medicare beneficiaries have clinically appropriated access to pharmaceutical treatments for mental illness, including but not limited to schizophrenia, bipolar disorder, depression, anxiety disorder, dementia, and attention deficit disorder/attention deficit hyperactivity disorder and neurological illnesses resulting in epileptic episodes.

The conferees anticipate that disabled individuals will enroll in one of the many private sector prescription drug plans or MA–PD plans. Competition will necessitate plans offering the full complement of medicines, including atypical antipsychotics, to treat the severely mentally ill. If a plan chooses not to offer or restrict access to a particular medication to treat the mentally ill, the disabled will have the freedom to choose a plan that has appropriate access to the medicine needed. The Conferees believe this is critical as the severely mentally ill are a unique population with unique prescription drug needs as individual responses to mental health medications are different.

Beneficiary Outreach Demonstration Program. (Section 924 of the Conference Agreement, Section 924 of the House Bill, Section 535 of the Senate Bill).

Present Law

No provision.

House Bill

The Secretary would be required to conduct a 3-year demonstration program where Medicare specialists would provide assistance to beneficiaries in at least 6 local Social Security offices (2 would be located in rural areas) that have a high volume of visits by Medicare beneficiaries. The Secretary would be required to evaluate the results of the demonstration regarding the feasibility and cost-effectiveness of permanently outstationing Medicare specialists at local Social Security offices and report to Congress. The provision would be effective upon enactment.

Senate Bill

Same provision

Conference Agreement

The conference agreement requires the Secretary to conduct a 3-year demonstration program where Medicare specialists would provide assistance to beneficiaries in at least 6 local Social Security offices (2 would be located in rural areas) that have a high volume of visits by Medicare beneficiaries. The Secretary is required to evaluate the results of the demonstration regarding the feasibility and cost-effectiveness of permanently outstationing Medicare specialists at local Social Security offices and report to Congress. The agreement is effective upon enactment.

Inclusion of Additional Information in Notices to Beneficiaries About Skilled Nursing Facility Benefits. (Section 925 of the Conference Agreement, Section 925 of the House Bill, Section 551 of the Senate Bill).

Present Law

Although the statute requires that beneficiaries receive a statement listing the items and services for which payment has been made, there is no explicit statutory instruction that requires the notice to include information about the number of days of coverage remaining in either the hospital or skilled nursing facility (SNF) benefit or the spell of illness.

House Bill

The Secretary would be required to provide information about the number of days of coverage remaining under the SNF benefit and the spell of illness involved in the explanation of Medicare benefits. The provision would be effective for notices provided during calendar quarters beginning more than 6 months after the date of enactment.

Senate Bill

Same provision.

Conference Agreement

The conference agreement requires the Secretary to provide information about the number of days of coverage remaining under the SNF benefit and the spell of illness involved in the explanation of Medicare benefits. The agreement applies to notices provided during calendar quarters beginning more than 6 months after the date of enactment.

Information on Medicare-Certified Skilled Nursing Facilities in Hospital Discharge Plans. (Section 926 of the Conference Agreement, Section 926 of the House Bill, Section 552 of the Senate Bill).

Present Law

The hospital discharge planning process requires evaluation of a patient's likely need for post-hospital services including hospice and home care.

House Bill

The Secretary would be required to make information publicly available regarding

whether SNFs are participating in the Medicare program. Hospital discharge planning would be required to evaluate a patient's need for SNF care.

The provision would apply to discharge plans made on or after the date specified by the Secretary, but not later than six months after the Secretary provides information regarding SNFs that participate in the Medicare program.

Senate Bill

Same provision.

Conference Agreement

The conference agreement requires the Secretary to make information publicly available regarding whether SNFs are participating in the Medicare program. Hospital discharge planning is required to evaluate a patient's need for SNF care.

The agreement applies to discharge plans made on or after the date specified by the Secretary, but not later than six months after the Secretary provides information regarding SNFs that participate in the Medicare program.

Transfer of Responsibility for Medicare Appeals. (Section 931 of the Conference Agreement, Section 931 of the House Bill, Sections 511 and 519 of the Senate Bill).

Present Law

Denials of claims for Medicare payment may be appealed by beneficiaries (or providers who are representing the beneficiary) or in certain circumstances, providers or suppliers directly. The third level of appeal is to an administrative law judge (ALJ). The ALJs that hear Medicare cases are employed by the Social Security Administration—a legacy from the inception of the Medicare program when Medicare was part of Social Security. BIPA section 522 requires that appeals of local coverage determinations be heard by ALJs of the Social Security Administration (SSA). As a result, if the ALJ function were moved from SSA to HHS, these local coverage determination appeals would still need to be heard by SSA ALJs.

House Bill

The Secretary and the Commissioner of the Social Security Administration (SSA) would be required to develop a plan to transfer the functions of the administrative law judges (ALJs) who are responsible for hearing Medicare cases from SSA to HHS. This plan would be due to Congress not later than October 1, 2004. A GAO evaluation of the plan would be due within 6 months of the plan's submission. ALJ functions would be transferred no earlier than July 1, 2005 and no later than October 1, 2005.

The Secretary would be required to place the ALJs in an administrative office that is organizationally and functionally separate from the Centers for Medicare & Medicaid Services and the ALJs would be required to report to, and be under the general supervision of the Secretary. No other official within the Department would be permitted to supervise the ALJs. The Secretary would be required to provide for appropriate geographic distribution of ALJs, would have the authority to hire ALJs and support staff, and would be required to enter into arrangements with the Commissioner, as appropriate, to share office space, support staff and other resources with appropriate reimbursement.

Authorizes to be appropriated such sums as are necessary for FY2005 and each subsequent fiscal year to increase the number of ALJs, improve education and training of ALJs and to increase the staff of the Departmental Appeals Board (the final level of appeal).

Senate Bill

The Secretary and Commissioner of Social Security would be required to develop and transmit to Congress and the Comptroller General a plan for transferring the functions of administrative law judges (ALJs) responsible for hearing cases under Medicare from the Social Security Administration to HHS no later than April 1, 2004. The plan would be required to include information on: workload; cost projections and financing; transition timetable; regulations; development of a case tracking system; feasibility of precedential authority; feasibility of electronic appeals filings and teleconference; steps needed to assure independence of ALJs, including assuring that they are in an office that is operationally and functionally separate from the Centers for Medicare & Medicaid Services and the Center for Medicare Choices; geographic distribution of ALJs; steps for hiring ALJs; performance standards of ALJs; sharing resources with Social Security regarding ALJs; training; and recommendations for further Congressional action. The GAO would be required to evaluate the Secretary's and Commissioner's plan and report to Congress on the result of the evaluation within 6 months of the receiving the plan. The Secretary would be prohibited from implementing the plan developed until no earlier than 6 month after the GAO report.

The statutory language that requires SSA ALJs be used to hear appeals of local coverage determinations would be eliminated. The requirement that these appeals be heard by ALJs would be retained. The provision would be effective upon enactment.

Conference Agreement

The conference agreement requires the Secretary and the Commissioner of Social Security to develop a plan to transfer the administrative law judge function from SSA to HHS for Medicare appeals. Their plan is due to Congress and the Comptroller General not later than April 1, 2004. The plan is required to include information on: anticipated workload and staffing requirements; funding requirements; transition timetable; regulations; case tracking system; feasibility of developing a process to give Department Appeals Board decisions binding precedential authority; feasibility of filing appeals with ALJs electronically and conducting hearings using tele- or video-conferencing technologies; steps that should be taken to ensure the independence of ALJs; steps that should be taken to provide for an appropriate geographic distribution of ALJs throughout the United States; steps that should be taken to hire ALJs and support staff; appropriateness of establishing performance standards; steps that should be taken to carry out any needed shared resources with SSA; needed training; and any additional recommendations for further Congressional action.

A GAO evaluation of the plan is required within 6 months of the plan's submission. ALJ functions are required to be transferred no earlier than July 1, 2005 and no later than October 1, 2005.

The Secretary is required to place the ALJs in an administrative office that is organizationally and functionally separate from the Centers for Medicare & Medicaid Services and the ALJs would be required to report to, and be under the general supervision of the Secretary. No other official within the Department is permitted to supervise the ALJs. The Secretary is required to provide for appropriate geographic distribution of ALJs, would have the authority to hire ALJs and support staff, and is required to enter into arrangements with the Commissioner, as appropriate, to share office space, support staff and other resources with appropriate reimbursement.

In addition to any amounts otherwise appropriated, the agreement authorizes to be appropriated such sums as are necessary for FY 2005 and each subsequent fiscal year to increase the number of ALJs, improve education and training of ALJs, and to increase the staff of the Departmental Appeals Board (the final level of appeal).

The conference agreement strikes the statutory language that requires SSA ALJs be used to hear appeals of local coverage determinations. The requirement that these appeals be heard by ALJs is retained. This provision is effective upon enactment.

Process for Expedited Access to Review. (Section 932 of the Conference Agreement, Section 932 of the House Bill, Sections 512 and 513 of the Senate Bill).

Present Law

In general, administrative appeals must be exhausted prior to judicial review. The statute requires the automatic suspension of nurse aide training programs in skilled nursing facilities that have been subject to extended survey (that is, found to provide substandard care), have had serious sanctions imposed, or have waivers for required licensed nurse staffing.

House Bill

The Secretary would be required to establish a process where a provider, supplier, or a beneficiary may obtain expedited access to judicial review when a 3-member review panel (composed of ALJs, members of the Departmental Appeals Board, or qualified individuals from qualified independent contractors designated by the Secretary) determines, within 60 days of a complete written request, that it does not have the authority to decide the question of law or regulation and where material facts are not in dispute. The decision would not be subject to review by the Secretary. Interest would be assessed on any amount in controversy and would be awarded by the reviewing court in favor of the prevailing party. This expedited access to judicial review would also be permitted for cases where the Secretary does not enter into or renew provider agreements.

Expedited review would also be established for certain remedies imposed against SNFs. The remedies in the provision are termination of participation, denial of payments, and imposition of temporary management. The Secretary would be required to develop a process for reinstating approval of nurse aide training programs that have been terminated (before the end of the mandatory 2-year disapproval period) if the only reason for the termination was the assessment of a civil money penalty of $5,000 or more. The appropriation of such sums as needed for FY2005 and subsequent years would be authorized to reduce by 50% the average time for administrative determinations, to increase the number of ALJs and appellate staff at the DAB, and to educate these judges and their staffs on long-term care issues. This provision would be effective for appeals filed one or after October 1, 2004.

Senate Bill

The Secretary would be required to establish a process where a provider, supplier, or a beneficiary may obtain expedited access to judicial review when a review entity (up to 3 qualified reviewers drawn from the ALJs or Departmental Appeals Board) determines, within 60 days of a complete written request, that it does not have the authority to decide the question of law or regulation and where material facts are not in dispute. The decision would not be subject to review by the Secretary. Interest would be assessed on any amount in controversy and is awarded by the reviewing court in favor of the prevailing party. Expedited access to judicial review would be permitted for cases where the Secretary does not enter into or renew provider

agreements. The provision would be effective for appeals filed on or after October 1, 2004.

The Secretary also would be required to develop and implement a process to expedite review for certain remedies imposed against skilled nursing facilities (SNFs): termination of participation, immediate denial of payments, immediate imposition of temporary management, and suspension of nurse aide training programs.

This provision would authorize the appropriation of such sums as needed for FY2004 and subsequent years to reduce by 50% the average time for administrative determinations, to increase the number of ALJs and appellate staff at the DAB, and to educate these judges and their staffs on long-term care issues.

The Comptroller General would be required to report to Congress on the access of Medicare beneficiaries and health care providers to judicial review of actions of the Secretary and HHS after February 29, 2000 (the date of the decision of *Shalala* v. *Illinois Council on Long Term Care, Inc.* (529 U.S. 1 (2000)). The report would be due not later than one year after enactment.

Conference Agreement

The conference agreement requires the Secretary to establish a process where a provider, supplier, or a beneficiary may obtain access to judicial review when a review entity (up to 3 qualified reviewers drawn from the ALJs or Departmental Appeals Board) determines, within 60 days of a complete written request, that it does not have the authority to decide the question of law or regulation and where material facts are not in dispute. The decision is subject to review by the Secretary. Interest is assessed on any amount in controversy and is awarded by the reviewing court in favor of the prevailing party. Expedited access to judicial review is permitted for cases where the Secretary does not enter into or renew provider agreements. The conference agreement is effective for appeals filed on or after October 1, 2004.

The agreement requires the Secretary to establish a process to expedite appeals of provider terminations and certain other remedies imposed on skilled nursing facilities, including denial of payment for new admissions and temporary management, if imposed on an immediate basis. Providers who are subject to the remedies of denial of payment or temporary management may only access the expedited process when these remedies are imposed on an immediate basis and where the facility has no opportunity to correct the deficiency. The agreement would also allow an expedited appeal where a finding of substandard quality of care has resulted in the disapproval of a skilled nursing facility's nurse aide training program. The agreement requires the Secretary to give priority to cases where termination has been imposed on a provider.

The agreement includes a provision allowing the Secretary to waive disapproval of a nurse aide training program, upon application by a nursing facility if the disapproval resulted from the imposition of a civil monetary penalty that was not related to quality of care provided to residents of the facility. Quality of care in such instances refers to direct, hands on care provided to residents of a facility. This agreement does not permit the Secretary to waive the CMP.

In addition to any amounts otherwise appropriated, the conference agreement authorizes the appropriation of such sums as needed for FY2004 and subsequent years in order to reduce by 50% the average time for administrative determinations, to increase the number of ALJs and appellate staff at the DAB, and to educate these judges and their staffs on long-term care issues.

Revisions to Medicare Appeals Process. (Section 933 of the Conference Agreement, Section 933 of the House Bill, Section 514 of the Senate Bill).

(a) Requiring Full and Early Presentation of Evidence

Present Law

No provision. New evidence can be presented at any stage of the appeals process.

House Bill

The provision would require providers and suppliers to present all evidence for an appeal at the reconsideration level that is conducted by a qualified independent contractor (QIC) unless good cause precluded the introduction of the evidence. The provision would be effective October 1, 2004.

Senate Bill

No provision.

Conference Agreement

The conference agreement requires providers and suppliers to present all evidence for an appeal at the reconsideration level that is conducted by a qualified independent contractor (QIC) unless good cause precluded the introduction of the evidence. The conference agreement provision is effective October 1, 2004.

(b) Use of Patients' Medical Records

Present Law

No provision.

House Bill

The provision would provide for the use of beneficiaries' medical records in appeals reconsiderations by qualified independent contractors (QICs). The provision would be effective upon enactment.

Senate Bill

Beneficiaries' medical records would be able to be used in appeals reconsiderations by qualified independent contractors. The provision would be effective upon enactment.

Conference Agreement

The conference agreement provides for the use of beneficiaries' medical records in appeals reconsiderations by QICs. The conference agreement is effective upon enactment.

(c) Notice Requirements for Medicare Appeals

Present Law

No statutory provision. Determinations and denials of appeals currently include the policy, regulatory, or statutory reason for the denial and information on how to appeal the denial. The Benefits Improvement and Protection Act (BIPA) of 2000, changed the appeals process and created a new independent review (the qualified independent contractors or QICs), which has not yet been implemented.

House Bill

The provision would require that when claims are denied the written notice of determination include the reasons for the determination, including whether a local medical review policy or a local coverage determination was used; the procedures for obtaining additional information concerning the determination including, when requested, the specific provision of the policy, manual, or regulation used in making the determination; and notification of the right to seek an appeal and instructions for appealing the determination.

In the case when a redetermination (the first level of appeal) is denied, the written notice would be required to include: the specific reasons for the redetermination; as appropriate, a summary of the clinical or scientific evidence used in making the redetermination; a description of the procedures for obtaining additional information concerning the redetermination. The notice would be required to be written in a manner calculated to be understood by a beneficiary. A beneficiary receiving such a notice would be permitted to request and receive information on the specific provision of the policy, manual, or regulation used in making the redetermination.

In the case when a reconsideration (the second level of appeal) is decided, the written notice would be required to be written in a manner calculated to be understood by the beneficiary and information regarding appeal rights and processes provided.

For appeals (to either the ALJ or Departmental Appeals Board (DAB)), the notice of the decision would be required to be in writing and written in a manner calculated to be understood by the beneficiary, to include the specific reasons for the determination, including to the extent appropriate a summary of the clinical or scientific evidence used in making the determination; the procedures for obtaining additional information regarding the decision; and notification of the right to appeal and how to initiate such an appeal. The provision also requires that the qualified independent contractor submit information that is needed for an appeal of a decision.

Senate Bill

The provision would require that when claims are denied, the written notice of the decision at every level of the appeal or with the initial determination would be required to be written in a manner to be understood by the beneficiary and include notification of the right to appeal the decision and instruction on how to initiate an appeal.

In addition, the determination would be required to include the reasons for the determination including, as appropriate, the provision of the policy, manual, or regulation that resulted in the denial if requested; and the procedures for obtaining additional information concerning the determination.

In the case when a redetermination (the first level of appeal) is denied, the written notice would be required to include: the reasons for the decision and, as appropriate, the provision of the policy, manual, or regulation that resulted in the denial if requested, and a summary of the clinical or scientific evidence used in making the redetermination; and a description of the procedures for obtaining additional information concerning the redetermination.

In the case when a reconsideration (the second level of appeal) is decided, the written notice would be required to include a detailed explanation of the decision as well as a discussion of the pertinent facts and applicable regulations applied in making the decision, to the extent appropriate; and in the case of a decision regarding whether an item or service is reasonable and necessary for the diagnosis or treatment of illness or injury, an explanation of the medical or scientific rationale for the decision.

For appeals (to either the ALJ or Departmental Appeals Board (DAB)), the notice of the decision would be required to include the specific reasons for the determination including, to the extent appropriate, a summary of the clinical or scientific evidence used in making the determination; and the procedures for obtaining additional information concerning the decision.

Conference Agreement

The conference agreement requires that when claims are denied in either the initial determination or in subsequent appeals, a written notice of the decision is required and to be written in a manner calculated to be understood by the beneficiary and to include notification of the right to appeal the decision and instruction on how to initiate an appeal.

In addition, the determination is required to include the reasons for the determination, including whether a local medical review policy or a local coverage determination was used; and the procedures for obtaining additional information concerning the determination including, when requested, the specific provision of the policy, manual, or regulation used in making the determination.

In the case when a redetermination (the first level of appeal) is denied, the written notice is required to include: the specific reasons for the redetermination; as appropriate, a summary of the clinical or scientific evidence used in making the redetermination; a description of the procedures for obtaining additional information concerning the redetermination. A beneficiary receiving such a notice is permitted to request and receive information on the specific provision of the policy, manual, or regulation used in making the redetermination.

In the case when a reconsideration (the second level of appeal) is decided, the written notice is required to be written in a manner calculated to be understood by the beneficiary and information regarding appeal rights and processes provided.

For appeals (to either the ALJ or Departmental Appeals Board (DAB)), the notice of the decision is required to be in writing and written in a manner calculated to be understood by the beneficiary, to include the specific reasons for the determination, including to the extent appropriate a summary of the clinical or scientific evidence used in making the determination; the procedures for obtaining additional information regarding the decision; and notification of the right to appeal and how to initiate such an appeal.

The conference agreement also requires that the qualified independent contractor submit information that is needed for an appeal of a decision. The conference agreement is effective upon enactment.

(d) Qualified Independent Contractors

Present Law

BIPA established a new and independent second level of appeal called the qualified independent contractors (QICs). BIPA called for at least 12 QICs. The QICs have not yet been implemented.

House Bill

The provision would clarify eligibility requirements for qualified independent contractors and their reviewer employees including medical and legal expertise, independence requirements, and the prohibition on compensation being linked to decisions rendered. The required number of qualified independent contractors would be reduced from not fewer than 12 to not fewer than 4. The provisions regarding the eligibility requirements of QICs and QIC reviews would be effective as if included in the enactment of BIPA.

Senate Bill

The provision would clarify eligibility requirements for qualified independent contractors and their reviewer employees including medical and legal expertise, independence requirements, and prohibitions on compensation being linked to decisions rendered. The required minimum number of qualified independent contractors would be reduced from 12 to 4.

In addition, the provision would delay the effective date of certain appeals provisions until December 1, 2004. Expedited determinations would be delayed until October 1, 2003. The provision would allow the transitional use of peer review organizations (now called quality improvement organizations by the Secretary) to conduct expedited determinations until the QICs are operating.

Conference Agreement

The conference agreement clarifies eligibility requirements for qualified independent contractors and their reviewer employees including medical and legal expertise, independence requirements, and the prohibition on compensation being linked to decisions rendered. The required number of qualified independent contractors is reduced from not fewer than 12 to not fewer than 4. The provisions regarding the eligibility requirements of QICs and QIC reviews are effective as if included in the enactment of BIPA.

Implementation of Certain BIPA Effective Dates

Present Law

The BIPA claims appeals provisions were effective October 1, 2002 but have not been implemented.

House Bill

No provision.

Senate Bill

The provision would delay the effective date of certain appeals provisions until December 1, 2004. Expedited determinations would be delayed until October 1, 2003. The provision would allow the transitional use of peer review organizations (now called quality improvement organizations by the Secretary) to conduct expedited determinations until the QICs are operating.

Conference Agreement

No provision.

Prepayment Review. (Section 934 of the Conference Agreement, Section 934 of the House Bill, Section 541 of the Senate Bill).

Present Law

No explicit statutory instruction. Under administrative authorities, CMS has instructed the contractors to use random prepayment reviews to develop contractor-wide and program-wide error rates. Non-random payment reviews are permitted in certain circumstances laid out in instructions to the contractors.

House Bill

Medicare contractors would be permitted to conduct random prepayment reviews only to develop a contractor-wide or program-wide error rate or such additional circumstances as the Secretary provides for in regulations that were developed in consultation with providers and suppliers. Random prepayment review would only be permitted in accordance with standard protocol developed by the Secretary. Nonrandom payment reviews would be permitted only when there was a likelihood of sustained or high level of payment error. The Secretary would be required to issue regulations regarding the termination and termination dates of non-random prepayment review. Variation in termination dates would be permitted depending upon the differences in the circumstances triggering prepayment review.

The Secretary would be required to issue the required regulations not later than one year after enactment. The provision regarding the use of standard protocols when conducting prepayment reviews would apply to random prepayment reviews conducted on or after the date specified by the Secretary (but not later than one year after enactment). The remaining provisions would be effective one year after enactment.

Senate Bill

The conduct of random prepayment review would be limited only to those done in accordance with a standard protocol developed by the Secretary. Non-random reviews would be prohibited unless a likelihood of sustained or high level of payment error (as defined by the Secretary) existed and the Secretary would be required to establish protocols for terminating the non-random reviews within one year of enactment. The Secretary would be required to publish implementing regulations and develop and publish protocols not later than one year after enactment. The provision would be effective for random reviews conducted on or after the date specified by the Secretary (but not later than one year after enactment).

Conference Agreement

The conference agreement permits Medicare contractors to conduct random prepayment reviews only to develop a contractor-wide or program-wide error rate or such additional circumstances as the Secretary provides for in regulations that are developed in consultation with providers and suppliers. Random prepayment reviews are only permitted in accordance with standard protocol developed by the Secretary. Nonrandom payment reviews are permitted only when there is a likelihood of sustained or high level of payment error. The Secretary is required to issue regulations regarding the termination and termination dates of non-random prepayment review. Variation in termination dates is permitted depending upon the differences in the circumstances triggering prepayment review.

The Secretary is required to issue the required regulations not later than 1 year after enactment. The provision regarding the use of standard protocols when conducting prepayment reviews applies to random prepayment reviews conducted on or after the date specified by the Secretary (but not later than 1 year after enactment). The remaining provisions are effective 1 year after enactment.

Recovery of Overpayments. (Section 935 of the Conference Agreement, Section 935 of the House Bill, Section 542 of the Senate Bill).

Present Law

No explicit statutory instruction. Under administrative authorities, CMS negotiates extended repayment plans with providers that need additional time to repay Medicare overpayments.

House Bill

In situations where repaying a Medicare overpayment within 30 days would be a hardship for a provider or supplier, the Secretary would be required to enter into an extended repayment plan of at least 6 months duration. The repayment plan would not be permitted to go beyond 3 years (or 5 years in the case of extreme hardship, as determined by the Secretary). Interest would be required to accrue on the balance through the repayment period. Hardship would be defined if, for providers that file cost reports, the aggregate amount of the overpayment exceeded 10 percent of the amount paid by Medicare to the provider for the time period covered by the most recently submitted cost report. In the case of a provider or supplier that is not required to file a cost report, hardship would be defined if the aggregate amount of the overpayment exceeded 10 percent of the amount paid under Medicare for the previous calendar year. The Secretary would be required to develop rules for the case of a provider or supplier that was not paid under Medicare during the previous year or for only a portion of the year. Any other repayment plans that a provider or supplier has with the Secretary, would not be taken into account by the Secretary in calculating hardship. If the Secretary has reason to suspect that the provider or supplier may file for bankruptcy or otherwise cease to do business or discontinue participation in Medicare or there is an indication of fraud or abuse, the Secretary would not be obligated to enter into an extended repayment plan with the provider or supplier. If a provider or supplier fails to make a payment according to the repayment plan, the Secretary would be permitted to immediately seek to offset

or recover the total outstanding balance of the repayment plan, including interest.

The Secretary would be prohibited from recouping any overpayments until a reconsideration-level appeal (or a redetermination by the fiscal intermediary or carrier if the QICs are not yet in place) was decided, if a reconsideration was requested. Interest would be required to be paid to the provider if the appeal was successful (beginning from the time the overpayment is recouped) or that interest would be required to be paid to the Secretary if the appeal was unsuccessful (and if the overpayment was not paid to the Secretary).

Extrapolation would be limited to those circumstances where there is a sustained or high level of payment error, as defined by the Secretary in regulation, or documented educational intervention has failed to correct the payment error.

Medicare contractors would be permitted to request the periodic production of records or supporting documentation for a limited sample of submitted claims to ensure that the previous practice is not continuing in the case of a provider or supplier with prior overpayments.

The Secretary would be able to use consent settlements to settle projected overpayments under certain conditions. Specifically the Secretary would be required to communicate with the provider or supplier that medical record review has indicated an overpayment exists, the nature of the problems identified, the steps needed to address the problems, and afford the provider or supplier 45 days to furnish additional information regarding the medical records for the claims reviewed. If, after reviewing the additional information an overpayment continues to exist, the Secretary would be required to provide notice and an explanation of the determination and then may offer the provider two mechanisms to resolve the overpayment: either an opportunity for a statistically valid random sample or a consent settlement (without waiving any appeal rights).

The Secretary would be required to establish a process to provide notice to certain providers and suppliers in cases where billing codes were over-utilized by members of that class in certain areas, in consultation with organizations that represent the affected provider or supplier class.

If post-payment audits were conducted, the Medicare contractor would be required to provide the provider or supplier with written notice of the intent to conduct the audit. The contractor would further be required to give the provider or supplier a full and understandable explanation of the findings of the audit and permit the development of an appropriate corrective action plan, inform the provider or supplier of appeal rights and consent settlement options, and give the provider or supplier the opportunity to provide additional information to the contractor, unless notice or findings would compromise any law enforcement activities.

The Secretary would be required to establish a standard methodology for Medicare contractors to use in selecting a sample of claims for review in cases of abnormal billing patterns.

In general the provisions would be effective upon enactment. The limitation on extrapolation would apply to samples initiated after the date that is 1 year after the date of enactment. The Secretary would be required to establish the process for notice of over-utilization of billing codes not later than 1 year after enactment. The Secretary would be required to establish a standard methodology for selecting sample claims for abnormal billing patterns not later than 1 year after enactment.

Senate Bill

This provision would add a new subsection (h) to 1874A that would require establishment of at least a 1 year repayment plan—but not longer than three years—when a provider requests a repayment plan, unless the Secretary believes the provider may declare bankruptcy. If a provider or supplier fails to make a scheduled payment, the Secretary could immediately offset or recover the outstanding balance. The Secretary would be required to develop standards for the recovery of overpayments not later than one year after enactment.

The Secretary would be barred from recouping any overpayments until a reconsideration-level appeal was decided (if one were requested). The paragraph provides that interest would be required to be paid to the provider if the appeal was successful (beginning from the time the overpayment is recouped) or that interest would be required to be paid to the Secretary if the appeal was unsuccessful (and if the overpayment was not paid to the Secretary).

The provision would also require that if post-payment audits were conducted, the Medicare contractor would be required to provide the provider or supplier with written notice of the intent to conduct the audit. The contractor would further be required to give the provider or supplier a full and understandable explanation of the findings of the audit and permit the development of an appropriate corrective action plan, inform the provider or supplier of appeal rights and consent settlement options, and give the provider or supplier the opportunity to provide additional information to the contractor, unless notice or findings would compromise any law enforcement activities.

The Secretary would be required to establish a process to provide notice to certain providers and suppliers in cases where billing codes were over-utilized by members of that class in certain areas, in consultation with organizations that represent the affected provider or supplier class. The process would be required not later than one year after enactment.

Not later than one year after enactment, the Secretary would be required to establish a standard methodology for Medicare contractors to use in selecting a sample of claims for review in cases of abnormal billing patterns.

The Secretary would be authorized to use a consent settlement process to settle projected overpayments under certain specified conditions.

The provisions affecting post-payment audits and consent settlements would be effective to audits initiated and consent settlements entered into after the date of enactment. Other provisions would be effective for action taken 1 year after enactment.

Conference Agreement

In situations where repaying a Medicare overpayment within 30 days would be a hardship for a provider or supplier, the conference agreement requires the Secretary to enter into an extended repayment plan of at least 6 months duration. The repayment plan is not permitted to go beyond 3 years (or 5 years in the case of extreme hardship, as determined by the Secretary). Interest is required to accrue on the balance through the repayment period. Hardship is defined if, for providers that file cost reports, the aggregate amount of the overpayment exceeded 10 percent of the amount paid by Medicare to the provider for the time period covered by the most recently submitted cost report. In the case of a provider or supplier that is not required to file a cost report, hardship is defined if the aggregate amount of the overpayment exceeded 10 percent of the amount paid under Medicare for the previous calendar year. The Secretary is required to develop rules for the case of a provider or supplier that was not paid under Medicare during the previous year or for only a portion of the year. Any other repayment plans that a provider or supplier has with the Secretary, are not taken into account by the Secretary in calculating hardship. If the Secretary has reason to suspect that the provider or supplier may file for bankruptcy or otherwise cease to do business or discontinue participation in Medicare or there is an indication of fraud or abuse, the Secretary is not obligated to enter into an extended repayment plan with the provider or supplier. If a provider or supplier fails to make a payment according to the repayment plan, the Secretary may immediately seek to offset or recover the total outstanding balance of the repayment plan, including interest.

The Secretary is prohibited from recouping any overpayments until a reconsideration-level appeal (or a redetermination by the fiscal intermediary or carrier if the QICs are not yet in place) was decided, if a reconsideration was requested. Interest is required to be paid to the provider if the appeal is successful (beginning from the time the overpayment is recouped) or interest is required to be paid to the Secretary if the appeal is unsuccessful (and if the overpayment was not paid to the Secretary).

Extrapolation is limited to those circumstances where there is a sustained or high level of payment error, as defined by the Secretary in regulation, or document educational intervention has failed to correct the payment error.

Medicare contractors are permitted to request the periodic production of records or supporting documentation for a limited sample of submitted claims to ensure that the previous practice is not continuing in the case of a provider or supplier with prior overpayments.

The Secretary is permitted to use consent settlements to settle projected overpayments under certain conditions. Specifically the Secretary is required to communicate with the provider or supplier that medical record review has indicated an overpayment exists, the nature of the problems identified, the steps needed to address the problems, and afford the provider or supplier 45 days to furnish additional information regarding the medical records for the claims reviewed. If, after reviewing the additional information an overpayment continues to exist, the Secretary is required to provide notice and an explanation of the determination and then may offer the provider two mechanisms to resolve the overpayment: either an opportunity for a statistically valid random sample or a consent settlement (without waiving any appeal rights).

The Secretary is required to establish a process to provide notice to certain providers and suppliers in cases where billing codes were over-utilized by members of that class in certain areas, in consultation with organizations that represent the affected provider or supplier class.

If post-payment audits are conducted, the Medicare contractor is required to provide the provider or supplier with written notice of the intent to conduct the audit. The contractor is further required to give the provider or supplier a full and understandable explanation of the findings of the audit and permit the development of an appropriate corrective action plan, inform the provider or supplier of appeal rights and consent settlement options, and give the provider or supplier the opportunity to provide additional information to the contractor, unless notice or findings would compromise any law enforcement activities.

The Secretary is required to establish a standard methodology for Medicare contractors to use in selecting a sample of claims for review in cases of abnormal billing patterns.

In general, the provisions are effective upon enactment. The limitation on extrapolation would apply to samples initiated after the date that is 1 year after the date of enactment. The Secretary is required to establish the process for notice of overutilization of billing codes not later than 1 year after enactment. The Secretary is required to establish a standard methodology for selecting sample claims for abnormal billing patterns not later than 1 year after enactment.

Provider Enrollment Process; Right of Appeal. (Section 936 of the Conference Agreement, Section 936 of the House Bill, Section 515 of the Senate Bill).

Present Law

No explicit statutory instruction. Under administrative authorities, CMS has established provider enrollment processes in instructions to the contractors.

House Bill

The Secretary would be required to establish in regulation a provider enrollment process with hearing rights in the case of a denial or non-renewal. The process would be required to include deadlines for actions on applications for enrollment and enrollment renewals. The Secretary would be required to monitor the performance of the Medicare contractors in meeting the deadlines he establishes. Before changing provider enrollment forms, the Secretary would be required to consult with providers and suppliers. The provision would also establish hearing rights in cases where the applications have been denied.

The enrollment process would be required to be established within 6 months of enactment. The consultation process on provider enrollment forms would be required for changes in the form beginning January 1, 2004. The provision of hearing rights would apply to denials that occur 1 year after enactment or an earlier date specified by the Secretary.

Senate Bill

Same provisions.

Conference Agreement

The conference agreement requires the Secretary to establish in regulation a provider enrollment process with hearing rights in the case of a denial or non-renewal. The process is required to include deadlines for actions on applications for enrollment and enrollment renewals. The Secretary is required to monitor the performance of the Medicare contractors in meeting the deadlines he establishes. Before changing provider enrollment forms, the Secretary is required to consult with providers and suppliers. The conference agreement also establishes hearing rights in cases where the applications have been denied.

The enrollment process is required to be established within 6 months of enactment. The consultation process on provider enrollment forms is required for changes in the form beginning

January 1, 2004. The provision of hearing rights applies to denials that occur 1 year after enactment or an earlier date specified by the Secretary.

Process for Correction of Minor Errors and Omissions without Pursuing Appeals Process. (Section 937 of the Conference Agreement, Section 937 of the House Bill, Section 543 the Senate Bill).

Present Law

No explicit statutory instruction. Administratively, the Medicare contractors send a claim's denial when a claim has been submitted that lacks required information. Amendments to cost reports are not allowed once a cost report is settled.

House Bill

This provision would require the Secretary to establish a process so providers and suppliers could correct minor errors in claims that were submitted for payment. The provision would also require the Secretary to permit hospitals to correct wage data errors that affect geographic reclassification even if the cost report has been settled. For FY 2004 alone, resubmittal of the application for geographic reclassification would be permitted. The provision would be effective upon enactment.

Senate Bill

This provision would require the Secretary to establish a process so providers and suppliers could correct minor errors in claims that were submitted for payment. The provision would require that the process be developed not later than 1 year after enactment.

Conference Agreement

The conference agreement requires the Secretary to establish a process so providers and suppliers could correct minor errors in claims that were submitted for payment within 1 year after enactment.

Prior Determination Process for Certain Items and Services; Advance Beneficiary Notices. (Section 938 of the Conference Agreement, Section 938 of the House Bill, Section 535(b) of the Senate Bill).

Present Law

Medicare law prohibits payment for items and services that are not medically reasonable and necessary for the diagnosis or treatment of an illness or an injury. Under certain circumstances, however, Medicare will pay for noncovered services that have been provided if both the beneficiary and the provider of the services did not know and could not have reasonably been expected to know that Medicare payment would not be made for these services.

A provider may be held liable for providing uncovered services, if, for example, specific requirements are published by the Medicare contractor or the provider has received a denial or reduction of payment on the same or similar service. In cases where the provider believes that the service may not be covered as reasonable and necessary, an acceptable advance notice of Medicare's possible denial of payment must be given to the patient if the provider does not want to accept financial responsibility for the service. The notice must be given in writing, in advance of providing the service; include the patient's name, date and description of service as well as reasons why the service would not be covered; and must be signed and dated by the patient to indicate that the beneficiary will assume financial liability for the service if Medicare payment is denied or reduced.

House Bill

The Secretary would be required to establish a process through regulation where physicians and beneficiaries can establish whether Medicare covers certain categories of items and services before such services are provided. An eligible requestor would be a physician, but only in case of items and services for which the physician is paid directly and a Medicare beneficiary who receives an advance beneficiary notice from a physician would receive direct payment for that service. The provisions would establish (1) that such prior determinations would be binding on the Medicare contractor, absent fraud or misrepresentation of facts; (2) the right to redetermination in the case of a denial; (3) the applicability of existing deadlines with respect to those redeterminations; (4) that contractors' advance determinations (and redeterminations) are not subject to further administrative or judicial review; and (5) an individual retains all rights to usual administrative or judicial review after receiving the service or receiving a determination that a service would not be covered. These provisions would not affect a Medicare beneficiary's right not to seek an advance determination. The prior determination process would be established in time to address such requests that are filed by 18 months of enactment. The Secretary would be required to collect data on the advance determinations and to establish a beneficiary outreach and education program. GAO is required to report on the use of the advance beneficiary notice and prior determination process within 18 months of its implementation.

Senate Bill

The Secretary would be required to establish a demonstration project to test the administrative feasibility of providing a process for beneficiaries and providers to request and receive a determination as to whether the item or service is covered under Medicare by reasons of Medical necessity, before the item or service involved is furnished to the beneficiary.

Conference Agreement

The conference agreement requires the Secretary to establish a prior determination process through regulation where physicians and beneficiaries can determine whether Medicare covers certain physician services before such services are provided. An eligible requestor is a physician, but only in case of services for which the physician is paid directly, or a Medicare beneficiary, who receives an advance beneficiary notice from a physician who would receive direct payment for that service. The provision establishes (1) that such prior determinations would be binding on the Medicare contractor, absent fraud or misrepresentation of facts; (2) the right to redetermination in the case of a denial; (3) the applicability of existing deadlines with respect to those redeterminations; (4) that contractors' advance determinations (and redeterminations) are not subject to further administrative or judicial review; and (5) an individual retains all rights to usual administrative or judicial review after receiving the service or receiving a determination that a service would not be covered. These provisions do not affect a Medicare beneficiary's right not to seek an advance determination. The prior determination process is required to be established in time to address such requests that are filed by 18 months after enactment and it sunsets 5 years later. For purposes of calculating the physician fee schedule sustainable growth rate, this provision is not to be considered to be a change in law or regulation. The Secretary is required to collect data on the advance beneficiary notices and to establish a beneficiary outreach and education program. GAO is required to report on the use of the advance beneficiary notices within 18 months of the implementation of the prior determination process. The GAO is also required to report on the use of the prior determination process within 36 months of the implementation of the prior determination process.

Appeals by Providers When There is No Other Party Available. (Section 939 of the Conference Agreement, Section 516 of the Senate Bill).

Present Law

Section 1870 of the Social Security Act provides for the recovery of overpayments and the settlement of claims for benefits on behalf of a deceased beneficiary

House Bill

No provision.

Senate Bill

In the case where a beneficiary dies before assigning appeal rights, a provider or supplier would be permitted to appeal a payment denial by a Medicare contractor. The provision would be effective for items and services furnished on or after enactment.

Conference Agreement

In the case where a beneficiary dies before assigning appeal rights, the conference agreement permits a provider or supplier to appeal a payment denial by a Medicare contractor. The provision is effective for items and services furnished on or after enactment.

Revisions to Appeals Timeframes and Amounts. (Section 940 of the Conference Agreement, Section 518 of the Senate Bill).

Present Law

BIPA revised the timeframes for Medicare appeals. For the first level of appeal, the ''redetermination'' level, the timeframe for decisions was reduced from 90 days for a part A appeal and 45 days for a part B appeal to 30 days; for the second level, the ''reconsideration'' level, the timeframe was reduced from 120 days for a part B appeal to 30 days (this is a new level of appeal for part A appeals); for the third level, appeals before administrative law judges, the timeframe was reduced from no time limit to 90 days; and the fourth level, appeals before the Department Appeals Board, the timeframe was reduced from no time limit to 90 days. BIPA also provided that a beneficiary could ''escalate'' his or her appeal to the next level if the appeal was not decided in a timely fashion.

To appeal a claim, the beneficiary must have an ''amount in controversy'' of $100 or more. Judicial review is available only for amounts in controversy of $1,000 or more. Claims are permitted to be aggregated in order to reach the amount in controversy if certain conditions are met.

House Bill

No provision.

Senate Bill

This provision would add 30 days to the timeframe for deciding an appeal at each of the four levels of appeal. No provision regarding the indexing of amounts in controversy.

Conference Agreement

The conference agreement adds 30 days to the timeframe for deciding an appeal at the redetermination and reconsideration levels of appeal (that is, the first two levels of appeal). The conference agreement also indexes the amount in controversy for appeals to the CPI–U, rounded to the nearest multiple of $10 beginning in 2005.

Mediation Process for Local Coverage Determinations (Section 940A of the Conference Agreement, Section 517 of the Senate Bill).

Present Law

Only beneficiaries have standing to appeal local coverage decisions by Medicare contractors. Mediation is not currently used in Medicare to resolve disputes.

House Bill

No provision.

Senate Bill

The parties that have standing to appeal local coverage decisions would be expanded to include providers or suppliers adversely affected by the determination. The Secretary would be required to establish a process whereby a provider or supplier may request a local coverage determination under certain circumstances. A provider or supplier could seek a local coverage determination if the Secretary determined that: (A) there have been at least five reversals by an ALJ of redeterminations made by a Medicare contractor in at least two different cases; (B) that each reversal involved substantially similar material facts; (C) each reversal involved the same medical necessity issue; and (D) at least 50% of the total claims submitted by the provider within the past year involving the requisite facts and medical necessity issue have been denied and then reversed by an ALJ. Such sums as necessary to carry out the provisions above would be authorized to be appropriated. Also the provision would require the Secretary to study and report to Congress on the feasibility and advisability of requiring Medicare contractors to track the subject and status of claims denials that are appealed and final determinations.

The expansion in standing would be effective for any review or request of any local coverage determination filed on or after October 1, 2003 and for any local coverage determination made on or after October 1, 2003. The requirement to establish a process for a provider or supplier to request a local coverage determination would be effective for requests filed on or after the date of enactment. The report would be due to Congress not later than one year after the date of enactment.

Conference Agreement

The conference agreement requires the Secretary to establish a mediation process using a physician trained in mediation and employed by CMS. This process is to be used to mediate disputes between groups representing providers, physicians, and suppliers and the medical director for the Medicare contractor in any area that the relevant CMS regional administrator determines that there is a systematic pattern and a large volume of complaints from such groups regarding decisions of the medical director or there is a complaint from the co-chair of the advisory committee for that contractor. The Secretary is required to include in the contract with Medicare Administrative Contractors the performance duties expected of a medical director including professional relations. The provision is effective upon enactment.

Policy Development Regarding Evaluation and Management (E&M) Documentation Guidelines. (Section 941 of the Conference Agreement, Section 941 of the House Bill, Section 553 of the Senate Bill).

Present Law

No provision.

House Bill

The Secretary would not be permitted to implement any new documentation guidelines for, or clinical examples of, evaluation and management (E&M) physician services unless the Secretary: (1) developed the guidelines in collaboration with practicing physicians (both generalists and specialists) and provided for an assessment of the proposed guidelines by the physician community; (2) established a plan containing specific goals, including a schedule, for improving the use of the guidelines; (3) conducted pilot projects to test modifications to the guidelines; (4) finds the guidelines have met established objectives; and (5) established and implemented an education program on the use of the guidelines with appropriate outreach. The Secretary would make changes to existing E&M guidelines to reduce paperwork burdens on physicians. The provision establishes objectives for modifications of the E&M guidelines: (1) identification of clinically relevant documentation needed to code accurately and assess coding levels accurately; (2) decrease the level of non-clinically pertinent and burdensome documentation time and content in the medical record; (3) increase accuracy of reviewers; and (4) education of physicians and reviewers.

The pilot projects would be required to be conducted on a voluntary basis in consultation with practicing physicians (both generalists and specialists) and be of sufficient length to educate physicians and contractors on E&M guidelines. A range of different projects would be established and include at least one project: using a physician peer review method, using an alternative method based on face-to-face encounter time with the patient, in a rural area, outside a rural area, and where physicians bill under physician services in a teaching setting and nonteaching setting. The projects would examine the effect of modified E&M guidelines on different types of physician practices in terms of the cost of compliance. Data collected under these projects would not be the basis for overpayment demands or post-payment audits. This protection would apply to claims filed as part of the project, would last the duration of the project and would last for as long as the provider participated in the project. Each pilot conducted would examine the effect of the new E&M documentation guidelines on different types of physician practices (including those with fewer than 10 full-time equivalent employees) and the costs of physician compliance including education implementation, auditing, and monitoring. The Secretary would be required to submit periodic reports to Congress on these pilot projects.

The provision would require a study of an alternative system for documenting physician claims. Specifically the Secretary would be required to study developing a simpler system for documenting claims for evaluation and management services and to consider systems other than current coding and documentation requirements. The Secretary would be required to consult with practicing physicians in designing and carrying out the study. This study would be due to Congress no later than October 1, 2005. MedPAC would be required to analyze the results of the study and report to Congress. The Secretary would also be required to study the appropriateness of coding in cases of extended office visits in which no diagnosis is made and report to Congress no later than October 1, 2005. The Secretary would be required to include in the report recommendations on how to code appropriately for these visits in a manner that takes into account the amount of time the physician spent with the patient.

Senate Bill

The Secretary would be required to ensure, before making changes in documentation guidelines for, or clinical examples of, or codes to report E&M physician services, that the process used in developing the guidelines, examples, or codes was widely consultative among physicians, reflects a broad consensus among specialties, and would allow verification of reported and furnished services.

Conference Agreement

The conference agreement does not permit the Secretary to implement any new or modified documentation guidelines (including clinical examples) for evaluation and management (E&M) physician services unless the Secretary has: (1) developed the guidelines in collaboration with practicing physicians (both generalists and specialists) and provided for an assessment of the proposed guidelines by the physician community; (2) established a plan containing specific goals, including a schedule, for improving the use of the guidelines; (3) conducted pilot projects to test modifications to the guidelines; (4) found the guidelines have met established objectives; and (5) established

and implemented an education program on the use of the guidelines with appropriate outreach. The conference agreement requires the Secretary to make changes to existing E&M guidelines to reduce paperwork burdens on physicians. The conference agreement establishes objectives for modifications of the E&M guidelines: (1) identification of clinically relevant documentation needed to code accurately and assess coding levels accurately; (2) decrease the level of non-clinically pertinent and burdensome documentation time and content in the medical record; (3) increase accuracy of reviewers; and (4) education of physicians and reviewers.

The pilot projects are required to be conducted on a voluntary basis in consultation with practicing physicians (both generalists and specialists) and are of sufficient length (but, in no case longer than 1 year) to educate physicians and contractors on E&M guidelines. A range of different projects would be established and include at least one project that: (1) uses a physician peer review method (that is not used by a Medicare contractor) that evaluates medical record information for claims submitted by physicians identified as statistical outliers relative to codes used for billing purposes for these services; (2) uses an alternative method based on face-to-face encounter time with the patient; (3) is conducted for services furnished in a rural area and one for services furnished outside a rural area; and (4) is conducted in a setting where physicians bill under physician services in a teaching setting and one in a nonteaching setting. The projects would examine the effect of modified E&M guidelines on different types of physician practices in terms of the cost of compliance. Each pilot conducted is required to examine the effect of the new E&M documentation guidelines on different types of physician practices (including those with fewer than 10 full-time equivalent employees) and the costs of physician compliance including education implementation, auditing, and monitoring. The provision requires the Secretary to submit a report to Congress on these pilot projects within 6 months of completion of the pilots.

A study of an alternative system for documenting physician claims is also required. Specifically, the Secretary is required to study developing a simpler system for documenting claims for evaluation and management services and to consider systems other than current coding and documentation requirements. The Secretary is required to consult with practicing physicians in designing and carrying out the study. This study is due to Congress no later than October 1, 2005. MedPAC would be required to analyze the results of the study and report to Congress. The Secretary is also required to study the appropriateness of coding in cases of extended office visits in which no diagnosis is made and report to Congress no later than October 1, 2005. The Secretary is required to include in the report recommendations on how to code appropriately for these visits in a manner that takes into account the amount of time the physician spent with the patient.

Improvement in Oversight of Technology and Coverage. (Section 942 of the Conference Agreement, Section 942 of the House bill, Section 554 of the Senate Bill).

(a) Council for Technology and Innovation

Present Law

No provision.

House Bill

The Secretary would be required to establish a Council for Technology and Innovation within the Centers for Medicare & Medicaid Services (CMS). The council would be composed of senior CMS staff and clinicians with a chairperson designated by the Secretary who reports to the CMS administrator. The Chairperson would serve as the Executive Coordinator for Technology and Innovation would be the single point of contact for outside groups and entities regarding Medicare coverage, coding, and payment processes. The Council would coordinate Medicare's coverage, coding, and payment processes as well as information exchange with other entities with respect to new technologies and procedures, including drug therapies.

Senate Bill

The provision would require the Secretary to establish a Council for Technology and Innovation composed of senior CMS staff and clinicians to coordinate coverage, coding, and payment processes under Title XVIII and the exchange of information on new technologies between CMS and other entities that make similar decisions.

Conference Agreement

The conference agreement requires the Secretary establish a Council for Technology and Innovation within the Centers for Medicare & Medicaid Services (CMS). The council is to be composed of senior CMS staff and clinicians with a chairperson designated by the Secretary who reports to the CMS administrator. The Chairperson will serve as the Executive Coordinator for Technology and Innovation and will be the single point of contact for outside groups and entities regarding Medicare coverage, coding, and payment processes. The Council is required to coordinate Medicare's coverage, coding, and payment processes as well as information exchange with other entities with respect to new technologies and procedures, including drug therapies.

(b) Methods for Determining Payment Basis for New Lab Tests

Present Law

Outpatient clinical diagnostic laboratory tests are paid on the basis of area wide fee schedules. The law establishes a cap on the payment amounts, which is currently set at 74 percent of the median for all fee schedules for that test. The cap is set at 100 percent of the median for tests performed after January 1, 2001 that the Secretary determines are new tests for which no limitation amount has previously been established.

House Bill

The Secretary would be required to establish procedures (by regulation) for determining the basis for and amount of payments for new clinical diagnostic laboratory tests. New laboratory tests would be defined as those assigned a new, or substantially revised Health Care Procedure Coding System (HCPCS) code on or after January 1, 2005. The Secretary, as part of this procedure, would be required to (1) provide a list (on an Internet site or other appropriate venue) of tests for which payments are being established in that year; (2) publish a notice of a meeting in the Federal Register on the day the list becomes available; (3) hold the public meeting no earlier than 30 days after the notice to receive public comments and recommendations; (4) take into account the comments, recommendations and accompanying data in both proposed and final payment determinations. The Secretary would set forth the criteria for making these determinations; make public the available data considered in making such determinations; and could convene other public meetings as necessary. Effective for codes assigned on or after January 1, 2005.

Senate Bill

No provision.

Conference agreement

The conference agreement requires the Secretary to establish procedures (by regulation) for determining the basis for and amount of payments for new clinical diagnostic laboratory tests. New laboratory tests are defined as those assigned a new, or substantially revised Health Care Procedure Coding System (HCPCS) code on or after January 1, 2005. The Secretary, as part of this procedure, is required to (1) provide a list (on an Internet site or other appropriate venue) of tests for which payments are being established in that year; (2) publish a notice of a meeting in the Federal Register on the day the list becomes available; (3) hold the public meeting no earlier than 30 days after the notice to receive public comments and recommendations; (4) take into account the comments, recommendations and accompanying data in both proposed and final payment determinations. The Secretary sets forth the criteria for making these determinations, which include whether a test should be established through gap-filling or cross-walking to an existing code. In these cases, carriers and CMS cannot substitute an alternative service for a gap filled amount, the Secretary shall make public the available data considered in making such determinations; and convenes other public meetings as necessary. The provision is effective for codes assigned on or after January 1, 2005.

(c) GAO Study on Improvements in External Data Collection for Use in the Medicare Inpatient Payment System.

Present Law

No provision.

House Bill

The GAO would be required to study which external data can be collected in a shorter time frame by CMS to use in calculating payments for inpatient hospital services. The GAO could evaluate feasibility and appropriateness of using quarterly samples or special surveys and would include an analysis of whether other executive agencies are best suited to collect this information. The report would be due to Congress no later than October 1, 2004.

Senate Bill

No provision.

Conference Agreement

The conference agreement requires the GAO to study which external data can be collected in a shorter time frame by CMS to use in calculating payments for inpatient hospital services. The GAO may evaluate feasibility and appropriateness of using quarterly samples or special surveys and is required to include an analysis of whether other executive agencies are best suited to collect this information. The report is due to Congress no later than October 1, 2004.

(d) Process for Adoption of ICD Codes as Data Standard

Present Law

The Secretary is required to rely on the recommendations from the National Committee on Vital and Health Statistics (NCVHS) before adopting health information standards and codes. The current standard for procedure codes is the International Classification of Diseases, 9th Revision, clinical modification (ICD–9–CM is the basis of the Medicare inpatient hospital PPS payment system). The NCVHS made a recommendation on November 5th to the Secretary about adopting the latest revision, the ICD–10–PCS (Procedure Coding System) or ICD–10–CM as a coding standard.

House Bill

The Secretary would be permitted to adopt the ICD–10–PCS and the ICD–10–CM within 1–year of enactment without receiving a recommendation from the National Committee on Vital and Health Statistics (NCVHS).

Senate Bill

No provision.

Conference Agreement

No provision. Because the NCVHS made a recommendation to the Secretary, Conferees believed the House provision was no longer necessary.

Conferees urge the Secretary, however, to accept the recommendation of the NCVHS and issue a notice of proposed rule making to initiate the regulatory process for the concurrent adoption of ICD–10–CM and ICD–10–PCS. ICD–10 would replace the 23-year-old ICD–9–CM coding classification system, which has highly limited reporting capabilities for today's needs and growth capacity for future needs, making it an unacceptable coding classification system for both inpatient and outpatient diagnosis. ICD–10 would be able to keep pace with advances in modern medicine, thus ensuring accurate reimbursement rates for emerging technologies and patient access to the highest quality care.

Since 1997, NCVHS has closely examined this issue and received testimonies and letters from more than 80 public- and private-sector groups representing the full range of interests in the health care community. NCVHS and other parties have commissioned numerous studies, all of which NCVHS also has carefully considered. The Committee finds that the recommendation made by NCVHS is based on sound evidence and is, in the words of NCVHS, ''in the best interests of the country as a whole.'' Conferees encourage the Secretary to implement the recommendation as quickly as possible.

Treatment of Hospitals for Certain Services Under Medicare Secondary Payor (MSP) Provisions. (Section 943 of the Conference Agreement, Section 943 of the House Bill).

Present Law

In certain instances when a beneficiary has other insurance coverage, Medicare becomes the secondary insurance. Medicare Secondary Payer is the Medicare program's coordination of benefits with other insurers. Section 1862(b)(6) of the Social Security Act requires an entity furnishing a Part B service to obtain information from the beneficiary on whether other insurance coverage is available.

House Bill

The Secretary would not require a hospital or a critical access hospital to ask questions or obtain information relating to the Medicare secondary payer provisions in the case of reference laboratory services if the same requirements are not imposed upon those provided by an independent laboratory. Reference laboratory services would be those clinical laboratory diagnostic tests and interpretations of same that are furnished without a face-to-face encounter between the beneficiary and the hospital where the hospital submits a claim for the services.

Senate Bill

No provision.

Conference Agreement

The conference agreement prohibits the Secretary from requiring a hospital or a critical access hospital to ask questions or obtain information relating to the Medicare secondary payer provisions in the case of reference laboratory services if the same requirements are not imposed upon those provided by an independent laboratory. Reference laboratory services are those clinical laboratory diagnostic tests and interpretations of same that are furnished without a face-to-face encounter between the beneficiary and the hospital where the hospital submits a claim for the services.

EMTALA Improvements. (Section 944 of the Conference Agreement, Section 944 of the House Bill).

Present Law

Medicare requires participating hospitals that operate an emergency room to provide necessary screening and stabilization services to any patient who comes to an emergency room requesting examination or treatment in order to determine whether an emergency medical situation exists.

Hospitals that are found to be in violation of Emergency Medical Treatment and Active Labor Act (EMTALA) requirements may face civil monetary penalties and termination of their provider agreement. Prior to imposing a civil monetary penalty, the Secretary is required to request a peer review organization (PRO—currently called quality improvement organizations or QIOs) to assess whether the involved beneficiary had an emergency condition, which had not been stabilized and provide a report on its findings. Except in the case where a delay would jeopardize the health or safety, the Secretary provides 60-day period for the requested PRO review.

House Bill

Emergency room services provided to screen and stabilize a Medicare beneficiary furnished after January 1, 2004, would be evaluated for Medicare's ''reasonable and necessary'' requirement on the basis of the information available to the treating physician or practitioner at the time the services were ordered; this would include the patient's presenting symptoms or complaint and not the patient's principal diagnosis. The Secretary would not be able to consider the frequency with which the item or service was provided to the patient before or after the time of admission or visit. The Secretary would be required to establish a procedure to notify hospitals and physicians when an EMTALA investigation is closed.

Except in the case where a delay would jeopardize the health and safety of individuals, the Secretary would be required to request a PRO review before making a compliance determination that would terminate a hospital's Medicare participation because of EMTALA violations and provide a period of 5 business days for such review. The PRO would be required to provide a copy of the report on its findings to the hospital or physician, consistent with existing confidentiality requirements. This provision would apply to terminations initiated on or after enactment

Senate Bill

No provision.

Conference Agreement

The conference agreement requires emergency room services provided to screen and stabilize a Medicare beneficiary furnished after January 1, 2004, to be evaluated for Medicare's ''reasonable and necessary'' requirement on the basis of the information available to the treating physician or practitioner at the time the services were ordered; this includes the patient's presenting symptoms or complaint and not the patient's principal diagnosis. The Secretary is prohibited from considering the frequency with which the item or service was provided to the patient before or after the time of admission or visit.

The Secretary is required to establish a procedure to notify hospitals and physicians when an EMTALA investigation is closed.

Except in the case where a delay would jeopardize the health and safety of individuals, the Secretary is required to request a PRO review before making a compliance determination that would terminate a hospital's Medicare participation because of EMTALA violations and provide a period of 5 business days for such review. The PRO is required to provide a copy of the report on its findings to the hospital or physician, consistent with existing confidentiality requirements. This provision applies to terminations initiated on or after enactment.

Emergency Medical Treatment and Active Labor Act (EMTALA) Technical Advisory Group. (Section 945 of the Conference Agreement, Section 945 of the House Bill).

Present Law

No provision.

House Bill

The Secretary would be required to establish a 19–member technical advisory group under specified requirements to review issues related to EMTALA. The advisory group would be comprised of: the CMS Administrator; the HHS Inspector General; 4 hospital representatives who have EMTALA experience, (2 of whom have not experienced EMTALA violations) 7 practicing physicians with specified experience; 2 patient representatives; 2 regional CMS staff involved in EMTALA investigations; 1 representative from a State survey organization and 1 from peer review organization. The Secretary would select qualified individuals who are nominated by organizations representing providers and patients.

The advisory group would review EMTALA regulations; provide advice and recommendations to the Secretary; solicit public comments from interested parties; and disseminate information on the application of the EMTALA regulations. The advisory group would be required to (1) elect a member to as chairperson; (2) schedule its first meeting at the direction of the Secretary and meet at least twice a year subsequently; and (3) terminate 30 months after the date of its first meeting. The Secretary would be required to establish the advisory group regardless of any limitation that may apply to the number of advisory committees that may be established within HHS.

Senate Bill

No provision.

Conference Agreement

The conference agreement requires the Secretary to establish a 19–member technical advisory group under specified requirements to review issues related to EMTALA. The advisory group would be comprised of: the CMS Administrator; the HHS Inspector General; 4 hospital representatives who have EMTALA experience (2 of whom have not experienced EMTALA violations); 7 practicing physicians with specified experience; 2 patient representatives; 2 regional CMS staff involved in EMTALA investigations; 1 representative from a State survey organization and 1 from peer review organization. The Secretary is required to select qualified individuals who are nominated by organizations representing providers and patients.

The advisory group will review EMTALA regulations; provide advice and recommendations to the Secretary; solicit public comments from interested parties; and disseminate information on the application of the EMTALA regulations. The advisory group is required to: (1) elect a member to as chairperson; (2) schedule its first meeting at the direction of the Secretary and meet at least twice a year subsequently; and (3) terminate 30 months after the date of its first meeting. The Secretary is required to establish the advisory group regardless of any limitation that may apply to the number of advisory committees that may be established within HHS.

Authorizing Use of Arrangements to Provide Core Hospice Services in Certain Circumstances. (Section 946 of the Conference Agreement, Section 946 of the House Bill, Section 406 of the Senate Bill).

Present Law

A hospice is a public agency or private organization that is primarily engaged in providing and making available certain care to a terminally ill Medicare beneficiary under a written plan.

House Bill

A hospice would be permitted to (1) enter into arrangements with another hospice program to provide care in extraordinary, exigent or other non-routine circumstances, such as unanticipated high patient loads, staffing shortages due to illness, or temporary travel by a patient outside the hospice's service area; and (2) bill and be paid for the hospice care provided under these arrangements. The provision would be effective for hospice care provided on or after the date of enactment.

Senate Bill

Same provision.

Conference Agreement

The conference agreement permits a hospice to: (1) enter into arrangements with another hospice program to provide care in extraordinary, exigent or other non-routine circumstances, such as unanticipated high patient loads, staffing shortages due to illness, or temporary travel by a patient outside the hospice's service area; and (2) bill and be paid for the hospice care provided under these arrangements. The provision is effective for hospice care provided on or after the date of enactment.

Application of OSHA Bloodborne Pathogens Standard to Certain Hospitals. (Section 947 of the Conference Agreement, Section 947 of the House Bill).

Present Law

Section 1866 establishes certain conditions of participation that providers must meet in order to participate in Medicare.

House Bill

Public hospitals that are not otherwise subject to the Occupational Safety and Health Act of 1970 would be required to comply with the Bloodborne Pathogens standard under section 1910.1030 of title 29 of the Code of Federal Regulations. A hospital that fails to comply with the requirement would be subject to a civil monetary penalty, but would not be terminated from participating in Medicare. The provision would apply to hospitals as of July 1, 2004.

Senate Bill

No provision.

Conference Agreement

The conference agreement requires that public hospitals, not otherwise subject to the Occupational Safety and Health Act of 1970, comply with the Bloodborne Pathogens standard under section 1910.1030 of title 29 of the Code of Federal Regulations. A hospital that fails to comply with the requirement will be subject to a civil monetary penalty, but cannot be terminated from participating in Medicare. The provision applies to hospitals as of July 1, 2004.

BIPA-Related Technical Amendments and Corrections. (Section 948 of the Conference Agreement, Section 948 of the House Bill).

Present Law

BIPA established an advisory process for national coverage determinations where panels of experts formed by advisory committees could forward their recommendations directly to the Secretary without prior approval of the advisory committee or the Executive Committee.

House Bill

The statutory reference in BIPA would be changed from the Social Security Act to the Public Health Service Act. Other BIPA references would be changed from ''policy'' to ''determinations.'' The provision is effective as if included in the enactment of BIPA.

Senate Bill

No provision.

Conference Agreement

The conference agreement changes the statutory reference in BIPA from the Social Security Act to the Public Health Service Act. Other BIPA references would be changed from ''policy'' to ''determinations.'' The provision is effective as if included in the enactment of BIPA.

Conforming Authority to Waive a Program Exclusion. (Section 949 of the Conference Agreement, Section 949 of the House Bill, Section 544 of the Senate Bill).

Present Law

The Secretary is required to exclude individuals and entities from participation in federal health programs that are (1) convicted of a criminal offense related to health care delivery under Medicare or under state health programs; (2) convicted of a criminal offense related to patient abuse or neglect under federal or state law; (3) convicted of a felony relating to fraud, theft, or financial misconduct relating to a health care program finance or operated by the federal, state or local government; or (4) convicted of a felony related to a controlled substance.

House Bill

The administrator of a federal health program would be permitted to waive certain 5-year exclusions if the exclusion of a sole community physician or source of specialized services in a community would impose a hardship. The mandatory exclusions that could be waived would be those related to convictions associated with program-related crimes; health care fraud and controlled substance. The provision would be effective upon enactment.

Senate Bill

Same provision.

Conference Agreement

The conference agreement permits the administrator of a federal health program to waive certain 5-year exclusions if the exclusion of a sole community physician or source of specialized services in a community will impose a hardship. The mandatory exclusions that can be waived are those related to convictions associated with program-related crimes; health care fraud and controlled substance. The provision is effective upon enactment.

Treatment of Certain Dental Claims. (Section 950 of the Conference Agreement, Section 950 of the House Bill, Section 555 of the Senate Bill).

Present Law

The Medicare benefit does not include most dental services. Some insurers may require a claim denial from Medicare before accepting the dental claim for payment review, even if the service is not covered by Medicare.

House Bill

A group health plan providing supplemental or secondary coverage to Medicare beneficiaries would not be able to require dentists to obtain a claim denial from Medicare for noncovered dental services before paying the claim. The provision would be effective 60 days after enactment.

Senate Bill

Same provision.

Conference Agreement

The conference agreement provides that a group health plan providing supplemental or secondary coverage to Medicare beneficiaries cannot require dentists to obtain a claim denial from Medicare for dental services that are not covered by Medicare before paying the claim. The provision is effective 60 days after enactment.

Furnishing Hospitals with Information to Compute DSH Formula. (Section 951 of the Conference Agreement, Section 951 of the House Bill).

Present Law

Disproportionate share hospital (DSH) payments under Medicare are calculated using a formula that includes the number of patient days for patients eligible for Medicaid.

House Bill

The provision would require the Secretary to provide information that hospitals need to calculate the number of Medicaid patient days used in the Medicare DSH payment formula, not later than 1 year after enactment.

Senate Bill

No provision.

Conference Agreement

The conference agreement requires the Secretary to arrange for the provision of information that hospitals need to calculate the Medicare DSH payment formula not later than 1 year after enactment.

Revisions to Reassignment Provisions (Section 952 of the Conference Agreement, Section 952 of the House Bill, Section 434 of the Senate Bill).

Present Law

In general, Medicare Part B payments may be made only to a Medicare beneficiary or to physician or other person who provided the service. Section 1842(b)(6) of the Social Security Act establishes the Medicare reassignment prohibitions and does not permit physicians to reassign their Medicare payments to entities with which they have a relationship on an independent contractor basis. In order for an independent contractor to reassign Medicare benefits, the services must be performed on the premises of the entity to which the benefits will be reassigned.

House Bill

Medicare payment for Part B services would be permitted to be made to an entity, as defined by the Secretary, that has a contractual arrangement with the physician or other person who provided the service for the entity to bill for the service and the contractual arrangement meets program integrity and other safeguards specified by the Secretary.

The provision would be effective for payments made on or after one year after the date of enactment.

Senate Bill

Same provision, but would include a conforming amendment.

Conference Agreement

This provision amends the Social Security Act to allow physicians and non-physician practitioners to reassign payment for Medicare-covered services, regardless of where the arrangement (including but not limited to a hospital, clinic, medical group, a physician practice management organization, or a staffing company) so long as there is a contractual arrangement between the physician and the entity under which the entity submits the bill for such service. As a result, the Secretary could enroll these entities in the Medicare program. The Secretary may also provide for other enrollment qualifications to assure program integrity, including joint and several liability.

This provision will streamline Medicare enrollment while also enhancing HHS' program integrity efforts. By permitting entities that retain independent contractors to enroll with the Medicare program and thereby directly bill the Medicare program, HHS

will be able to monitor the claims submitted by the entities that retain independent contractors as well as those entities that employ physicians. The Committee supports appropriate program integrity efforts (e.g. joint and several liability) for any entities billing the Medicare program including entities with employees as well as independent contractors. Further, the Committee believes that physicians' and non-physician practitioners' should be entitled to unrestrictive access to billings submitted on their behalf by the entity with which they have contracted. The Committee intends that the Secretary will implement this provision via program instructions to the Medicare contractors. The changes made by this provision shall apply to Medicare payments made on or after date of enactment.

The provision is effective upon enactment.

Other Provisions. (Section 953 of the Conference Agreement, Section 953 of the House Bill).

Present Law

No provisions.

House Bill

GAO Report on Physician Compensation. No later than six months from enactment, GAO would be required to report to Congress on the appropriateness of the updates in the conversion factor including the appropriateness of the sustainable growth rate (SGR) formula for 2002 and subsequently. The report would examine the stability and the predictability of the updates and rate as well as the alternatives for use of the SGR in the updates. No later than 12 months from enactment, GAO would be required to report to Congress on all aspects of physician compensation for Medicare services. The report would review the alternatives for the physician fee schedule.

Annual Publication of List of National Coverage Determinations. The Secretary would be required to publish an annual list of nation coverage determinations made under Medicare in the previous year. Included would be information on how to get more information about the determinations. The list would be published to the public in an appropriate annual publication.

GAO Report on Flexibility in Applying Home Health Conditions of Participation to Patients Who Are Not Medicare Beneficiaries. The GAO would be required to report to Congress on the implications if the Medicare conditions of participation for home health agencies were applied flexibly with respect to groups or types of patients who are not Medicare beneficiaries. The report would include an analysis of the potential impact of this flexibility on clinical operations and the recipients of such services and an analysis of methods for monitoring the quality of care provided to these recipients. The report would be due no later than six months after enactment.

OIG Report on Notices Relating to Use of Hospital Lifetime Reserve Days. The Inspector General of HHS would be required to report to Congress on the extent to which hospitals provide notice to Medicare beneficiaries, in accordance with applicable requirements, before they use the 60 lifetime reserve days under the hospital benefit. The report would also include the appropriateness and feasibility of hospitals providing a notice to beneficiaries before they exhaust the lifetime reserve days. The report would be due no later than one year after enactment.

Senate Bill

No provision.

Conference Agreement

GAO Report on Physician Compensation. The conference agreement requires that, no later than six months from enactment, the GAO report to Congress on the appropriateness of the updates in the conversion factor including the appropriateness of the sustainable growth rate (SGR) formula for 2002 and subsequent years. The report will examine the stability and the predictability of the updates and rate as well as the alternatives for use of the SGR in the updates. No later than 12 months from enactment, GAO is required to report to Congress on all aspects of physician compensation for Medicare services. The report is required to review the alternatives for the physician fee schedule.

Annual Publication of List of National Coverage Determinations. The conference agreement requires the Secretary publish an annual list of national coverage determinations made under Medicare in the previous year. Information on how to get more information about the determinations is required to be included in the publication. The list and the information are required to be published in an appropriate annual publication that is publicly available.

GAO Report on Flexibility in Applying Home Health Conditions of Participation to Patients Who Are Not Medicare Beneficiaries. The conference agreement requires the GAO to report to Congress on the implications if the Medicare conditions of participation for home health agencies were applied flexibly with respect to groups or types of patients who are not Medicare beneficiaries. The report is required to include an analysis of the potential impact of this flexibility on clinical operations and the recipients of such services and an analysis of methods for monitoring the quality of care provided to these recipients. The report is due no later than six months after enactment.

OIG Report on Notices Relating to Use of Hospital Lifetime Reserve Days. The conference agreement requires the Inspector General of HHS to report to Congress on the extent to which hospitals provide notice to Medicare beneficiaries, in accordance with applicable requirements, before they use the 60 lifetime reserve days under the hospital benefit. The report is required to include the appropriateness and feasibility of hospitals providing a notice to beneficiaries before they exhaust the lifetime reserve days. The report is due no later than one year after enactment.

Streamlining and Simplification of Medicare Regulations (Section 504 of the Senate Bill).

Present Law

No provision.

House Bill

No provision.

Senate Bill

The Secretary would be required to analyze Medicare regulations for the purposes of determining how to streamline the regulations and reduce the number of words in the regulations by two-thirds by October 1, 2004. If the Secretary determines that the two-thirds reduction is infeasible, he would be required to inform Congress in writing by July 1, 2004 of the reasons and then establish a feasible reduction to be achieved by January 1, 2005. The provision would be effective upon enactment.

Conference Agreement

No provision.

Elimination of the Requirement for De Novo Review by the Departmental Appeals Board (Section 520 of the Senate Bill).

Present Law

BIPA section 521 requires that the Departmental Appeals Board (DAB), the fourth level of appeal, review appeals cases *de novo.* Prior to BIPA, the DAB reviewed appeals based on the record established during the previous three levels of appeal.

House Bill

No provision.

Senate Bill

The DAB would be required to review a decision and render a decision or remand the appeal to the ALJ within the 90–day period. The provision would be effective upon enactment.

Conference Agreement

No provision.

TITLE X—MEDICAID AND MISCELLANEOUS PROVISIONS

Subtitle A—Medicaid Provisions

Medicaid Disproportionate Share (DSH) Hospital Payments—Temporary Increase. (Section 1001(a) of the Conference Agreement, Section 1001 of the House Bill, and Section 601 of the Senate Bill)

Present Law

Hospitals that serve a large number of uninsured patients and Medicaid enrollees receive additional Medicaid disproportionate share hospital (DSH) payments. As established in the BBA 1997, the federal share of Medicaid DSH payments is capped at specified amounts for each state for FY1998 through FY2002. For most states, those specified amounts declined over the 5-year period. A state's allotment for FY2003 and for later years is equal to its allotment for the previous year increased by the percentage change in the consumer price index for urban consumers (CPI–U) for the previous year. In addition, each state's DSH payment for FY2003 and subsequent years is limited to no more than 12% of total spending for medical assistance in each state for that year.

BIPA provided states with a temporary reprieve from the declining allotments by establishing a special rule for the calculation of DSH allotments for 2 years, raising allotments for FY2001 and for FY2002. The provision also clarified that the FY2003 allotments were to be calculated as specified under BBA 1997, using the lower, pre-BIPA levels for FY2002 in those calculations.

DSH payments to each inpatient general hospital are limited to some percentage of the costs of providing inpatient and outpatient services to Medicaid and uninsured patients at that hospital, less payments received from or on behalf of Medicaid and uninsured patients. These costs are considered to be unreimbursed costs. DSH payments to private hospitals may be no greater than 100% of unreimbursed costs. Public hospitals, for the two state fiscal years beginning after September 2002, cannot receive DSH payments that exceed 175% of unreimbursed costs. Thereafter, those hospitals would be limited to DSH payments of no more than 100% of unreimbursed costs.

House Bill

The provision would establish a temporary increase in DSH allotments for FY2004 and for certain subsequent fiscal years. Allotments for FY2004 would be set at 120% of FY2003 allotments as under BIPA and would not be subject to the ceiling capping states' allotments at 12% of medical assistance payments. Allotments for subsequent years would be equal to the allotments for FY2004 unless the Secretary determines that the allotments as would have been calculated prior to the enactment of this bill would equal or exceed the FY2004 amounts. For such fiscal years, allotments would be equal to allotments for the prior fiscal year increased by the percentage change in the consumer price index for all urban consumers for the previous fiscal year. The provision would be effective upon enactment.

Senate Bill

The special DSH rule established by BIPA that raised DSH allotments, subject to the current law limit of 12% of spending for medical assistance, would be extended for FY2004

and FY2005. Allotments for FY2004 would be calculated to be equal to FY2004 allotments (as established by BBA 1997) increased by the product of 0.50; and the difference between: (a) FY2002 allotments (as established by BIPA 2000) increased by the percentage change in the CPI–U for each of fiscal years 2002 and 2003, and (b) FY2004 allotments (as established by BBA 1997). Allotments FY2005 would be calculated to be equal to FY2005 allotments (as established by BBA 1997) increased by the product of 0.50; and the difference between: (a) FY2002 allotments (as established by the BIPA 2000) increased by the percentage change in the CPI–U for each of fiscal years, 2002, 2003, and 2004, and (b) FY2005 allotments (as established by BBA 1997). For FY2006 and thereafter, DSH allotments would be calculated based on the previous years' amount (as established by BBA 1997 and subject to the current law limit of 12% of spending for medical assistance) increased by the percentage change in the CPI–U for the previous fiscal year. All allotments would remain subject to the current law limit of 12% of medical assistance spending.

A separate calculation of the DSH allotment for the District of Columbia for FY2004 would be specified. The DSH allotment for the District of Columbia for FY2004 would be raised, subject to the current law limit of 12% of spending for medical assistance, by multiplying $49 million by the percentage change in the CPI–U for each of FY2000, FY2001, FY2002, and FY2003. The provision would be effective upon enactment.

Conference Agreement

The conference agreement will establish a temporary increase in DSH allotments for FY2004 and for certain subsequent fiscal years. Allotments for FY2004 are to be set at 116% of FY2003 allotments as under BIPA and will not be subject to the ceiling capping states' allotments at 12% of medical assistance payments. Allotments for subsequent years will be equal to the allotments for FY2004 unless the Secretary determines that the allotments as would have been calculated prior to the enactment of this bill would equal or no longer exceed the FY2004 amounts. For such fiscal years, allotments will be equal to allotments for the prior fiscal year increased by the percentage change in the consumer price index for all urban consumers for the previous fiscal year. The provision is effective upon enactment.

Increase in the Floor for Treatment as an Extremely Low DSH States Under the Medicaid Program for Fiscal Years 2004 and 2005. (Section 1001(b) of the Conference Agreement, Section 602 of the Senate Bill)

Present Law

Extremely low DSH states are those states whose FY1999 federal and state DSH expenditures (as reported to CMS on August 31, 2000) are greater than zero but less than 1% of the state's total medical assistance expenditures during that fiscal year. DSH allotments for the extremely low DSH states for FY2001 would be equal to 1% of the state's total amount of expenditures under their plan for such assistance during that fiscal year. For subsequent fiscal years, the allotments for extremely low DSH states would be equal to their allotment for the previous year, increased by the percentage change in the CPI–U for the previous year, subject to a ceiling of 12% of that state's total medical assistance payments in that year.

House Bill

No provision.

Senate Bill

Allotments for certain extremely low DSH states for FY2004 and FY2005 would be increased. For states with DSH expenditures for FY2000 (as reported to CMS as of August 31, 2003) that are greater than zero but less than 3% of the state's total medical assistance expenditures during that fiscal year, the provision would raise the DSH allotments for FY2004 to 3% of the state's total amount of expenditures for such assistance during that fiscal year. States with DSH expenditures for FY2001 (as reported to CMS as of August 31, 2004) that are greater than zero but less than 3% of the state's total medical assistance expenditures during that fiscal year would have the DSH allotments for FY2005 equal to such state's DSH allotment for FY2004 increased by the percentage change in the CPI–U for FY2004.

A special DSH allotment adjustment for certain states would be specified for FY2004 and FY2005. For Tennessee, if its state-wide Section 1115 waiver is revoked or terminated during FY2004 and/or FY2005, the Secretary of HHS would permit the state to submit an amendment to its state plan that would describe the methodology to be used by the state to identify and make payments for disproportionate share hospitals (including children's hospitals, and institutions for mental diseases, or other mental health facilities—other than state-owned institutions or facilities), based on the proportion of patients served by such hospitals that are low-income patients with special needs. The state would be required to provide data for the computation of an appropriate DSH allotment that does not result in greater expenditures under this title than would have been made if such waiver had not been revoked or terminated. The provision would be effective upon enactment.

Conference Agreement

The conference agreement will raise the temporary floor for extremely low DSH states as defined under current law for fiscal years 2004 through 2008 by 16% above current amounts.

Increased Reporting Requirements to Ensure the Appropriateness of Payment Adjustments to Disproportionate Share Hospitals Under the Medicaid Program. (Section 1001(c) of the Conference Agreement, Section 603 of the Senate Bill)

Present Law

BBA 1997 required each state to submit to the Secretary an annual report describing the disproportionate share payments made to each disproportionate share hospital (DSH) and the methodology used by the state for prioritizing payments to such hospitals.

House Bill

No provision.

Senate Bill

As a condition of receiving federal Medicaid payments for FY2004 and each fiscal year thereafter, the provision would require each state to submit to the Secretary an annual report (for the previous fiscal year) identifying each disproportionate share hospital that received a payment, the amount such hospital received, as well as other information the Secretary determines necessary to ensure the appropriateness of the DSH payments for the previous fiscal year. The provision would be effective upon enactment.

Conference Agreement

As a condition of receiving federal Medicaid payments for FY2004 and each fiscal year thereafter, the conference agreement will require each state to submit to the Secretary an annual report (for the previous fiscal year) identifying each disproportionate share hospital that received a payment, the amount such hospital received, as well as other information the Secretary determines necessary to ensure the appropriateness of the DSH payments for the previous fiscal year. In addition, the conference agreement will require states to submit annually to the Secretary an independent certified audit verifying: the extent to which hospitals receiving DSH payments have reduced their uncompensated care costs to reflect DSH payments received; the states' compliance with the hospital-specific payment ceilings; the methodology used to calculate those ceilings; and the documentation maintained by the states regarding claimed costs, expenditures and payments under this section. The conference agreement will be effective upon enactment.

Clarification of Inclusion of Inpatient Drug Prices Charged to Certain Public Hospitals in the Best Price Exemptions for the Medicaid Drug Rebate Program. (Section 1002 of the Conference Agreement, Section 1002 of the House Bill, and Section 604 of the Senate Bill)

Present Law

Medicaid drug rebates are calculated based on the difference between the average manufacturer's price (AMP) and the manufacturer's ''best price.'' In determining the ''best price'' for a drug sold by a manufacturer, certain discounted prices and fee schedules are disregarded. The special discounted prices for outpatient drugs negotiated by the Office of Pharmacy Affairs (of HHS) with drug manufacturers on behalf of certain clinics and safety net providers are one example of prices excluded from Medicaid's ''best price'' determination. Because of this exclusion from Medicaid's ''best price'' definition, the discounts available to safety net providers have no bearing on the calculation of drug rebates under the Medicaid program, allowing those providers to negotiate better rates with manufacturers, since Medicaid rebates will not change with the size of their negotiated discounts. Discounted prices for inpatient drugs for many safety net providers, however, are not disregarded in the Medicaid ''best price'' determination.

House Bill

The provision would modify the definition of ''best price'' for the purpose of calculating Medicaid drug rebates, to also disregard the discounted inpatient drug prices charged to certain public safety net hospitals. Those hospitals would also be subject to the same auditing and record keeping requirements as other providers with similar exemptions from Medicaid's ''best price'' determination. The provision would be effective upon enactment.

Senate Bill

The provision would modify the definition of ''best price'' for the purpose of calculating Medicaid drug rebates, to also exclude the discounted inpatient drug prices charged to certain public safety net hospitals. Those hospitals would also be subject to the same auditing and record keeping requirements as other providers with similar exemptions from Medicaid's ''best price'' determination. The provision would be effective October 1, 2003.

Conference Agreement

The conference agreement will modify the definition of ''best price'' for the purpose of calculating Medicaid drug rebates, to also exclude the discounted inpatient drug prices charged to certain public safety net hospitals. Those hospitals will also be subject to the same auditing and record keeping requirements as other providers with similar exemptions from Medicaid's ''best price'' determination. The provision will be effective upon enactment.

Assistance for States for Legal Immigrants

Present Law

''Qualified aliens'' who entered the United States after the enactment of the Personal

Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA, August 22, 1996) are not eligible to receive federally funded benefits under Medicaid or SCHIP for 5 years. Qualified aliens who entered the United States prior to the enactment of PRWORA are eligible for federally funded Medicaid coverage as a state option, as are qualified aliens arriving after August 22, 1996 who have been present in the United States for more than 5 years.

A person who executed an affidavit of support for an alien under Senate Section 213A of the Immigration and Nationality Act (INA) is liable to reimburse the federal or state government for the public benefits received by the sponsored alien until the alien naturalizes or has accumulated 40 quarters of work. Senate Section 213A was enacted as a part of PRWORA on August 22, 1996.

House Bill

No provision.

Senate Bill

The provision would lift the 5–year ban and would allow states the option to provide medical assistance to certain lawfully residing individuals under Medicaid (including under a waiver authorized by the Secretary) or SCHIP for any of fiscal years 2005 through 2007. Those eligible would include lawfully residing women during pregnancy and the 60–day period after delivery, and children otherwise eligible for Medicaid or SCHIP as defined by the state plan. States opting to provide coverage to such lawfully residing individuals under SCHIP must also provide coverage to such individuals under Medicaid. If services are provided under the Medicaid program, the alien's sponsor would not be liable to reimburse the federal or state government for the cost of such services. The provision would be effective upon enactment.

Conference Agreement

No provision.

GAO Study Regarding Impact of Assets Test for Low-income Beneficiaries. (Section 607 of the Senate Bill)

Present Law

No provision.

House Bill

No provision.

Senate Bill

The provision would require the General Accounting Office (GAO) to conduct a study to determine the extent to which drug utilization and access to covered drugs differs between: (1) individuals who qualify for the transitional assistance prescription drug card program or for the premiums and cost sharing subsidies available to certain low-income beneficiaries (including qualified Medicare beneficiaries, specified low-income Medicare beneficiaries or qualifying individual under Senate Section 1860(D)), and (2) individuals who do not qualify for the transitional assistance prescription drug card program or for the premiums and cost sharing subsidies available to certain low-income beneficiaries solely as a result of the application of an assets test to the income eligibility requirements of such individuals. The GAO would be required to submit to Congress the final report (including recommendations for legislation) no later than September 30, 2007. The provision would be effective upon enactment.

Conference Agreement

No provision.

Clarification Regarding Non-Regulation of Transfers

Present Law

No specific provision

House bill

No provision

Senate bill

No provision

Conference Agreement

The final conference agreement permits the Secretary, in limited instances, to allow a publicly-owned regional medical center to utilize the disproportionate share hospital allotment of another State. This provision will apply through December 31, 2005.

Urban Health Provider Adjustment. (Section 625 of the Senate Bill)

Present Law

There are two other types of ceilings on DSH payments, in addition to the state-wide allotments. The ''hospital-specific'' ceiling limits payments to hospitals to some percentage of the each hospital's costs of providing inpatient and outpatient services to Medicaid and uninsured patients, less payments received from or on behalf of Medicaid and uninsured patients (''unreimbursed costs''). DSH payments to public hospitals are limited to 100% of these unreimbursed costs except in fiscal years 2003 and 2004 when the percentage of unreimbursed costs that can be covered by DSH rises to 175%. The hospital-specific ceiling for private hospitals is 100% of unreimbursed costs and for certain public hospitals in the state of California is 175% permanently.

House Bill

No provision.

Senate Bill

DSH payments made to hospitals that are owned and operated by the state of Indiana and located in Marion County would be made without regard to the state's DSH allotment limitation so long as those payment amounts, fit FY2004 and each fiscal year thereafter do not exceed 175% of the ''unreimbursed costs'' of furnishing hospital services.

Conference Agreement

No provision.

100% FMAP for Medical Assistance Provided to a Native Hawaiian Through a Federally-Qualified Health Center or a Native Hawaiian Health Care System Under the Medicaid Program. (Section 632 of the Senate Bill)

Present Law

The Medicaid program is jointly financed by the states and the federal government. The federal government share is based on each state's federal medical assistance percentage (FMAP). The FMAP for a state is calculated using a formula reflecting the state per capita income relative to the average U.S. per capita income. The formula is designed to give a higher FMAP to states with a per capita income below the U.S. average. No state can have an FMAP of less than 50% or more than 83%. Certain services including family planning are paid at an alternative FMAP rate, as are administrative expenses. In addition, the law provides that services provided through an Indian Health Service facility operated by the Indian Health Service or an Indian tribe or tribal organization have an FMAP of 100%.

The Jobs and Growth Tax Relief Reconciliation Act of 2003 (JEGTRRA, P.L. 108–026) altered the statutory calculation of the FMAPs by providing a hold harmless for declines from the prior year for each state FMAP, and a temporary increase of 2.95 percentage points for the last 2 quarters of fiscal year 2003 and the first three quarters of fiscal year 2004. The calculated statutory FMAPs for Hawaii would be 58.77% for fiscal year 2003 and 58.90% for fiscal year 2004. The JEGTRRA changes result in an FMAP of 61.75% for the last 2 quarters of fiscal year 2003, and 61.85% for the first three quarters of fiscal year 2004. The FMAP for services provided to a Native Hawaiian is the same as for services provided to other Medicaid beneficiaries in Hawaii.

House Bill

No provision.

Senate Bill

For services provided to a Native Hawaiian by a federally qualified health center or a Native Hawaiian health care system, the FMAP would be 100%. Services qualifying for the 100% FMAP would include those provided by referral, and under contract or other arrangement between a health care provider and the federally qualified health center or Native Hawaiian health care system. The provision would be effective for medical assistance provided on or after the date of enactment.

Conference Agreement

No provision.

Extension of Moratorium. (Section 633 of the Senate Bill)

Present Law

Medicaid payment for services provided by an institution for mental disease (IMD) may be made only for beneficiaries who are under age 21 or over 65. IMD means a hospital, nursing facility, or other institution of more than 16 beds, that is primarily engaged in providing diagnosis, treatment, or care of persons with mental diseases, including medical attention, nursing care, and related services. For two facilities in Michigan—Kent Community Hospital Complex and Saginaw Community Hospital—previous legislation has imposed a moratorium on determination of the facilities as IMDs through December 31, 2002.

House Bill

No provision.

Senate Bill

The moratorium on the determination of Saginaw Community Hospital as an IMD would be permanently extended. The provision would be effective as if included in the Balanced Budget Act of 1997.

Conference Agreement

The moratorium on the determination of Saginaw Community Hospital as an IMD would be extended for 2 years. The provision would be effective as if included in the Balanced Budget Act of 1997.

Subtitle B—Miscellaneous Provisions

Employer Flexibility. (Section 1011 of the Conference Agreement, and Section 631 of the Senate Bill)

Present Law

No provision.

House Bill

No provision.

Senate Bill

The provision would amend the Age Discrimination in Employment Act of 1967 to allow an employee benefit plan that provides medical benefits to be offered to retirees who are not eligible for Medicare benefits or benefits provided under a State plan without offering medical benefits, or the same medical benefits, to Medicare-eligible retirees or retirees eligible for benefits under a State plan. Under the provision, an employee benefit plan that distinguishes between those retirees and other retirees would not violate the ADEA. The provision would be effective upon enactment.

Conference Agreement

No provision. However, the conferees reviewed the ADEA and its legislative history and believe the legislative history clearly articulates the intent of Congress that employers should not be prevented from providing

voluntary benefits to retirees only until they become eligible to participate in the Medicare program.

Federal Reimbursement of Emergency Health Services Furnished to Undocumented Aliens

Present Law

The Balanced Budget Act of 1997 (BBA97) provided $25 million in funding for state emergency health services furnished to undocumented aliens for each of FY1998 through 2001. Funds were distributed among the 12 states with the highest number of undocumented aliens. In a fiscal year, each state's portion of the total funds available was based on its share of total undocumented aliens in all of the eligible states. The share of undocumented aliens in each state were based on the estimates provided by the Statistics Division of the Immigration and Naturalization Service (INS).

House Bill

No provision.

Senate Bill

For each of fiscal years 2005 through 2008 the provision would appropriate for allotment among states $250 million in funds for emergency health services furnished to undocumented aliens. Each such fiscal year the Secretary would distribute $167 million of $250 million among all states. Each state would receive an amount equal to the product of the total amount available in each fiscal year, and the proportion of the state's share of undocumented aliens to the total count of undocumented aliens residing in all states as determined by the Statistics Division of the Immigration and Naturalization Service, as of January 2003, based on the decennial census.

For each of fiscal years 2005 through 2008, the Secretary would distribute $83 million of $250 million among the 6 states with the highest number of undocumented alien apprehensions for such fiscal year. Each such state would receive an amount that bears the same ratio to the total amount available for allotments to such states (in each fiscal year) as the ratio of the number of undocumented alien apprehensions in the state (in each fiscal year) to the total number of undocumented alien apprehensions for all such states (in each fiscal year) based on the four most recent quarterly apprehensions rates for undocumented aliens as reported by the Immigration and Naturalization Service.

From the state allotments described above, the Secretary would pay directly to local governments, hospitals, or other providers located in the state (including providers of services rendered through an Indian Health Service facility) for costs incurred in providing emergency health care services furnished to undocumented aliens during that fiscal year (even if the care is furnished to aliens who have been allowed to enter for the sole purpose of receiving emergency health care services). No later than September 1, 2004, the Secretary would be required to establish a process, that includes measures to protect against fraud and abuse, under which entities would apply for reimbursement from the state's allotments for claims associated with emergency health care services furnished to undocumented aliens. Advanced payments would be made quarterly based on the applicants projected expenditures. The Secretary would also be required to set up a process to allow for prior period adjustments resulting from underpayment or over payment to an entity in a prior quarter. Funds shall remain available until they are expended. The provision would be effective upon enactment.

Conference Agreement

For each of fiscal years 2005 through 2008 the Conference agreement appropriates for allotment among eligible providers in the 50 states and the District of Columbia $250 million in additional federal funding for emergency health services furnished to undocumented aliens. For each such fiscal year, the Secretary must distribute $167 million of $250 million among eligible providers in all states. Each state's share of this amount will be based on its proportion of total number of undocumented aliens in all states as determined by the Statistics Division of the Immigration and Naturalization Service, as of January 2003, based on the decennial census.

For each of fiscal years 2005 through 2008, the Secretary must distribute $83 million of $250 million among eligible providers in the six states with the highest number of undocumented alien apprehensions for such fiscal year. Each state's share of this amount is equal to the product of the total amount available for allotments to such states (in each fiscal year), and the proportion of the number of undocumented alien apprehensions in the state (in each fiscal year) to the total number of undocumented alien apprehensions for all such states (in the preceding fiscal year) based on apprehensions rates for undocumented aliens as reported by the Immigration and Naturalization Service in the four consecutive-quarter period ending before the beginning of the fiscal year for which such information is available.

From the $250 million in state allotments described above, the Secretary will pay directly to eligible providers located in the state (including hospitals, physicians, or providers of ambulance services, and Indian Health Service facilities) for unreimbursed costs incurred by providing emergency health care services during that fiscal year to: (1) Undocumented aliens; (2) aliens who have been paroled in the United States at a port of entry for the purpose of receiving eligible services; and (3) Mexican citizens permitted to enter the United States for not more than 72 hours under the authority of a specified identification card. In establishing a payment methodology, the Secretary may establish different methodologies for different types of eligible providers, may calculate payments to hospitals based on hospital-specific cost-to-charge ratios, and shall make quarterly payments to eligible providers. Hospitals may elect to receive payment for hospital and all physician services in which case they may pass on payments for physician services directly to physicians without charging hospital administrative fees. If the amount of funds allotted to a state is insufficient to ensure that each eligible provider receives the amount described above then the Secretary is required to reduce the amount of payment to eligible providers to ensure that each eligible provider is paid.

No later than September 1, 2004, the Secretary must establish a process that includes measures to protect against fraud and abuse to ensure that inappropriate, excessive or fraudulent payments are not made from allotments. Advance payments may be made quarterly based on the applicants projected expenditures. The Secretary is also required to set up a process to allow for prior period adjustments resulting from under payments or over-payments. Funds will remain available until they are expended. The provision will be effective upon enactment.

Commission on Systematic Interoperability. (Section 1013 of the Conference Agreement)

Pediatric Palliative Care Demonstration

Medicare is designed for aged and disabled individuals (typically people over 65 years of age). It was not designed with children in mind.

The conferees are aware of potential barriers in the current system for children with life-threatening illnesses. First, in order to qualify for hospice, a doctor must certify that a child has 6–months to live. Determining how long a child has to live is often difficult. Second, the current system does not allow a patient to receive curative and palliative care simultaneously. This means that children can either receive treatment for their disease or they can receive palliative care.

HHS should conduct a demonstration project in up to 6 geographically diverse sites to determine whether palliative care for children may be improved under circumstances where such barriers are reduced or eliminated. Such demonstration shall take place over at least a three year period.

The Secretary, in conducting such demonstration project, should take into account the recommendations of the Institute of Medicine in its report: ''When Children Die: Improving Palliative and End-of-Life Care for Children and their Families.''

In particular, the Secretary should consider including as part of the demonstration:

1. Waivers to Elect Hospice Care and Receive Curative Treatment.
2. Care coordination from diagnosis to end of life.
3. Features to ensure that parents have information about existing pediatric hospice and palliative care programs to make decisions about the care of their child.
4. Bereavement counseling for the family and reimbursement to provider.

The conferees believe that it is important that the Secretary have flexibility when conducting such demonstration to provide additional benefits so long as they are consistent with the recommendations contained in the IOM Report and they are provided in budget neutral manner. The conferees also believe that the Secretary should provide reports to Congress, as appropriate, that include an evaluation of the short- and long-term costs and benefits of palliative care under traditional Medicare and the demonstration projects, determine the quality and duration of palliative care under the demonstration project, and evaluate whether there is an offset of savings by providing pediatric palliative care, and the projected cost of implementing the demonstrations on a national basis.

Present Law

No provision.

House Bill

No provision.

Senate Provision

No provision.

Conference Agreement

The conference agreement instructs the Secretary to establish a Commission on Systemic Interoperability to develop a comprehensive strategy for the adoption and implementation of health care information technology standards. In developing its strategy, the Commission must consider the costs and benefits of the standards, the current demand on industry resources to implement these and other electronic standards (including the HIPAA administrative simplification standards), and the most cost-effective and efficient means for industry to implement the standards. The Commission must not interfere with any ongoing process of developing or adopting standards, nor shall it replicate activities related to such standards or to the HHS National Health Information Infrastructure initiative. Not later than October 31, 2005, the Commission must submit a report to the Secretary and the Congress describing its strategy.

The Commission shall be composed of 11 members. The President shall appoint three members, including a Chairperson; the Senate Majority Leader, the Senate Minority

Leader, the Speaker, and the House Minority Leader shall each appoint two members. Commission membership must include nationally recognized experts in health finance and economics, health plans and integrated delivery systems, health care reimbursement, health care technology and information systems, and other related fields, as well as physicians, pharmacists, and other health care providers, who provide a mix of professionals, broad geographic representation, and a balance between urban and rural representation. Each member shall be appointed for the life of the Commission.

Commission members shall be paid for each day (including travel days) of service at a rate not exceeding the rate of basic pay for level IV of the Executive Schedule. Each member shall also receive travel expenses and a per diem. Federal employees who serve on the Commission may not receive any financial compensation.

A majority of Commission members shall constitute a quorum but a lesser number may hold hearings. The Commission Chairperson must appoint a Director, to be paid at a rate not exceeding the rate of basic pay for level IV of the Executive Schedule. With the Commission's approval, the Director may appoint additional staff, as well as temporary experts and consultants. Employees of federal agencies may also be detailed to the Commission to assist in carrying out its duties.

The Commission may, as appropriate, hold hearings, take testimony, and receive evidence. Any Commission member or agent may, if so authorized by the Commission, take any action which the Commission is authorized to take. The Commission may obtain official information from a federal agency and may accept, use and dispose of gifts, bequests, or devises of services or property, both real and personal. Gifts, bequests, or devices or money and proceeds from sales of other property received as gifts, bequests, or devices shall be deposited in the Treasury and available for disbursement upon order of the Commission. The Commission may use the U.S. mail under the same conditions as other federal agencies and may enter into contracts as may be necessary to conduct its work. Upon the Commission's request, the Administrator of General Services must provide administrative support services to the Commission on a reimbursable basis.

The Commission shall terminate 30 days after submitting its report to the Secretary and the Congress. The conference report authorizes to be appropriated such sums as may be necessary to carry out this Section.

Research on Outcomes of Health Care Items and Services. (Section 1014 of the Conference Agreement)

Present Law

The Agency for Healthcare Research and Quality (AHRQ) is an agency within the Department of Health and Human Services. AHRQ's mission is to support, conduct, and disseminate research that improves access to care and the outcomes, quality, cost, and utilization of health care services. The research agenda is designed to be responsive to the needs of its customers, including patients, clinicians, institutions, plans, purchasers, and federal, state and local governments. The research conducted by AHRQ is used to inform medical practice, educate consumer understanding of health care, and expand policymakers' ability to monitor and evaluate the impact of system changes on outcomes, quality, access, cost, and use of health care, and to devise policies to improve system performance.

House Bill

No provision.

Senate Bill

No provision.

Conference Agreement

The conference agreement authorizes and appropriates $50 million for fiscal year 2004 for the Secretary through the Agency for Healthcare Research and Quality to conduct research to address the scientific information needs and priorities identified by the Medicare, Medicaid, and State Children Health Insurance Programs. The information needs and priorities will relate to the clinical effectiveness and appropriateness of specified health services and treatments, and the health outcomes associated with such services and treatments. The needs and priorities also will address strategies for improving the efficiency and effectiveness of those health care programs. The Secretary is required to establish a process for developing research priorities. Not later than 6 months after the date of enactment, the Secretary must establish an initial list of priorities. The Secretary must complete the evaluation and synthesis of the scientific evidence related to that initial list within 18 months after development of such a list and disseminate the research findings to the public, prescription drug plans, and other plans. Not later than 18 months after the date of enactment, the Secretary is required to identify voluntary options that could be undertaken by public and private entities to improve information sharing regarding outcomes and quality of care, adopt innovative quality improvement strategies, develop management tools to improve oversight by state officials, support federal and state initiatives to improve the quality, safety, and efficiency of services, and provide a basis for estimating the fiscal and coverage impact of federal or state policy changes of the Medicare, Medicaid, and State Children's Health Insurance Programs. The Administrator for the Center for Medicare and Medicaid Services may not use data from the research conducted to withhold coverage of a prescription drug, to mandate a national standard, or require a specific approach to quality measurement and reporting.

Health Care that Works for All American-Citizens Health Care Working Group. (Section 1015 of the Conference Agreement, and Section 620 of the Senate Bill)

Present Law

No provision.

House Bill

No provision.

Senate Bill

The bill would authorize $3 million for each of the fiscal years 2005 and 2006 for the Secretary of HHS, acting through the Agency for Healthcare Research and Quality, to establish a group that would be called the ''Citizens' Health Care Working Group.'' The 25 members of the group would come from health care stakeholders and would be appointed by Congressional leaders. Working Group member appointments could not be made from elected officials. Appointments would be for a 2–year period. Once all the members of the Working Group have been appointed, Congressional leaders would appoint a chairperson from among the members. The Working Group would be responsible for holding hearings and producing public reports regarding expanding coverage options, the cost of health care, innovative state and community strategies to expand coverage or reduce costs, and the role of evidence-based medicine and technology in improving quality and lowering costs. The first hearing would be required to be held within 90 days after the chairperson was appointed and additional hearings would be permitted. Within 90 days of completing hearings, the Working Group would be required to prepare a report that discusses numerous health care issues including health care and related services used by individuals throughout their lifetimes, the cost of health care services, sources of coverage and payment, and reasons for uninsurance and underinsurance.

In addition to hearings, the Working Group would be required to hold community meetings throughout the United States in sufficient number to reflect geographic differences, diverse populations, and a balance among urban and rural populations. The Working Group would be required to prepare an interim set of recommendations on health care coverage and ways to improve and strengthen the health care system based on the information and preferences expressed at the community meetings within 180 days after the conclusion of the community meetings. There would be a 90–day public comment period on the recommendations. Not later than 120 days after the end of the public comment period, the Working Group would be required to submit to Congress and the President a final set of recommendations. Not later than 45 days after receiving the final recommendations, the President would be required to submit a report to Congress with additional views and comments on the recommendations and recommendations for legislation and administrative actions. Each congressional committee of jurisdiction would be required to hold at least one hearing on the report and the final recommendations.

The Working Group would be staffed by an Executive Director appointed by the chairperson, up to 20 Federal Government employees on detail, and could procure temporary or intermittent services of individuals. The Working Group would be required to report to Congress annually a detailed description of the expenditures of the Working Group used to carry out its duties. The Working Group would terminate when the report with the final recommendations is submitted to Congress, but not later than two years after the date on which Working Group members were appointed. The provision would be effective upon enactment.

Conference Agreement

The conference agreement authorizes $3 million for each of the fiscal years 2005 and 2006 for the Secretary of HHS, acting through the Agency for Healthcare Research and Quality, to establish a group called the ''Citizens'' Health Care Working Group.'' The working group will be composed of 15 members; one member will be the Secretary and the other 14 members will be appointed by the Comptroller General. Appointments will include certain consumers of heath services, and individuals with expertise in the health care industry. Appointment will not include elected officials. The duration of appointments will be for the life of the Working Group. Not later than 15 days after which all appointments have been made, the Comptroller General will designate a chairperson from the members. The Working Group will be responsible for holding hearings and producing public reports regarding expanding coverage options, the cost of health care, innovative state and community strategies to expand coverage or reduce costs, and the role of evidence-based medicine and technology in improving quality and lowering costs. The first hearing must be held within 90 days after designation of the chairperson, and additional hearings would be permitted as long as such hearings do not delay the Working Group's other activities. Within 90 days of completing hearings, the Working Group will prepare a report that discusses numerous health care issues including health care and related services used by individuals throughout their lifetimes, the cost of health care services, sources of coverage and payment,

and reasons for uninsurance and underinsurance.

In addition to hearings, the Working Group will hold community meetings throughout the United States in sufficient number to reflect geographic differences, diverse populations, and a balance among urban and rural populations. The Working Group will prepare an interim set of recommendations on health care coverage, and ways to improve and strengthen the health care system based on the information and preferences expressed at the community meetings within 180 days after the conclusion of such meetings. There will be a 90–day public comment period on the recommendations.

Not later than 120 days after the end of the public comment period, the Working Group will submit to Congress and the President a final set of recommendations. Not later than 45 days after receiving the final recommendations, the President will submit a report to Congress with additional views and comments on the recommendations, and recommendations for legislative and administrative actions. Each congressional committee of jurisdiction will hold at least one hearing on the report and the final recommendations.

The Working Group will be staffed by an Executive Director appointed by the chairperson, up to 20 Federal Government employees on detail, and could procure temporary or intermittent services of individuals. The Working Group will report annually to Congress a detailed description of the expenditures used by the Working Group to carry out its duties. The Working Group will terminate within 2 years after the date on which all members of the Working Group were appointed.

Establishment of Consumer Ombudsman Account. (Section 606 of the Senate Bill)

Present Law

The Omnibus Budget Reconciliation Act of 1990 established State Health Insurance Counseling Assistance grants to states to provide education and information to Medicare beneficiaries. Funding has been subject to annual appropriations.

House Bill

No provision.

Senate Bill

A Consumer Ombudsman Account would be established in the Medicare Trust Fund and $1 for every Medicare beneficiary would be appropriated to the account from the Trust Fund beginning with fiscal year 2005. The account would be used to make grants to State Health Insurance Counseling Programs. The provision would be effective upon enactment.

Conference Agreement

No provision.

Health Care Infrastructure Improvement. (Section 1016 of the Conference agreement and Section 608 of the Senate Bill)

Present Law

No provision.

House Bill

No provision.

Senate Bill

A loan program would be established to improve the cancer-related health care infrastructure in certain geographic areas of the United States. Examples of potentially eligible projects would include the construction, renovation, or other capital improvement of any hospital, medical research facility or other medical facility or the purchase of any equipment to be used in a hospital, research facility or other medical research facility. In order to receive assistance, the project applicant would be required to: (1) be engaged in research in the causes, prevention, and treatment of cancer; (2) be designated as a cancer center for the National Cancer Institute (NCI) or be designated by the state as the sole official comprehensive cancer effort for the state; and (3) be located in a state that on the date of enactment of this title has a population of less than 3 million individuals. $49 million in budget authority would be authorized for July 1, 2004 through FY2008 to carry out the loan program, $2 million of which may be used each year for administration of the program by the Secretary. Not later than 4 years after enactment, the Secretary would be required to submit to Congress a report summarizing the financial performance of the projects that have received assistance under this program, including recommendations on the future operation of the program. The provision would be effective upon enactment.

Conference Agreement

A loan program would be established to improve the cancer-related health care hospital infrastructure in the United States. Examples of potentially eligible projects would include the construction, renovation, or other capital improvement of any hospital. In order to receive assistance, the project applicant would be required to: (1) be engaged in research in the causes, prevention, and treatment of cancer; (2) be designated as a cancer center for the National Cancer Institute (NCI) or be designated by the state as the sole official comprehensive cancer effort for the state. $200 million in budget authority would be authorized for July 1, 2004 through FY2008 to carry out the loan program, $2 million of which may be used each year for administration of the program by the Secretary. Not later than 4 years after enactment, the Secretary would be required to submit to Congress a report summarizing the financial performance of the projects that have received assistance under this program, including recommendations on the future operation of the program. The provision would be effective upon enactment.

Capital Infrastructure Revolving Loan Program. (Section 609 of the Senate Bill)

Present Law

The Public Health Services Act establishes a fund in the Treasury from which the Secretary of HHS can make loans or loan guarantees in the amounts that have been specified in appropriations Acts from time to time. Under the Medicare Rural Hospital Flexibility Program established as part of Title XVIII, the Secretary may award grants to rural hospitals to cover the implementation costs associated with data systems needed to meet the BBA 97 requirements.

House Bill

No provision.

Senate Bill

The Secretary would be able to make loans to any rural entity to acquire land, renovate buildings, and purchase major moveable equipment or other appropriate projects. A rural entity would include rural health clinics, a medical facility with less than 50 beds in a county that is not part of a metropolitan statistical area or is in a rural census tract of such area, a hospital that is a rural referral center or a sole community hospital. An entity that has been geographically reclassified for the purposes of Medicare reimbursement would not be precluded from being considered a rural provider. Loan guarantees and interest subsidies of up to 3% of the net effective interest rate would be authorized. The total of the government's exposure with respect to this program would not exceed $50 million per year. The total of the principal amount of all loans directly made or guaranteed in any year may not exceed $250 million per year. In addition, rural providers could apply to receive $50,000 planning grants to help assess capital and infrastructure needs. The grants awarded in any year would not exceed $2.5 million. The program would expire after September 30, 2008. The provision would be effective upon enactment.

Conference Agreement

No provision.

Increase in Appropriation to the Health Care Fraud and Abuse Control Account. (Section 611 of the Senate Bill)

Present Law

The Health Insurance Portability and Accountability Act of 1996 (HIPAA, PL.104–91) established the Health Care Fraud and Abuse Control (HCFAC) Program which is administered by the HHS Office of Inspector General and the Department of Justice. Funds for the HCFAC program are appropriated from the Federal Hospital Insurance Trust Fund. HIPAA provided for annual increases of 15% in HCFAC funding through 2003, after which the appropriation for HCFAC and the amount earmarked for HHS–OIG remains the same. In FY2003 the available appropriation for HCFAC was $240,558,320 of which $150 million to $160 million was available to the HHS–OIG.

House Bill

No provision.

Senate Bill

Additional appropriations to HCFAC would be authorized. In FY2004, the increase would be $10 million over the FY2003 appropriation limit; in FY2005 the increase would be $15 million over the FY2003 limit; in FY2006 the increase would be $25 million above the FY2003 limit. Subsequent years appropriations would be at the 2003 limit. The HHS–OIG earmarked appropriations would increase as well: to $170 million in FY2004, $175 million in FY2005, $185 million in FY2006. In subsequent years, it would be not more than $150 million and not more than $160 million. The provision would be effective upon enactment.

Conference Agreement

No provision.

Increase in Civil Penalties Under the False Claims Act. (Section 612 of the Senate Bill)

Present Law

The False Claims Act imposes a liability on those who knowingly present or cause to be presented a false or fraudulent claim for payment by the government. In certain instances, the person may be liable for a civil penalty of not less than $5,000 and not more than $10,000, plus treble damages.

House Bill

No provision.

Senate Bill

For violations occurring on or after January 1, 2004, the minimum amount of the civil penalty would be increased from $5,000 to $7,500 and the maximum amount would increase from $10,000 to $15,000. The provision would be effective for violations occurring on or after January 1, 2004.

Conference Agreement

No provision.

Increase in Civil Monetary Penalties under the Social Security Act. (Section 613 of the Senate Bill)

Present Law

The Office of the Inspector General (OIG) has the authority to impose civil monetary penalties (CMPs) on any person (including an organization or other entity, but not a beneficiary) who knowingly presents, or causes to be presented, to a state or federal government employee or agent certain false or improper claims for medical or other items or services. CMPs may also be imposed for

other fraudulent activities such as inflating charges for services, providing services when not a properly licensed physician, billing for medically unnecessary services, falsely certifying that an individual meets the requirements for home health services, and offering or soliciting remuneration to influence the provision of medical services. Depending upon the violation, Section 1128A of the SSA authorizes the imposition of CMPs up to $10,000 for each item or service involved, up to $15,000 for individuals who provide false or misleading information in certain instances, and up to $50,000 per act in other instances as well as treble damages.

House Bill

No provision.

Senate Bill

The amount of penalties would be increased for violations that occur on or after January 1, 2004. In instances where penalties are limited to $10,000 would be increased to $12,500; those penalties that are limited to $15,000 would be increased to $18,750; and those that are limited to $50,000 would be increased to $62,500. The provision would be effective for violations occurring on or after January 1, 2004.

Conference Agreement

No provision.

Extension of Customs User Fees. (Section 614 of the Senate Bill)

Present Law

The U.S. Customs Service, the federal government's oldest revenue collecting agency is responsible for regulating the movement of persons, carriers, merchandise, and commodities between the United States and other countries. Its authority to impose user fees for certain services lapsed on September 30, 2003, but was subsequently restored.

House Bill

No provision.

Senate Bill

The authority to impose user fees would be extended until September 30, 2013.

Conference Agreement

No provision.

Provision of Information on Advance Directives. (Section 616 of the Senate Bill)

Present Law

Information about advance directives is required to be given to patients in hospitals, skilled nursing facilities, and served by home health agencies. The Secretary is required to provide Medicare beneficiaries annual information about Medicare benefits, limitations on payment, and a description of the limited benefits for long-term care. This information is provided to Medicare beneficiaries in the Medicare & You handbook that is mailed annually to all beneficiaries.

House Bill

No provision.

Senate Bill

The Secretary would be required to provide information on advance directives in the Medicare & You handbook. The information would be required to be presented in a separate Senate section on advance directives and would include specific information about living wills and durable power of attorney for health care. The Secretary would further be required to note the inclusion of this information in the introductory letter that accompanies the handbook. The provision would be effective upon enactment.

Conference Agreement

No provision.

Sense of the Senate Regarding Implementation of the Prescription Drug and Medicare Improvement Act of 2003. (Section 617 of the Senate Bill)

Present Law

No provision.

House Bill

No provision.

Senate Bill

The provision expresses a sense of the Senate that the Committee on Finance should hold at least four hearings to monitor implementation of the Prescription Drug and Medicare Improvement Act of 2003. The first hearing should be held within 60 days after enactment of the Act, the remaining hearings should be held May 2004, October 2004, and May 2005. The provision would be effective upon enactment.

Conference Agreement

No provision.

Extension of Municipal Health Service Demonstration Projects. (Section 618 of the Senate Bill)

Present Law

Under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended, the Municipal Health Service Demonstration projects will expire on December 31, 2004. The municipal health services demonstration program is a multi-site demonstration intended to improve access to primary care services in underserved urban areas and to reduce the cost of health care. BBA 1997 authorized the Secretary to extend the project through December 31, 2000, but only with respect to persons who had received at least one service for the period of January 1, 1996–August 7, 1997 (the enactment date of BBA 97). Sites who wanted the demonstration project extended were required to submit plans for the orderly transition of participants to a non-demonstration health care delivery system. Subsequent legislation extended the project through December 31, 2004.

House Bill

No provision.

Senate Bill

This provision would extend these demonstration projects to December 31, 2009, for individuals who reside in the city in which the project is operated. The provision would be effective upon enactment.

Conference Agreement

No provision.

Study on Making Prescription Pharmaceutical Information Accessible for Blind and Visually Impaired Individuals. (Section 619 of the Senate Bill)

Present Law

No provision.

House Bill

No provision.

Senate Bill

The Secretary would be required to study how to make prescription drug information, including drug labels and usage instructions, accessible to blind and visually impaired individuals. The study would be required to include a review of existing and emerging technologies. A report would be required within 18 months of enactment and would include recommendations for implementing usable formats and an estimate of the associated costs. The provision would be effective upon enactment.

Conference Agreement

No provision.

GAO Study of Pharmaceutical Price Controls and Patient Protections in the G–7 Countries. (Section 621/Duplicative Provision 634 of the Senate Bill)

Present Law

No provision.

House Bill

No provision.

Senate Bill

The GAO would be required to study price controls on pharmaceuticals in France, Germany, Italy, Japan, the United Kingdom, and Canada to review the impact they have on consumers, including American consumers, and on innovation in medicine. The provision would be effective upon enactment.

Conference Agreement

No provision.

Safety Net Organizations and Patient Advisory Commission. (Section 624/Duplicative Provision 635 of the Senate Bill)

Present Law

No provision.

House Bill

No provision.

Senate Bill

The provision would establish the Safety Net Organizations and Patient Advisory Commission that would conduct an ongoing review of the health care safety net programs including Medicaid, the State Children's Health Insurance Program (SCHIP), Maternal and Child Health Services Block Grant Programs, Federally qualified health center (FQHC) programs, rural health clinic (RHC) programs, disproportionate share hospital (DSH) payment programs, and the Emergency Medical Treatment and Active Labor Act (EMTALA). The Commission would review a variety of issues and data related to the safety net programs.

The Commission would be required to submit annual reports to the appropriate committees of Congress on the health care needs of the uninsured and the financial and infrastructure stability of the Nation's core health care safety net. The first report would be due June, 2005. Additional reports could be made if requested by the chairpersons or ranking minority members of appropriate committees of Congress or if the Commission deems such additional reviews and reports appropriate.

The Commission would have 13 members appointed by the Comptroller General of the United States in consultation with the appropriate committees of Congress. Members would be drawn from health professionals, employers, third-party payers, researchers, recipients of care from core health care safety net and individuals who provide and manage the delivery of care by the core health care safety net. The term of the members would be 3 years, although the initial appointments would be on a staggered basis. The Comptroller General would be required to establish a system for public disclosure of financial and other potential conflicts of interest by members of the Commission. The Commission could hire an executive director and other personnel without regard to the provisions of Title V of the United States Code. The Comptroller General would be required to appoint the initial members of the Commission by June 1, 2004.

Conference Agreement

No provision.

Committee on Drug Compounding. (Section 626 of the Senate Bill)

Present Law

No provision.

House Bill

No provision.

Senate Bill

The Secretary would be required to establish a committee on drug compounding within the Food and Drug Administration to ensure that patients are receiving necessary, safe, and accurate dosages of compounded drugs. The members of the committee would be appointed by the Secretary and would include representatives from the National Association of Boards of Pharmacy; pharmacy

groups; physician groups; consumer and patient advocate groups; the United States Pharmacopoeia; and other individuals determined appropriate by the Secretary. The Committee would be required to submit a report with recommendations of the Committee to improve and protect patient safety within 1 year of enactment. The Committee would terminate 1 year after enactment.

Conference Agreement

No provision.

Sense of the Senate Concerning the Structure of Medicare Reform and the Prescription Drug Benefit. (Section 627 of the Senate Bill)

Present Law

No provision.

House Bill

No provision.

Senate Bill

The provision provides a sense of the Senate that Medicare reform legislation should achieve certain principles.

Conference Agreement

No provision.

Sense of the Senate Regarding the Establishment of a Nationwide Permanent Lifestyle Modification Program for Medicare Beneficiaries. (Section 628 of the Senate Bill)

Present Law

No provision.

House Bill

No provision.

Senate Bill

The provision provides a sense of the Senate that coronary disease is expensive, the Medicare Lifestyle Modification Program has been operating in 12 states as a demonstration program, and such program of behavior modification should be conducted on a national basis for those beneficiaries who elect to participate. The provision would be effective upon enactment.

Conference Agreement

No provision.

TITLE XI—ACCESS TO AFFORDABLE PHARMACEUTICALS

Current Law

Section 804 of the Federal Food, Drug, and Cosmetic Act—Importation of Covered Products—was established under the medicine Equity and Drug Safety Act of 2000 (P.L. 106–387). This section of current law has not been implemented.

House Bill

Section 1121(a) of H.R. 1 would replace the existing Section 804 entirely. The House bill directs the Secretary to establish, upon certification of safety and cost savings, a program that would allow for the importation of drugs from Canada by pharmacists, wholesalers, and individuals. The House bill incorporates new safety measures such as: (1) the use of tamper-resistant and counterfeit-proof packaging; (2) a new requirement that drugs must contain a statement informing the consumer that the drug has left the country; (3) any drug may only be shipped back to the country by the first Canadian recipient; (4) new authority to the Secretary of HHS to limit importation to certain ports of entry; (5) the importer would be required to keep detailed records and to conduct drug testing; and (6) a manufacturer must provide the importer with approved labeling of the drug. This provision applies to prescription drugs as subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act other than a controlled substance, a biological product, an infused drug, an intravenously injected drug, a drug that is inhaled during surgery, or a parenteral drug that the Secretary determines poses a threat to the public health.

Senate Bill

Section 801(a) of S. 1 would replace the existing Section 804 entirely. The Senate bill directs the Secretary to establish, upon certification of safety and cost savings, a program that would allow for the importation of drugs from Canada by pharmacists, wholesalers, and individuals. The Senate bill incorporates new safety provisions as well as provides new authority to the Secretary of HHS to suspend the program if public safety is compromised. Specifically, between 12 and 18 months after the regulations are implemented, if the Secretary certifies to Congress that, based on substantial evidence, the benefits of the implementation of the importation program do not outweigh any detriment, drug imports under this section would cease 30 days after the certification is submitted. However, the certification may not be submitted unless, after a public hearing, the Secretary finds it is more likely than not that implementation will result in an increased risk to the public health. This provision applies to prescription drugs as subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act other than a controlled substance, a biological product, an infused drug, an intravenously injected drug, or a drug that is inhaled during surgery that the Secretary determines poses a threat to the public health.

Conference Agreement

The Conference agreement, virtually identical to Section 801(a) of S. 1, gives the Secretary, upon certification of safety and cost savings, authority to create a system for the importation of drugs from Canada by pharmacists, wholesalers, and individuals.

The agreement directs the Secretary of HHS, in consultation with appropriate government agencies, to conduct a comprehensive study that identifies current problems with the implementation of existing law as well as examines a range of issues associated with the importation of drugs. In conducting the study, the Secretary shall take into account the distinctions between—

Drugs that are biological products with licenses under section 351 of the Public Health Service Act; and

Drugs with approved applications under subsection (b) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act.

The details of the study shall include the following:

Identification of the limitations, including limitations in resources and, if applicable, in current law authorities that may inhibit the Secretary's ability to certify the safety of pharmaceutical products imported into the US.

Assessment of the pharmaceutical distribution chain and the need for, and feasibility of, modifications, in order to assure the safety of products that may be imported into the US.

Analysis of whether anti-counterfeiting technologies could improve the safety of products in the domestic market as well as those products that could be imported from foreign nations. This analysis shall identify the types of technologies, if available, and assess the limitations of these technologies to the distribution chain.

Estimate of costs borne by entities within the pharmaceutical distribution chain to utilize any new technologies identified in paragraph (3).

Assess the scope, volume, and safety of unapproved drugs, including controlled substances, entering the United States via mail shipment. This assessment should include the percentage of drugs commercially available in other countries that conform in all respects to FDA requirements, and the limitations of visual inspection, sampling, and other testing methods to determine its quality.

The extent to which foreign health agencies are willing and/or able to ensure the safety of drugs being exported from their country into the United States, including drugs that are transshipped through their countries.

Assessment of the potential short and long-term impacts on drug prices and prices for consumers and other system costs associated with importation of pharmaceuticals from Canada and other countries into the U.S.

Assessment of the impact on the research and development of drugs—and the associated impact on consumers and patients—if importation were permitted.

Estimation of agency resources, including additional field personnel, needed to adequately inspect the current amount of pharmaceutical products entering into the country. This estimate shall detail the number of field personnel needed in order to appropriately secure all ports of entry on a daily basis.

Identification of liability protections, if any, that should be in place, if importation is permitted, for entities within the pharmaceutical distribution chain.

Identify the ways in which importation could violate United States and international intellectual property rights and describe the additional legal protections and agency resources that would be needed to assure the effective enforcement of these rights.

The Conference agreement directs the Secretary to submit a report providing the findings of the study under this section to the appropriate committees of Congress no later than 12 months after the date of enactment of this Act.

Report on Trade in Pharmaceuticals

The Conference agreement directs the Secretary of Commerce, in consultation with the International Trade Commission, the Secretary of Health and Human Services and the United States Trade Representative, to conduct a study and report on drug pricing practices of countries that are members of the Organization for Economic Cooperation and Development and whether those practices utilize nontariff barriers with respect to trade in pharmaceuticals. The study shall include an analysis of the use of price controls, reference pricing, and other actions that affect the market access of United States pharmaceutical products.

The study shall include the following:

Identification of the countries that use price controls or other such practices with respect to pharmaceutical trade.

Assessment of the price controls and other such practices used by the countries identified.

Estimate of additional costs to U.S. consumers because of such price controls and other such practices, and the extent to which additional costs would be reduced for U.S. consumers if price controls and other such practices are reduced or eliminated.

Estimate of the impact such price controls, intellectual property laws, and other such measures have on fair pricing, innovation, generic competition, and research and development in the United States and each country identified.

Not later than 9 months after the date of enactment of this Act, the report shall be submitted to the Committees on Finance, the Judiciary, and Health, Education, Labor, and Pensions of the Senate, and the Committees on Ways and Means, the Judiciary, and Energy and Commerce of the House of Representatives.

In addition, the United States Trade Representative, the Secretary of Commerce, and the Secretary of Health and Human Services shall analyze whether bilateral or multilateral trade or other negotiations present an opportunity to address these price controls and other such practices and shall develop a strategy to address such issues in appropriate negotiations. In so doing, these agencies shall bear in mind the negotiating objective set forth in the Bipartisan Trade Promotion Authority Act of 2002 to achieve the elimination of government measures such as price controls and reference pricing which deny full market access for United States products. In so doing, the agencies shall provide periodic and timely briefings for the Committees of the House and Senate listed above, with an interim briefing no later than 90 days after enactment to address negotiations to establish a U.S.-Australia Free Trade Agreement and, as appropriate, other current negotiations.

Provisions Related to Hatch-Waxman Law

AMENDMENTS AND SUPPLEMENTS

In including this provision, Congress does not intend this provision to alter current U.S. Food and Drug Administration's (''FDA'') practice regarding acceptance of supplements to approved new drug applications (''NDAs''), or amendments and supplements to pending and approved abbreviated new drug applications (''ANDAs''). Instead, Congress intends this provision to reflect the FDA's current practice regarding those changes and variations to both innovator and generic drugs that may be approved under amendments and supplements to previously filed NDAs and ANDAs, and expects the Agency to maintain its current policy in designating ''listed drugs.'' The conferees intend that FDA continue to use its existing scientific discretion to determine whether different polymorphs present safety, effectiveness, or bioavailability differences and therefore should be considered the same or different active ingredients.

The single 30–month stay provisions are a centerpiece of this legislation, allowing lower-priced generic products to enter the market more quickly. As a result, this provision must not be construed as requiring an ANDA applicant to file a new application where, before its enactment, the applicant would have been allowed to file an amendment or supplement to an existing application. Such a construction would run directly contrary to Congress' intent.

DECLARATORY JUDGMENTS

The conferees expect that courts will find jurisdiction, where appropriate, to prevent an improper effort to delay infringement litigation between generic drug manufacturers and pioneer drug companies. The conferees expect courts to apply the ''reasonable apprehension'' test in a manner that provides generic drug manufacturers appropriate access to declaratory judgment relief to the extent required by Article III.

Through the modifications in this Act, the conferees do not intend for the courts to modify their application of the requirements under Article III that a declaratory judgment plaintiff must, to the extent required by the Constitution, demonstrate a ''reasonable apprehension'' of suit to establish jurisdiction. See, e.g., *Fina Oil and Chemical Co.* v. *Ewen, 123 F.3d 1466, 1471* (Fed. Cir. 1997). The conferees expect the courts to examine as part of their analysis the particular policies served by the Hatch-Waxman Act.

In determining whether a reasonable apprehension of suit exists where an ANDA has been filed with a paragraph IV certification and the patentee has not brought an infringement suit within the 45 days, the conferees expect courts to examine these specific factors as part of the totality of the circumstances. See, e.g., *Vanguard Research, Inc.* v. *Peat, Inc., 304 F.3d 1249, 1254* (Fed. Cir. 2002). In any given case, the conferees expect a court may or may not find a reasonable apprehension of suit where these two specific factors are present.

Counterclaims

Section 1101 of the Conference agreement prohibits the recovery of damages resulting from a successful counterclaim in a paragraph IV patent suit by an ANDA applicant seeking removal of a patent listed in the Orange Book. It is not the intent of Congress to prohibit the recovery by a counterclaimant in a paragraph IV suit of anti-trust or any other damages as a result of the improper listing of a patent in the Orange Book. The language found in this section simply means that in the absence of any other cause of action, a ruling in favor of the counterclaimant resulting in the removal of the patent does not entitle the counterclaimant to recover damages.

TITLE XII.—HEALTH SAVINGS INCENTIVES

Health Savings Accounts and Health Savings Security Accounts (sec. 1202 of the House bill and new sec. 223 of the Code)

Present Law

OVERVIEW

Present law contains a number of provisions dealing with the Federal tax treatment of health expenses and health insurance coverage.

EMPLOYER-PROVIDED HEALTH COVERAGE

In general, employer contributions to an accident or health plan are excludable from an employee's gross income (and wages for employment tax purposes).[1] This exclusion generally applies to coverage provided to employees (including former employees) and their spouses, dependents, and survivors. Benefits paid under employer-provided accident or health plans are also generally excludable from income to the extent they are reimbursements for medical care.[2] If certain requirements are satisfied, employer-provided accident or health coverage offered under a cafeteria plan is also excludable from an employee's gross income and wages.[3] Present law provides for two general employer-provided arrangements that can be used to pay for or reimburse medical expenses of employees on a tax-favored basis: flexible spending arrangements (''FSAs'') and health reimbursement arrangements (''HRAs''). While these arrangements provide similar tax benefits (i.e., the amounts paid under the arrangements for medical care are excludable from gross income and wages for employment tax purposes), they are subject to different rules. A main distinguishing feature between the two arrangements is that while FSAs are generally part of a cafeteria plan and contributions to FSAs are made on a salary reduction basis, HRAs cannot be part of a cafeteria plan and contributions cannot be made on a salary-reduction basis.[4]

Amounts paid or accrued by an employer within a taxable year for a sickness, accident, hospitalization, medical expense, or similar health plan for its employees are generally deductible as ordinary and necessary business expenses.[5]

SELF-EMPLOYED INDIVIDUALS

The exclusion for employer-provided health coverage does not apply to self-employed individuals. However, under present law, self-employed individuals (i.e., sole proprietors or partners in a partnership)[6] are entitled to deduct 100 percent of the amount paid for health insurance for themselves and their spouse and dependents.[7]

ITEMIZED DEDUCTION FOR MEDICAL EXPENSES

Under present law, individuals who itemize deductions may deduct amounts paid during the taxable year (to the extent not reimbursed by insurance or otherwise) for medical care of the taxpayer, the taxpayer's spouse, and dependents, to the extent that the total of such expenses exceeds 7.5 percent of the taxpayer's adjusted gross income.[8]

ARCHER MEDICAL SAVINGS ACCOUNTS

In general

In general, an Archer medical savings account (''MSA'') is a tax-exempt trust or custodial account created exclusively for the benefit of the account holder that is subject to rules similar to those applicable to individual retirement arrangements.[9]

Within limits, contributions to an Archer MSA are deductible in determining adjusted gross income if made by an eligible individual and are excludable from gross income and wages for employment tax purposes if made by the employer of an eligible individual. Earnings on amounts in an Archer MSA are not includible in gross income in the year earned (i.e., inside buildup is not taxable). Distributions from an Archer MSA for qualified medical expenses are not includible in gross income. Distributions not used for qualified medical expenses are includible in gross income and subject to an additional 15–percent tax unless the distribution is made after death, disability, or the individual attains the age of Medicare eligibility (i.e., age 65).

Qualified medical expenses are generally defined as under section 213(d), except that qualified medical expenses do not include expenses for health insurance other than long-term care insurance, premiums for health coverage during any period of continuation coverage required by Federal law, and premiums for health care coverage while an individual is receiving unemployment compensation under Federal or State law. For purposes of determining the itemized deduction for medical expenses, distributions from an Archer MSA for qualified medical expenses are not treated as expenses paid for medical care under section 213.

ELIGIBLE INDIVIDUALS

Archer MSAs are available only to employees of a small employer who are covered under an employer-sponsored high deductible health plan and to self-employed individuals covered under a high deductible health plan.[10] An employer is a small employer if it employed, on average, no more than 50 employees on business days during either of the

[1] Secs. 106, 3121(a)(2), and 3306(b)(2). All ''section,'' ''sec.,'' and ''Code'' references are to the Internal Revenue Code of 1986, as amended.

[2] Sec. 105. In the case of a self-insured medical reimbursement arrangement, the exclusion applies to highly compensated employees only if certain nondiscrimination rules are satisfied. Sec. 105(h). Medical care is defined as under section 213(d) and generally includes amounts paid for qualified long-term care insurance and services.

[3] Secs. 125, 3121(a)(5)(G), and 3306(b)(5)(G). Long-term care insurance and services may not be provided through a cafeteria plan.

[4] Notice 2002–45, 2002–28 I.R.B. 93 (July 15, 2002); Rev. Rul. 2002–41, 2002–28 I.R.B. 75 (July 15, 2002).

[5] Sec. 162.

[6] Self-employed individuals include more than two-percent shareholders of S. corporations who are treated as partners for purposes of fringe benefit rules pursuant to section 1372.

[7] Sec. 162(1).

[8] Sec. 213. The adjusted gross income percentage is 10 percent for purposes of the alternative minimum tax. Sec. 56(b)(1)(B).

[9] Sec. 220.

[10] Self-employed individuals include more than two-percent sharholders of S corporations who are treated as partners for purposes of fringe benefit rules pursuant to section 1372.

two preceding calendar years. An individual is not eligible for an Archer MSA if he or she is covered under any other health plan that is not a high deductible health plan (other than a plan providing certain limited types of coverage). Individuals entitled to benefits under Medicare are not eligible individuals. Eligible individuals do not include individuals who may be claimed as a dependent on another person's tax return.

TREATMENT OF CONTRIBUTIONS

Individual contributions to an Archer MSA are deductible (within limits) in determining adjusted gross income (i.e., ''above-the-line''). In addition, employer contributions are excludable from gross income and wages for employment tax purposes (within the same limits), except that this exclusion does not apply to contributions made through a cafeteria plan. In the case of an employee, contributions can be made to an Archer MSA either by the individual or by the individual's employer, but not by both.

The maximum annual contribution that can be made to an Archer MSA for a year is 65 percent of the annual deductible under the high deductible health plan in the case of self-only coverage and 75 percent of the annual deductible in the case of family coverage.

If an employer provides a high deductible health plan coupled with Archer MSAs for employees and makes employer contributions to the Archer MSAs, the employer must make available a comparable contribution on behalf of all employees with comparable coverage during the same period. Contributions are considered comparable if they are either of the same amount or the same percentage of the deductible under the high deductible health plan. If employer contributions do not satisfy the comparability rule during a period, then the employer is subject to an excise tax equal to 35 percent of the aggregate amount contributed by the employer to Archer MSAs of the employer for that period.

DEFINITION OF HIGH DEDUCTIBLE HEALTH PLAN

A high deductible health plan is a health plan with an annual deductible of at least $1,700 and no more than $2,500 in the case of self-only coverage and at least $3,350 and no more than $5,050 in the case of family coverage. In addition, the maximum out-of-pocket expenses with respect to allowed costs must be no more than $3,350 in the case of self-only coverage and no more than $6,150 in the case of family coverage.[11] Out-of-pocket expenses include deductibles, co-payments, and other amounts (other than premiums) that the individual must pay for covered benefits under the plan. A plan does not fail to qualify as a high deductible health plan merely because it does not have a deductible for preventive care as required under State law. A plan does not qualify as a high deductible health plan if substantially all of the coverage under the plan is certain permitted insurance or is coverage (whether provided through insurance or otherwise) for accidents, disability, dental care, vision care, or long-term care.

TREATMENT OF DEATH OF ACCOUNT HOLDER

Upon death, any balance remaining in the decedent's Archer MSA is includible in his or her gross estate. If the account holder's surviving spouse is the named beneficiary of the Archer MSA, then, after the death of the account holder, the Archer MSA becomes the Archer MSA of the surviving spouse and the amount of the Archer MSA balance may be deducted in computing the decedent's taxable estate, pursuant to the estate tax marital deduction.[12] If, upon the account holder's death, the Archer MSA passes to a named beneficiary other than the decedent's surviving spouse, the Archer MSA ceases to be an Archer MSA as of the date of the decedent's death, and the beneficiary is required to include the fair market value of the Archer MSA assets as of the date of death in gross income for the taxable year that includes the date of death. The amount includible in gross income is reduced by the amount in the Archer MSA used, within one year after death, to pay qualified medical expenses incurred prior to the death. If there is no named beneficiary for the decedent's Archer MSA, the Archer MSA ceases to be an Archer MSA as of the date of death, and the fair market value of the assets in the Archer MSA as of such date is includible in the decedent's gross income for the year of the death.

LIMIT ON NUMBER OF MSAS; TERMINATION OF MSA AVAILABILITY

The number of taxpayers benefiting annually from an Archer MSA contribution is limited to a threshold level (generally 750,000 taxpayers). The number of Archer MSAs established has not exceeded the threshold level.

After 2003, no new contributions can be made to Archer MSAs except by or on behalf of individuals who previously had Archer MSA contributions and employees who are employed by a participating employer.

House Bill

In general

The House bill creates health savings accounts (''HSAs'') and health savings security accounts (''HSSAs''), which provide tax-favored treatment for current medical expenses as well as the ability to save on a tax-favored basis for future medical expenses. In general, HSAs and HSSAs are tax-exempt trusts or custodial accounts created exclusively to pay for the qualified medical expenses of the account holder and his or her spouse and dependents that are subject to rules similar to those applicable to individual retirement arrangements.[13] Unless otherwise provided, the following description applies to both HSAs and HSSAs (jointly referred to as ''health accounts'').

Within limits, contributions to health accounts are deductible if made by an eligible individual and are excludable from gross income and wages for employment tax purposes if made by the employer of an eligible individual. In the case of HSSAs only, family members may make nondeductible contributions on behalf of an eligible individual. Distributions from health accounts for qualified medical expenses are not includible in gross income. Distributions that are not for qualified medical expenses are includible in gross income and subject to an additional 15 percent tax. The additional 15 percent tax does not apply after death, disability, or the individual attains the age of Medicare eligibility (i.e., age 65).

Eligible individuals

HSAS

Eligible individuals for HSAs are individuals who are covered by a high deductible health plan and no other health plan that is not a high deductible health plan. Individuals entitled to benefits under Medicare are not eligible to make contributions to an HSA. Eligible individuals do not include individuals who may be claimed as a dependent on another person's tax return.

An individual with other coverage in addition to a high deductible health plan is still eligible for an HSA if such other coverage is certain permitted insurance or permitted coverage. Permitted insurance is: (1) insurance if substantially all of the coverage provided under such insurance relates to (a) liabilities incurred under worker's compensation law, (b) tort liabilities, (c) liabilities relating to ownership or use of property (e.g., auto insurance), or (d) such other similar liabilities as the Secretary may prescribe by regulations; (2) insurance for a specified disease or illness; and (3) insurance that provides a fixed payment for hospitalization. Permitted coverage is coverage (whether provided through insurance or otherwise) for accidents, disability, dental care, vision care, or long-term care.

A high deductible health plan is a health plan that in the case of self-only coverage has an annual deductible between $1,000 and $2,500 and in the case of family coverage has an annual deductible between $2,000 and $5,050 (for 2003).[14] The maximum out-of-pocket expenses must be no more than $3,350 in the case of self-only coverage and no more than $6,150 in the case of family coverage. The annual deductible maximum and minimum and out-of-pocket expense amounts are indexed for inflation. A plan is not a high deductible health plan if substantially all of the coverage is for permitted coverage or coverage that may be provided by permitted insurance, as described above.

HSSAS

Individuals eligible for HSSAs are individuals who (1) are covered under a health plan meeting minimum deductible requirements and no other health plan that does not meet the minimum deductible requirements, or (2) are uninsured. Individuals entitled to benefits under Medicare are not eligible to make contributions to an HSSA. Eligible individuals do not include individuals who may be claimed as a dependent on another person's tax return.

An individual with other coverage in addition to a plan meeting the minimum deductible requirements is still eligible for an HSSA if such other coverage is for permitted coverage or coverage that may be provided by permitted insurance, as described above. In addition, an individual is treated as uninsured if his or her only coverage is permitted coverage or coverage that may be provided by permitted insurance.

A plan meets the minimum deductible requirements if the plan is a health plan with an annual deductible of at least $500 in the case of self-only coverage and at least $1,000 in the case of family coverage. These dollar amounts are indexed for inflation. There are no maximum deductible requirements and no limits on out-of-pocket expenses. A plan is not a minimum deductible plan if substantially all of the coverage is for permitted coverage or coverage that may be provided by permitted insurance, as described above.

TAX TREATMENT OF AND LIMITS ON CONTRIBUTIONS

Contributions to a health account made by an eligible individual are deductible (within limits) in determining adjusted gross income (i.e., ''above-the-line''). In addition, employer contributions to a health account (including salary reduction contributions made through a cafeteria plan) are excludable from gross income and wages for employment tax purposes to the extent the contribution would be deductible if made by the

[11] The deductible and out-of-pocket expenses dollar amounts are for 2003. These amounts are indexed for inflation in 450 increments.

[12] Sec. 2056.

[13] As under Archer MSAs, the House bill provision provides that the present-law requirement applicable to insurance companies that certain policy acquisition expenses must be capitalized and amortized (sec. 848) does not apply in the case of any contract that is a health account.

[14] Special rules apply for determining whether a health plan that is a preferred provider organization plan meets the requirements of a high deductible plan.

employee (e.g., in the case of an HSSA, subject to the adjusted gross income limits).[15] Nondeductible contributions may be made to an HSSA by a family member of an eligible individual. In the case of an employee, contributions to a health account may be made by both the individual (and family members in the case of an HSSA) and the individual's employer. All contributions are aggregated for purposes of the maximum annual contribution limit.

The maximum aggregate annual contribution that can be made to an HSA is 100 percent of the annual deductible under the high deductible plan.[16]

The maximum aggregate annual contribution that can be made to an HSSA is (1) $2,000 for (a) persons with self-only coverage and (b) uninsured individuals with no dependents[17] who do not file a joint return, and (2) $4,000 for (a) individuals with family coverage and (b) uninsured individuals with dependents or who file a joint return. In the case of individuals age 55 and older, the $2,000 and $4,000 HSSA annual contribution limits are increased by $500 in 2004, $600 in 2005, $700 in 2006, $800 in 2007, $900 in 2008, and $1,000 in 2009 and thereafter.

The maximum allowable contribution to an HSSA is phased out for taxpayers with adjusted gross income[18] above certain levels. In the case of individuals with self-only coverage (other than individuals filing a joint return), the phase-out range is $75,000 to $85,000. For individuals with family coverage and individuals filing a joint return, the phase-out range is $150,000 to $170,000. The adjusted gross income limits apply to HSSA contributions from all sources (e.g., both individual and employer contributions).

The maximum annual contribution limits for the health accounts are coordinated so that contributions to one type of health account reduce the annual contribution limit for the other type of health account.[19]

An excise tax applies to contributions in excess of the maximum contribution amount for the health account. The excise tax is generally equal to six percent of the cumulative amount of excess contributions that are not distributed from the health account to the contributor.[20]

Amounts can be rolled over into a health account from an Archer MSA or a health FSA on a tax-free basis. Amounts can be rolled over into an HSA from another HSA or HSSA and into an HSSA from another HSSA on a tax-free basis. Rollovers from an HSA into an HSSA are not permitted. Amounts transferred from another health account or Archer MSA are not taken into account under the annual contribution limits.

If an employer makes contributions to employees' health accounts, the employer must make available comparable contributions on behalf of all employees with comparable coverage during the same period. Contributions are considered comparable if they are either of the same amount or the same percentage of the deductible under the plan. The comparability rule is applied separately to part-time employees (i.e., employees who are customarily employed for fewer than 30 hours per week). The comparability rule does not apply to amounts transferred from an employee's health account, health FSA, or Archer MSA or to contributions made through a cafeteria plan.

If employer contributions do not satisfy the comparability rule during a period, then the employer is subject to an excise tax equal to 35 percent of the aggregate amount contributed by the employer to health accounts of the employer for that period. The excise tax is designed as a proxy for the denial of the deduction for employer contributions. In the case of a failure to comply with the comparability rule which is due to reasonable cause and not to willful neglect, the Secretary may waive part or all of the tax imposed to the extent that the payment of the tax would be excessive relative to the failure involved. For purposes of the comparability rule, employers under common control are aggregated.

TAXATION OF DISTRIBUTIONS

Distributions from a health account for qualified medical expenses of the individual and his or her spouse or dependents generally are excludable from gross income. In general, amounts in a health account can be used for qualified medical expenses even if the individual is not currently eligible for contributions to the health account.[21]

Qualified medical expenses generally are defined as under section 213(d) and include expenses for diagnosis, cure, mitigation, treatment, or prevention of disease, including prescription drugs, transportation primarily for and essential to such care, and qualified long-term care expenses. Qualified medical expenses do not include expenses for insurance other than for (1) long-term care insurance, (2) premiums for health coverage during any period of continuation coverage required by Federal law, and (3) premiums for health care coverage while an individual is receiving unemployment compensation under Federal or State law. In the case of HSSAs, qualified medical expenses also include (1) health insurance meeting the minimum deductible requirements if no portion of the cost of the insurance is paid by the employer or former employer of the individual or the individual's spouse,[22] and (2) health insurance for individuals who are older than age 65 (including Medicare expenses). For purposes of determining the itemized deduction for medical expenses, distributions from a health account for qualified medical expenses are not treated as expenses paid for medical care under section 213.

Distributions from a health account that are not for qualified medical expenses are includible in gross income (except to the extent that the distribution is attributable to a return of nondeductible family contributions in the case of an HSSA).[23] Distributions includible in gross income are also subject to an additional 15-percent tax unless made after death, disability, or the individual attains the age of Medicare eligibility (i.e., age 65).

TAX TREATMENT OF HSAS AND HSSAS AFTER DEATH

Upon death, any balance remaining in the decedent's health account is includible in his or her gross estate.

If the health account holder's surviving spouse is the named beneficiary of the health account, then, after the death of the health account holder, the health account becomes the health account of the surviving spouse and the amount of the health account balance may be deducted in computing the decedent's taxable estate, pursuant to the estate tax marital deduction.[24] The surviving spouse is not required to include any amount in gross income as a result of the death; the general rules applicable to the health account apply to the surviving spouse's health account (e.g., the surviving spouse is subject to income tax only on distributions from the health account for nonqualified expenses). The surviving spouse can exclude from gross income amounts withdrawn from the health account for expenses incurred by the decedent prior to death, to the extent they otherwise are qualified medical expenses.

If, upon death, the health account passes to a named beneficiary other than the decedent's surviving spouse, the health account ceases to be a health account as of the date of the decedent's death, and the beneficiary is required to include the fair market value of health account assets as of the date of death in gross income for the taxable year that includes the date of death. The amount includible in income is reduced by the amount in the health account used, within one year after death, to pay qualified medical expenses incurred by the decedent prior to the death. As is the case with other health account distributions, whether the expenses are qualified medical expenses is determined as of the time the expenses were incurred. In computing taxable income, the beneficiary may claim a deduction for that portion of the Federal estate tax on the decedent's estate that was attributable to the amount of the health account balance.[25]

If there is no named beneficiary of the decedent's health account, the health account ceases to be a health account as of the date of death, and the fair market value of the assets in the health account as of such date is includible in the decedent's gross income for the year of the death.

This rule applies in all cases in which there is no named beneficiary, even if the surviving spouse ultimately obtains the right to the health account assets (e.g., if the surviving spouse is the sole beneficiary of the decedent's estate).

REPORTING REQUIREMENTS

Employer contributions are required to be reported on the employee's Form W–2. Trustees of health accounts may be required to report to the Secretary of the Treasury amounts with respect to contributions, distributions, and other matters as determined appropriate by the Secretary. In addition, providers of health insurance are required to report information as may be prescribed by the Secretary.

[15] Employer contributions to a health account are excludable from wages for employment tax purposes if, at the time of payment, it is reasonable to believe that the employee will be able to exclude such payment from income (e.g., a reasonable basiss to believe that the employee's income is within the applicabale adjusted gross income limits for an HSSA).

[16] The annual contribution limit for a health account is the sum of the limits determined separately for each month, based on the individual's status and health plan coverage as of the first day of the month.

[17] Written declarations releasing a claim to a dependency exemption under section 152(e)(2) are disregarded in determining whether an individual has dependents.

[18] Adjusted gross income is defined generally as under the rules relating to individual retirement arrangements (''IRAs''), and is computed after the deduction for contributions to IRAs and before the deductions provided by the provision.

[19] The contribution limits are also coordinated with contributions to Archer MSAs.

[20] Ordering rules apply to determine the nature of any distributed excess contributions (e.g., nondeductible family contributions in the case of an HSSA or employer contributions).

[21] However, in any year for which a contribution is made to an HSA, withdrawals from the HSA maintained by that individual generally are excludable from income only if the individual for whom the expenses were incurred was covered under a high deductible plan for the month in which the expenses were incurred. The rule does not apply for continuation coverage or coverage while the individual is receiving unemployment compensation even if for an individual who is not an eligible individual.

[22] Amounts paid by the employer include salary reduction contributions.

[23] Ordering rules apply to determine the extent to which distributions are attributable to nondeductible contributions.

[24] Sec. 2056.

[25] The deduction is calculated in accordance with the present-law rules relating to income in respect of a decedent set forth in section 691(c).

Effective date.—The House bill provision is effective for taxable years beginning after December 31, 2003.

Senate Amendment

No provision.

Conference Agreement

The conference agreement does not include the House bill provision relating to HSSAs. The conference agreement includes the HSA provision from the House bill, with the following modifications.[26]

The conference agreement modifies the definition of a high deductible health plan applicable to HSAs by removing the limitation on the maximum amount of the deductible and increasing the limit on out-of-pocket expenses. Under the conference agreement, a high deductible health plan is a health plan that has a deductible that is at least $1,000 for self-only coverage or $2,000 for family coverage[27] and that has an out-of-pocket expense limit that is no more than $5,000 in the case of self-only coverage and $10,000 in the case of family coverage.[28] As under present law, out-of-pocket expenses include deductibles, co-payments, and other amounts (other than premiums) that the individual must pay for covered benefits under the plan.

Under the conference agreement, the maximum aggregate annual contribution[29] that can be made to an HSA is the lesser of (1) 100 percent of the annual deductible under the high deductible health plan, or (2) the maximum deductible permitted under an Archer MSA high deductible health plan under present law, as adjusted for inflation. For 2004, the amount of the maximum high deductible is estimated to be $2,600 in the case of self-only coverage and $5,150 in the case of family coverage.

Under the conference agreement, contributions made by or on behalf of an eligible individual are deductible by the individual. Thus, for example, contributions made by an eligible individual's family members are deductible by the eligible individual to the extent the contributions would be deductible if made by the individual.[30] As under the House bill, all contributions by or on behalf of an eligible individual are aggregated for purposes of the maximum annual contribution limit. Contributions to Archer MSAs reduce the annual contribution limit for HSAs.

The conference agreement increases the annual contribution limits for individuals who have attained age 55 by the end of the taxable year. In the case of policyholders and covered spouses who are age 55 or older, the HSA annual contribution limit is greater than the otherwise applicable limit by $500 in 2004, $600 in 2005, $700 in 2006, $800 in 2007, $900 in 2008, and $1,000 in 2009 and thereafter.[31] As under the House bill, contributions, including catch-up contributions, cannot be made once an individual is eligible for Medicare. Under the conference agreement, qualified medical expenses are expanded to include health insurance premiums for individuals eligible for Medicare, other than premiums for Medigap policies. Qualified health insurance premiums include, for example, Medicare Part A and Part B premiums, Medicare HMO premiums, and the employee share of premiums for employer- sponsored health insurance including employer-sponsored retiree health insurance.

Except as otherwise provide by the Secretary, preventative care is defined as under section 1871 of the Social Security Act. It is intended that the Secretary of the Treasury will amend the definition of preventative care if the definition used under the Social Security Act is inconsistent with the purposes of the provision. Under the conference agreement, the additional tax on nonqualified distributions is reduced to 10 percent (rather than 15 percent as in the House bill).

Under the conference agreement, amounts can be rolled over into an HSA from another HSA or from an Archer MSA. The conference agreement also clarifies information reporting requirements in the House bill.

Effective date.—The provision is effective for taxable years beginning after December 31, 2003.

Disposition of Unused Health Benefits in Flexible Spending Arrangements (sec. 1203 of the House bill and sec. 125 of the Code)

Present Law

A flexible spending arrangement (''FSA'') is defined under the Code as a benefit program which provides employees with coverage under which specified incurred expenses may be reimbursed and the maximum amount of reimbursement which is reasonably available to a participant for such coverage is less than 500 percent of the value of such coverage.[32] A health FSA is an FSA that provides for reimbursement of medical expenses.[33] Health FSAs are typically part of a cafeteria plan and may be funded through salary reduction.[34] Health FSAs are commonly used, for example, to reimburse employees for medical expenses not covered by insurance. There is no special exclusion for benefits provided under an FSA. Thus, health benefits provided under an FSA are excludable from income only if they qualify for exclusion under sections 105 or 106.

FSAs that are part of a cafeteria plan must comply with the rules applicable to cafeteria plans generally. One of these rules is that a cafeteria plan may not offer deferred compensation except through a qualified cash or deferred arrangement.[35] Under proposed Treasury regulations, a cafeteria plan is considered to permit the deferral of compensation if it includes a health FSA which reimburses participants for medical expenses incurred beyond the end of the plan year.[36] Thus, amounts in an employee's health account that are not used for medical expenses incurred before the end of a plan year must be forfeited. This rule is often referred to as the ''use it or lose it'' rule.

House Bill

The House bill allows up to $500 of unused health benefits in an employee's health FSA to be carried forward to the employee's health account for the next plan year of the health FSA or transferred to an HSA or HSSA maintained for the benefit of the employee.[37] Amounts transferred to an HSA or HSSA are treated as employer contributions for purposes of the HSA and HSSA rules. Under the House bill, if an individual is not eligible to contribute to an HSA or HSSA for the taxable year, the individual may transfer up to $500 of unused health benefits in the employee's health FSA to a tax-qualified retirement plan, a tax-sheltered annuity (section 403(b)), an individual retirement arrangement (''IRA''), or an eligible deferred compensation plan of a State or local government (section 457). An employee's unused health benefit is the excess of the maximum amount of reimbursement allowable to the employee over the actual amount of reimbursement made during the year. Amounts transferred are subject to the rules and limits on contributions that would otherwise apply to contributions to the transferee plan.

Effective date.—The House bill provision applies to taxable years beginning after December 31, 2003.

Senate Amendment

No provision.

Conference Agreement

The conference agreement does not include the House bill provision.

Exclusion from Gross Income of Certain Federal Subsidies for Prescription Drug Plans (new sec. 139A of the Code)

Present Law

Gross income includes all income from whatever source derived unless a specific exclusion applies.[38]

House Bill

No provision.

Senate Amendment

No provision.

Conference Agreement

The conference agreement provides that gross income does not include any special subsidy payment received under section 1860D–22 of the Social Security Act. The exclusion applies for purposes of both the regular tax and the alternative minimum tax (including the adjustment for adjusted current earnings).

The exclusion is not taken into account in determining whether a deduction is allowable with respect to costs taken into account in determining the subsidy payment. Accordingly, a taxpayer could claim a deduction for prescription drug expenses incurred even though the taxpayer also received an excludible subsidy related to the same expenses.

Effective date.—The provision is effective for taxable years ending after the date of enactment.

Exception to Information Reporting Requirements for Certain Health Arrangements (sec. 1204 of the House bill and sec. 6041 of the Code)

Present Law

Any person in a trade or business who, in the course of that trade or business, makes specified payments to another person totaling $600 or more in a year, must provide an information report to the IRS (as well as a copy to the recipient) on the payments.[39] Reporting is required to be done on Form 1099. In general, these information reports remind taxpayers of amounts of income that should be reflected on their tax returns and assist the IRS in verifying that taxpayers have correctly reported these amounts.

Treasury regulations specify that fees for professional services, including the services

[26] The rules for HSAs generally follow those of Archer MSAs unless otherwise provided.

[27] The $1,000 limit is indexed for inflation. The family coverage limit will always be twice the individual limit (as indexed for inflation).

[28] In the case of the plan using a network of providers, the plan does not fail to be a high deductible health plan (if it would otherwise meet the requirements of a high deductible health plan) solely because the out of-pocket expense limit for services provised outside of the network exceeds the $5,000 and $10,000 out-of-pocket expense limits. In addition, such plan's deductible for out-of-network services is not taken into account in determining the annual contribution limit (i.e., the deductible for services within the network is used for such purpose).

[29] The maximum annual contribution limit is calculated as the sum of limits determined for each month based on the individual's health plan coverage on the first day of the month.

[30] Under present law, contributions made on behalf of another individual are generally treated as gifts. The present-law gift tax rules apply to contributions made on behalf of another individual.

[31] As in determining the general annual contribution limit, the increase in the annual contribution limit for individuals who have attained age 55 is also determined on a monthly basis.

[32] Sec. 106(c).

[33] FSAs may also be used to provide certain other nontaxable benefits, such as dependent care.

[34] Long-term care insurance cannot be offered through a cafeteria plan. Sec. 125(f).

[35] Sec. 401(k).

[36] Prop. Treas. Reg. sec. 1.125–2 Q&A–5(a).

[37] Section 2 of the bill provides the eligibility rules for contributions to an HSA or HSSA.

[38] Sec. 61.

[39] Sec. 6041.

of physicians, must be reported.[40] Treasury regulations also provide a general exception from these information reporting requirements for payments made to corporations, except that this exception is inapplicable if the corporation is ''engaged in providing medical and health care services.''[41] Earlier this year, the IRS issued a revenue ruling describing whether employer-provided expense reimbursements made through debit or credit cards or other electronic media are excludible from gross income.[42] The ruling states that ''payments made to medical service providers through the use of debit, credit, and stored value cards are reportable by the employer on Form 1099–MISC under section 6041.''[43]

House Bill

The House bill provides an exception from the generally applicable information reporting provisions for payments for medical care made under either: (1) a flexible spending arrangement,[44] or (2) a health reimbursement arrangement that is treated as employer-provided coverage.

Effective date.—The House bill provision applies to payments made after December 31, 2002.

Senate Amendment

No provision.

Conference Agreement

The conference agreement follows the House bill.

TAX COMPLEXITY ANALYSIS

Section 4022(b) of the Internal Revenue Service Reform and Restructuring Act of 1998 (the ''IRS Reform Act'') requires the Joint Committee on Taxation (in consultation with the Internal Revenue Service and the Department of the Treasury) to provide a tax complexity analysis. The complexity analysis is required for all legislation reported by the Senate Committee on Finance, the House Committee on Ways and Means, or any committee of conference if the legislation includes a provision that directly or indirectly amends the Internal Revenue Code (the ''Code'') and has widespread applicability to individuals or small businesses.

The staff of the Joint Committee on Taxation has determined that a complexity analysis is not required under section 4022(b) of the IRS Reform Act because the bill contains no provisions that amend the Code and that have ''widespread applicability'' to individuals or small businesses

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ORRIN HATCH,
DON NICKLES,
BILL FRIST,
JON KYL,
MAX BAUCUS,
JOHN BREAUX,
Managers on the Part of the Senate.

[40] Treas. Reg. sec. 1.6041–1(d)(2).

[41] Treas. Reg. sec. 1.6041–3(p)(1). These regulations also provide an eception from these information reporting requirements if the payment is made to a hospital that is tax-exempt or that is owned and operated by a government entity.

[42] Rev. Rul. 2003–43, 2003–21 I.R.B. 935 (May 27, 2003).

[43] *Id.*

[44] This term is defined in sec. 106(c)(2).