

MEDICARE PART B IMPROVEMENT ACT OF 2017

JULY 25, 2017.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. BRADY of Texas, from the Committee on Ways and Means, submitted the following

R E P O R T

[To accompany H.R. 3178]

[Including cost estimate of the Congressional Budget Office]

The Committee on Ways and Means, to whom was referred the bill (H.R. 3178) to amend title XVIII of the Social Security Act to improve the delivery of home infusion therapy and dialysis and the application of the Stark rule under the Medicare program, and for other purposes, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

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The amendment is as follows:
Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) **SHORT TITLE.**—This Act may be cited as the “Medicare Part B Improvement Act of 2017”.

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

Sec. 1. Short title; table of contents.

TITLE I—IMPROVEMENTS IN PROVISION OF HOME INFUSION THERAPY

Sec. 101. Home infusion therapy services temporary transitional payment.

Sec. 102. Extension of Medicare Patient IVIG Access Demonstration Project.

Sec. 103. Orthotist’s and prosthetist’s clinical notes as part of the patient’s medical record.

TITLE II—IMPROVEMENTS IN DIALYSIS SERVICES

Sec. 201. Independent accreditation for dialysis facilities and assurance of high quality surveys.

Sec. 202. Expanding access to home dialysis therapy.

TITLE III—IMPROVEMENTS IN APPLICATION OF STARK RULE

Sec. 301. Modernizing the application of the Stark rule under Medicare.

Sec. 302. Funds from the Medicare Improvement Fund.

TITLE I—IMPROVEMENTS IN PROVISION OF HOME INFUSION THERAPY

SEC. 101. HOME INFUSION THERAPY SERVICES TEMPORARY TRANSITIONAL PAYMENT.

(a) **IN GENERAL.**—Section 1834(u) of the Social Security Act (42 U.S.C. 1395m(u)) is amended, by adding at the end the following new paragraph:

“(7) **HOME INFUSION THERAPY SERVICES TEMPORARY TRANSITIONAL PAYMENT.**—

“(A) **TEMPORARY TRANSITIONAL PAYMENT.**—

“(i) **IN GENERAL.**—The Secretary shall, in accordance with the payment methodology described in subparagraph (B) and subject to the provisions of this paragraph, provide a home infusion therapy services temporary transitional payment under this part to an eligible home infusion supplier (as defined in subparagraph (F)) for items and services described in subparagraphs (A) and (B) of section 1861(iii)(2)) furnished during the period specified in clause (ii) by such supplier in coordination with the furnishing of transitional home infusion drugs (as defined in clause (iii)).

“(ii) **PERIOD SPECIFIED.**—For purposes of clause (i), the period specified in this clause is the period beginning on January 1, 2019, and ending on the day before the date of the implementation of the payment system under paragraph (1)(A).

“(iii) **TRANSITIONAL HOME INFUSION DRUG DEFINED.**—For purposes of this paragraph, the term ‘transitional home infusion drug’ has the meaning given to the term ‘home infusion drug’ under section 1861(iii)(3)(C), except that clause (ii) of such section shall not apply if a drug described in such clause is identified in clauses (i), (ii), (iii) or (iv) of subparagraph (C) as of the date of the enactment of this paragraph.

“(B) **PAYMENT METHODOLOGY.**—For purposes of this paragraph, the Secretary shall establish a payment methodology, with respect to items and services described in subparagraph (A)(i). Under such payment methodology the Secretary shall—

“(i) create the three payment categories described in clauses (i), (ii), and (iii) of subparagraph (C);

“(ii) assign drugs to such categories, in accordance with such clauses;

“(iii) assign appropriate Healthcare Common Procedure Coding System (HCPCS) codes to each payment category; and

“(iv) establish a single payment amount for each such payment category, in accordance with subparagraph (D), for each infusion drug administration calendar day in the individual’s home for drugs assigned to such category.

“(C) **PAYMENT CATEGORIES.**—

“(i) PAYMENT CATEGORY 1.—The Secretary shall create a payment category 1 and assign to such category drugs which are covered under the Local Coverage Determination on External Infusion Pumps (LCD number L33794) and billed with the following HCPCS codes (as identified as of July 1, 2017, and as subsequently modified by the Secretary): J0133, J0285, J0287, J0288, J0289, J0895, J1170, J1250, J1265, J1325, J1455, J1457, J1570, J2175, J2260, J2270, J2274, J2278, J3010, or J3285.

“(ii) PAYMENT CATEGORY 2.—The Secretary shall create a payment category 2 and assign to such category drugs which are covered under such local coverage determination and billed with the following HCPCS codes (as identified as of July 1, 2017, and as subsequently modified by the Secretary): J1559 JB, J1561 JB, J1562 JB, J1569 JB, or J1575 JB.

“(iii) PAYMENT CATEGORY 3.—The Secretary shall create a payment category 3 and assign to such category drugs which are covered under such local coverage determination and billed with the following HCPCS codes (as identified as of July 1, 2017, and as subsequently modified by the Secretary): J9000, J9039, J9040, J9065, J9100, J9190, J9200, J9360, or J9370.

“(iv) INFUSION DRUGS NOT OTHERWISE INCLUDED.—With respect to drugs that are not included in payment category 1, 2, or 3 under clause (i), (ii), or (iii), respectively, the Secretary shall assign to the most appropriate of such categories, as determined by the Secretary, drugs which are—

“(I) covered under such local coverage determination and billed under HCPCS codes J7799 or J7999 (as identified as of July 1, 2017, and as subsequently modified by the Secretary); or

“(II) billed under any code that is implemented after the date of the enactment of this paragraph and included in such local coverage determination or included in subregulatory guidance as a home infusion drug described in subparagraph (A)(i).

“(D) PAYMENT AMOUNTS.—

“(i) IN GENERAL.—Under the payment methodology, the Secretary shall pay eligible home infusion suppliers, with respect to items and services described in subparagraph (A)(i) furnished during the period described in subparagraph (A)(ii) by such supplier to an individual, at amounts equal to the amounts determined under the physician fee schedule established under section 1848 for services furnished during the year for codes and units of such codes described in clauses (ii), (iii), and (iv) with respect to drugs included in the payment category under subparagraph (C) specified in the respective clause, determined without application of any adjustment under such section.

“(ii) PAYMENT AMOUNT FOR CATEGORY 1.—For purposes of clause (i), the codes and units described in this clause, with respect to drugs included in payment category 1 described in subparagraph (C)(i), are one unit of HCPCS code 96365 plus four units of HCPCS code 96366 (as identified as of July 1, 2017, and as subsequently modified by the Secretary).

“(iii) PAYMENT AMOUNT FOR CATEGORY 2.—For purposes of clause (i), the codes and units described in this clause, with respect to drugs included in payment category 2 described in subparagraph (C)(i), are one unit of HCPCS code 96369 plus four units of HCPCS code 96370 (as identified as of July 1, 2017, and as subsequently modified by the Secretary).

“(iv) PAYMENT AMOUNT FOR CATEGORY 3.—For purposes of clause (i), the codes and units described in this clause, with respect to drugs included in payment category 3 described in subparagraph (C)(i), are one unit of HCPCS code 96413 plus four units of HCPCS code 96415 (as identified as of July 1, 2017, and as subsequently modified by the Secretary).

“(E) CLARIFICATIONS.—

“(i) INFUSION DRUG ADMINISTRATION DAY.—For purposes of this subsection, a reference, with respect to the furnishing of transitional home infusion drugs or home infusion drugs to an individual by an eligible home infusion supplier, to payment to such supplier for an infusion drug administration calendar day in the individual’s home shall refer to payment only for the date on which professional services (as described in section 1861(iii)(2)(A)) were furnished to administer such

drugs to such individual. For purposes of the previous sentence, an infusion drug administration calendar day shall include all such drugs administered to such individual on such day.

“(ii) TREATMENT OF MULTIPLE DRUGS ADMINISTERED ON SAME INFUSION DRUG ADMINISTRATION DAY.—In the case that an eligible home infusion supplier, with respect to an infusion drug administration calendar day in an individual’s home, furnishes to such individual transitional home infusion drugs which are not all assigned to the same payment category under subparagraph (C), payment to such supplier for such infusion drug administration calendar day in the individual’s home shall be a single payment equal to the amount of payment under this paragraph for the drug, among all such drugs so furnished to such individual during such calendar day, for which the highest payment would be made under this paragraph.

“(F) ELIGIBLE HOME INFUSION SUPPLIERS.—In this paragraph, the term ‘eligible home infusion supplier’ means a supplier that is enrolled under this part as a pharmacy that provides external infusion pumps and external infusion pump supplies and that maintains all pharmacy licensure requirements in the State in which the applicable infusion drugs are administered.

“(G) IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary may implement this paragraph by program instruction or otherwise.”

(b) CONFORMING AMENDMENT.—Section 1842(b)(6)(I) of the Social Security Act (42 U.S.C. 1395u(b)(6)(I)) is amended by inserting “or, in the case of items and services described in clause (i) of section 1834(u)(7)(A) furnished to an individual during the period described in clause (ii) of such section, payment shall be made to the eligible home infusion therapy supplier” after “payment shall be made to the qualified home infusion therapy supplier”.

SEC. 102. EXTENSION OF MEDICARE PATIENT IVIG ACCESS DEMONSTRATION PROJECT.

Section 101(b) of the Medicare IVIG Access and Strengthening Medicare and Repaying Taxpayers Act of 2012 (42 U.S.C. 1395l note) is amended—

(1) in paragraph (1), by inserting after “for a period of 3 years” the following: “and, subject to the availability of funds under subsection (g)—

“(A) if the date of enactment of the Medicare Part B Improvement Act of 2017 is on or before September 30, 2017, for the period beginning on October 1, 2017, and ending on December 31, 2020; and

“(B) if the date of enactment of such Act is after September 30, 2017, for the period beginning on the date of enactment of such Act and ending on December 31, 2020”; and

(2) in paragraph (2), by adding at the end the following new sentence: “Subject to the preceding sentence, a Medicare beneficiary enrolled in the demonstration project on September 30, 2017, shall be automatically enrolled during the period beginning on the date of the enactment of the Medicare Part B Improvement Act of 2017 and ending on December 31, 2020, without submission of another application.”

SEC. 103. ORTHOTIST’S AND PROSTHETIST’S CLINICAL NOTES AS PART OF THE PATIENT’S MEDICAL RECORD.

Section 1834(h) of the Social Security Act (42 U.S.C. 1395m(h)) is amended by adding at the end the following new paragraph:

“(5) DOCUMENTATION CREATED BY ORTHOTISTS AND PROSTHETISTS.—For purposes of determining the reasonableness and medical necessity of orthotics and prosthetics, documentation created by an orthotist or prosthetist shall be considered part of the individual’s medical record to support documentation created by eligible professionals described in section 1848(k)(3)(B).”

TITLE II—IMPROVEMENTS IN DIALYSIS SERVICES

SEC. 201. INDEPENDENT ACCREDITATION FOR DIALYSIS FACILITIES AND ASSURANCE OF HIGH QUALITY SURVEYS.

(a) ACCREDITATION AND SURVEYS.—

(1) IN GENERAL.—Section 1865 of the Social Security Act (42 U.S.C. 1395bb) is amended—

(A) in subsection (a)—

- (i) in paragraph (1), in the matter preceding subparagraph (A), by striking “or the conditions and requirements under section 1881(b)”;
- and
- (ii) in paragraph (4), by inserting “(including a renal dialysis facility)” after “facility”; and

(B) by adding at the end the following new subsection:

“(e) With respect to an accreditation body that has received approval from the Secretary under subsection (a)(3)(A) for accreditation of provider entities that are required to meet the conditions and requirements under section 1881(b), in addition to review and oversight authorities otherwise applicable under this title, the Secretary shall (as the Secretary determines appropriate) conduct, with respect to such accreditation body and provider entities, any or all of the following more frequently than is otherwise required to be conducted under this title with respect to other accreditation bodies or other provider entities:

“(1) Validation surveys referred to in subsection (d).

“(2) Accreditation program reviews (as defined in section 488.8(c) of title 42 of the Code of Federal Regulations, or a successor regulation).

“(3) Performance reviews (as defined in section 488.8(a) of title 42 of the Code of Federal Regulations, or a successor regulation).”

(2) TIMING FOR ACCEPTANCE OF REQUESTS FROM ACCREDITATION ORGANIZATIONS.—Not later than 90 days after the date of enactment of this Act, the Secretary of Health and Human Services shall begin accepting requests from national accreditation bodies for a finding described in section 1865(a)(3)(A) of the Social Security Act (42 U.S.C. 1395bb(a)(3)(A)) for purposes of accrediting provider entities that are required to meet the conditions and requirements under section 1881(b) of such Act (42 U.S.C. 1395rr(b)).

(b) REQUIREMENT FOR TIMING OF SURVEYS OF NEW DIALYSIS FACILITIES.—Section 1881(b)(1) of the Social Security Act (42 U.S.C. 1395rr(b)(1)) is amended by adding at the end the following new sentence: “Beginning 180 days after the date of the enactment of this sentence, an initial survey of a provider of services or a renal dialysis facility to determine if the conditions and requirements under this paragraph are met shall be initiated not later than 90 days after such date on which both the provider enrollment form (without regard to whether such form is submitted prior to or after such date of enactment) has been determined by the Secretary to be complete and the provider’s enrollment status indicates approval is pending the results of such survey.”

SEC. 202. EXPANDING ACCESS TO HOME DIALYSIS THERAPY.

(a) ALLOWING USE OF TELEHEALTH FOR MONTHLY END STAGE RENAL DISEASE-RELATED VISITS.—

(1) IN GENERAL.—Paragraph (3) of section 1881(b) of the Social Security Act (42 U.S.C. 1395rr(b)) is amended—

(A) by redesignating subparagraphs (A) and (B) as clauses (i) and (ii), respectively;

(B) in clause (i), as redesignated by subparagraph (A), by striking “under this subparagraph” and inserting “under this clause”;

(C) in clause (ii), as redesignated by subparagraph (A), by inserting “subject to subparagraph (B),” before “on a comprehensive”;

(D) by striking “With respect to” and inserting “(A) With respect to”; and

(E) by adding at the end the following new subparagraph:

“(B)(i) Subject to clause (ii), an individual who is determined to have end stage renal disease and who is receiving home dialysis may choose to receive monthly end stage renal disease-related visits, furnished on or after January 1, 2019, via telehealth.

“(ii) Clause (i) shall apply to an individual only if the individual receives a face-to-face visit, without the use of telehealth—

“(I) in the case of the initial three months of home dialysis of such individual, at least monthly; and

“(II) after such initial three months, at least once every three consecutive months.”

(2) CONFORMING AMENDMENT.—Paragraph (1) of such section is amended by striking “paragraph (3)(A)” and inserting “paragraph (3)(A)(i)”.

(b) EXPANDING ORIGINATING SITES FOR TELEHEALTH TO INCLUDE RENAL DIALYSIS FACILITIES AND THE HOME FOR PURPOSES OF MONTHLY END STAGE RENAL DISEASE-RELATED VISITS.—

(1) IN GENERAL.—Section 1834(m) of the Social Security Act (42 U.S.C. 1395m(m)) is amended—

(A) in paragraph (4)(C)(ii), by adding at the end the following new subclauses:

“(IX) A renal dialysis facility, but only for purposes of section 1881(b)(3)(B).

“(X) The home of an individual, but only for purposes of section 1881(b)(3)(B).”; and

(B) by adding at the end the following new paragraph:

“(5) TREATMENT OF HOME DIALYSIS MONTHLY ESRD-RELATED VISIT.—The geographic requirements described in paragraph (4)(C)(i) shall not apply with respect to telehealth services furnished on or after January 1, 2019, for purposes of section 1881(b)(3)(B), at an originating site described in subclause (VI), (IX), or (X) of paragraph (4)(C)(ii), subject to applicable State law requirements, including State licensure requirements.”.

(2) NO FACILITY FEE IF ORIGINATING SITE FOR HOME DIALYSIS THERAPY IS THE HOME.—Section 1834(m)(2)(B) of the Social Security (42 U.S.C. 1395m(m)(2)(B)) is amended—

(A) by redesignating clauses (i) and (ii) as subclauses (I) and (II), respectively, and by indenting each of such subclauses 2 ems to the right;

(B) in subclause (II), as redesignated by subparagraph (A), by striking “clause (i) or this clause” and inserting “subclause (I) or this subclause”;

(C) by striking “SITE.—With respect to” and inserting “SITE.—

“(i) IN GENERAL.—Subject to clause (ii), with respect to”; and

(D) by adding at the end the following new clause:

“(ii) NO FACILITY FEE IF ORIGINATING SITE FOR HOME DIALYSIS THERAPY IS THE HOME.—No facility fee shall be paid under this subparagraph to an originating site described in subclause (X) of paragraph (4)(C)(ii).”.

(c) CLARIFICATION REGARDING TELEHEALTH PROVIDED TO BENEFICIARIES.—Section 1128A(i)(6) of the Social Security Act (42 U.S.C. 1320a–7a(i)(6)) is amended—

(1) in subparagraph (H), by striking “; or” and inserting a semicolon;

(2) in subparagraph (I), by striking the period at the end and inserting “; or”; and

(3) by adding at the end the following new subparagraph:

“(J) the provision of telehealth on or after January 1, 2019, to individuals with end stage renal disease under title XVIII by a health care provider for the purpose of furnishing of telehealth.”.

(d) STUDY AND REPORT ON FURTHER EXPANSION.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study to examine the benefits and drawbacks of expanding the coverage under the Medicare program under title XVIII of the Social Security Act of renal dialysis services as telehealth services, pursuant to the amendments made by this section, to include coverage of renal dialysis services furnished via telehealth and store-and-forward technologies.

(2) REPORT.—Not later than two years after the date of the enactment of this Act, the Comptroller General shall submit to Congress a report on the results of the study conducted under paragraph (1).

TITLE III—IMPROVEMENTS IN APPLICATION OF STARK RULE

SEC. 301. MODERNIZING THE APPLICATION OF THE STARK RULE UNDER MEDICARE.

(a) CLARIFICATION OF THE WRITING REQUIREMENT AND SIGNATURE REQUIREMENT FOR ARRANGEMENTS PURSUANT TO THE STARK RULE.—

(1) WRITING REQUIREMENT.—Section 1877(h)(1) of the Social Security Act (42 U.S.C. 1395nn(h)(1)) is amended by adding at the end the following new subparagraph:

“(D) WRITTEN REQUIREMENT CLARIFIED.—In the case of any requirement pursuant to this section for a compensation arrangement to be in writing, such requirement shall be satisfied by such means as determined by the Secretary, including by a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties involved.”.

(2) SIGNATURE REQUIREMENT.—Section 1877(e) of the Social Security Act (42 U.S.C. 1395nn(e)) is amended—

(A) in paragraph (1)(A)(i), by inserting “before or not later than 90 days after the effective date of the lease” after “signed by the parties”;

(B) in paragraph (1)(B)(i), by inserting “before or not later than 90 days after the effective date of the lease” after “signed by the parties”; and

(C) in paragraph (3)(A)(i), by inserting “before or not later than 90 days after the effective date of the arrangement” after “signed by the parties”.

(b) INDEFINITE HOLDOVER FOR LEASE ARRANGEMENTS AND PERSONAL SERVICES ARRANGEMENTS PURSUANT TO THE STARK RULE.—Section 1877 of the Social Security Act (42 U.S.C. 1395nn) is amended—

(1) in subsection (e)—

(A) in paragraph (1), by adding at the end the following new subparagraph:

“(C) HOLDOVER LEASE ARRANGEMENTS.—In the case of a holdover lease arrangement for the lease of office space or equipment, which immediately follows a lease arrangement described in subparagraph (A) for the use of such office space or subparagraph (B) for the use of such equipment and that expired after a term of at least one year, payments made by the lessee to the lessor pursuant to such holdover lease arrangement, if—

“(i) the lease arrangement met the conditions of subparagraph (A) for the lease of office space or subparagraph (B) for the use of equipment when the arrangement expired;

“(ii) the holdover lease arrangement is on the same terms and conditions as the immediately preceding arrangement; and

“(iii) the holdover arrangement continues to satisfy the conditions of subparagraph (A) for the lease of office space or subparagraph (B) for the use of equipment.”; and

(B) in paragraph (3), by adding at the end the following new subparagraph:

“(C) HOLDOVER PERSONAL SERVICE ARRANGEMENT.—In the case of a holdover personal service arrangement, which immediately follows an arrangement described in subparagraph (A) that expired after a term of at least one year, remuneration from an entity pursuant to such holdover personal service arrangement, if—

“(i) the personal service arrangement met the conditions of subparagraph (A) when the arrangement expired;

“(ii) the holdover personal service arrangement is on the same terms and conditions as the immediately preceding arrangement; and

“(iii) the holdover arrangement continues to satisfy the conditions of subparagraph (A).”; and

(2) in subsection (h)(1), as amended by subsection (a)(1)—

(A) in the heading, by inserting “; HOLDOVER ARRANGEMENT” after “REMUNERATION”; and

(B) by adding at the end the following new subparagraph:

“(E) HOLDOVER ARRANGEMENT.—The term ‘holdover arrangement’ means an arrangement, with respect to an agreement (including a lease or other arrangement) that has expired but as of the date of such expiration had been in compliance with the applicable requirements of this section, under which the parties to such expired agreement have, since such date of expiration, continued to perform under the terms and conditions of such expired agreement.”.

SEC. 302. FUNDS FROM THE MEDICARE IMPROVEMENT FUND.

Section 1898(b)(1) of the Social Security Act (42 U.S.C. 1395iii(b)(1)) is amended by striking “during and after fiscal year 2021, \$270,000,000” and inserting “during and after fiscal year 2021, \$245,000,000”.

I. SUMMARY AND BACKGROUND

A. PURPOSE AND SUMMARY

The bill, H.R. 3178, the “Medicare Part B Improvement Act of 2017,” as ordered reported by the Committee on Ways and Means on July 13, 2017, would improve the delivery of home infusion therapy and dialysis and the application of the Stark rule under the Medicare program.

H.R. 3178 includes bipartisan policies sponsored by several Committee Members aimed at improving both the program and beneficiary experience that would:

- Create a transitional Medicare payment for home infusion services to expand access and ensure beneficiaries do not experience a gap in care before the permanent home infusion benefit takes effect in 2021;

- Extend an ongoing intravenous immunoglobulin (IVIG) demonstration program to increase patient education and appropriate utilization of infusion services;
- Streamline rules to preserve access to orthotics and prosthetics for patients in need;
- Allow telehealth technologies to monitor patients receiving dialysis in their home;
- Expedite accreditation of dialysis facilities for Medicare billing purposes by allowing private organizations to accredit new facilities; and
- Modify Medicare’s physician self-referral laws to clarify rules for providers.

B. BACKGROUND AND NEED FOR LEGISLATION

On July 11, 2017, Representative Brady (R–TX) and Representative Neal (D–MA) introduced H.R. 3178, legislation to improve Medicare Part B programs, including expanding access to in-home treatments for patients. The Committee on Ways and Means received an additional referral for the bill because it includes Medicare provisions that fall within the jurisdiction of the Committee, including changes to relevant provisions of the Social Security Act (SSA). As the Medicare program continues to take steps towards prioritizing value based care over volume, it is the Committee’s priority to continually strengthen Medicare for beneficiaries and the providers who serve them. This goal, along with the principles of expanding patients’ choices in where they can receive care and increasing provider’s abilities to collaborate and manage the continuum of care whether the patient is at home or in a provider’s office, were the nexus for the policies in this markup.

C. LEGISLATIVE HISTORY

Background

H.R. 3178 was introduced on July 11, 2017, and was referred to the Committee on Energy and Commerce and additionally to the Committee on Ways and Means.

Committee hearings

On June 8, 2017, the Committee held a hearing on The Department of Health and Human Services’ Fiscal Year 2018 Budget Request where topics such as telehealth and Stark law were discussed.

On September 14, 2016, the Subcommittee on Health held a Hearing on Exploring the Use of Technology and Innovation to Create Efficiencies and Higher Quality in Health Care in which telehealth was a focus.

On June 8, 2016, the Subcommittee on Health held a Member Day hearing on various proposals to make improvements to the Medicare program and strengthen it ensure it is able to provide affordable care in the future.

Committee action

The Committee on Ways and Means marked up H.R. 3178, the Medicare Part B Improvement Act of 2017, on July 13, 2017, and

ordered the bill, as amended, favorably reported (with a quorum being present).

II. EXPLANATION OF THE BILL

A. MEDICARE PART B IMPROVEMENT ACT OF 2017

PRESENT LAW

Section 101:

The 21st Century Cures Act (Cures) (1) changed the way Medicare pays for home infusion services beginning in 2017, and (2) created a new Medicare benefit for home infusion education and services provided by clinicians delivering infusion to patients in their homes but not until 2021.

Section 102:

Section 101(b) of the Medicare intravenous immunoglobulin (IVIg) Access and Strengthening Medicare and Repaying Taxpayers Act of 2012 enacted the demonstration policy in 2012 until September 31, 2017.

Section 103:

Section 1834(h) of the SSA determines that Medicare pays for orthotics and prosthetics for beneficiaries who medically need those items.

Section 201:

Section 1865 of the SSA requires that facilities that provide care for Medicare beneficiaries must satisfactorily complete both a state survey and certification process as well as the Medicare accreditation process in order to participate in the Medicare program. While other Medicare providers may use an outside agency to accredit their facility for Medicare participation, under the statute dialysis facilities are not able to exercise this option.

Section 202:

Currently, beneficiaries receiving dialysis in their homes are not able to receive monitoring via telehealth.

Section 301:

Section 1877(h)(1) of the SSA, referred to as the “Stark Laws” provides rules to prevent clinician financial interests from interfering with medical decisions regarding patients. The Stark laws prohibit physicians from referring Medicare beneficiaries to facilities in which they (or a close family member) have a financial stake and prohibit such facility from billing for Medicare services performed as a result of such a referral. The law does not differentiate between technical Stark violations and intentional ones.

Section 302:

Section 1898(b)(1), the Medicare Improvement Fund (MIF), currently retains \$270,000,000 in funds for the purposes of Medicare improvements.

REASONS FOR CHANGE

Section 101:

The new payment methodology for home infusion drugs took effect in January 2017; however, the new home infusion nursing benefit does not begin until 2021. This gap could cause beneficiaries to experience issues with access to home infusion during the four years between the change in payment policy and the new home infusion nursing benefit.

Section 102:

This legislation would extend the demonstration policy originally enacted in 2012 for an additional three years, until 2020. This extension would benefit those who have both been utilizing services within the demonstration as well as those who beneficiaries who would enroll in the demonstration after September 30, 2017. Additionally, the Centers for Medicare & Medicaid Services (CMS) would have further time to study and evaluate the benefits of this demonstration.

Section 103:

Medicare's claims review process to prevent fraud and abuse in certain cases has led to payment denials for medically necessary orthotics or prosthetics as a result of insufficient evidence and incomplete medical record notes to document medical necessity. Currently, some suppliers are experiencing a delay in payment for prosthetics already supplied to Medicare beneficiaries.

Section 201:

While some Medicare providers may use an outside agency to accredit their health care facility for Medicare participation, this option is not available to dialysis facilities. This may result in access issues for end-stage renal disease (ESRD) patients in areas where accreditation of dialysis facilities does not keep pace with new facilities seeking Medicare participation privileges.

Section 202:

For ESRD patients who choose to undergo dialysis treatment at home, telehealth could allow for necessary monitoring without additional visits to a providers' office or dialysis facility, as well as alert providers if an emergent health need arises immediately.

Section 301:

Violations of Stark law can range from unknowing to willful. CMS recently changed Stark law regulations relating to when leases were in violation of the Stark laws and when signatures were required to document the terms of legal arrangements.

EXPLANATION OF PROVISIONS

Section 101:

This legislation would address the home infusion service gap created by changing the payments for home infusion drugs in 2017 and creating a home infusion nursing benefit in 2021 by creating

a temporary transition service and education Medicare payment for home infusion beginning in 2019.

Section 102:

This legislation provides a three year extension of the IVIG demonstration policy and would evaluate the benefits of providing payment for items and services needed for the in-home administration of IVIG for the treatment of primary immune deficiency diseases.

Section 103:

This legislation would allow additional information provided by prosthetists and orthotists, who evaluate and fit the beneficiary for the prosthetics and orthotics, to be considered by Medicare to support documentation of medical necessity for prosthetics and orthotics.

Section 201:

This legislation would allow dialysis facilities to seek outside accreditation, from organizations approved by Medicare, in order to be able to bill Medicare for ESRD services. It is the Committee's intent that implementation should not increase burdens on providers, particularly small independent providers.

Section 202:

This legislation would allow ESRD providers to utilize telehealth for home dialysis patient monitoring.

Section 301:

This legislation codifies the changes CMS made in regulations to streamline and clarify rules for providers regarding compliance with the Stark anti-kickback laws, including leases that were in violation and when signatures were required to document the terms of legal arrangements.

Section 302:

This legislation would reduce funding in the Medicare Improvement Fund (MIF), otherwise available to the Department of Health and Human Services, by \$31 million to offset the policies contained in the legislation.

EFFECTIVE DATE

For section 101, the legislation becomes effective beginning in 2019.

For section 102, the demonstration policy is extended an additional three years, ending in 2020.

For section 103, the legislation becomes effective upon enactment.

For section 201, the legislation becomes effective not later than 90 days after the date of enactment.

For section 202, the provision becomes effective on or after January 1, 2019 to individuals with ESRD under title XVIII by a health care provider for the purpose of furnishing telehealth.

For section 301, the legislation becomes effective upon enactment.

For section 302, the legislation becomes effective upon enactment.

III. VOTES OF THE COMMITTEE

In compliance with clause 3(b) of rule XIII of the Rules of the House of Representatives, the following statement is made concerning the vote of the Committee on Ways and Means in its consideration of H.R. 3178, the Medicare Part B Improvement Act of 2017, on July 13, 2017.

The Chairman’s amendment in the nature of a substitute was adopted by a voice vote (with a quorum being present).

Mr. Nunes’ motion to table Mr. Doggett’s appeal of the ruling of the Chair was agreed to by a roll call vote of 20 yeas and 16 nays (with a quorum being present). The vote was as follows:

Representative	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Brady	✓	Mr. Neal	✓
Mr. Johnson	Mr. Levin	✓
Mr. Nunes	✓	Mr. Lewis	✓
Mr. Tiberi	✓	Mr. Doggett	✓
Mr. Reichert	✓	Mr. Thompson	✓
Mr. Roskam	✓	Mr. Larson	✓
Mr. Buchanan	✓	Mr. Blumenauer	✓
Mr. Smith (NE)	✓	Mr. Kind	✓
Ms. Jenkins	✓	Mr. Pascrell	✓
Mr. Paulsen	✓	Mr. Crowley	✓
Mr. Marchant	Mr. Davis	✓
Ms. Black	✓	Ms. Sanchez	✓
Mr. Reed	✓	Mr. Higgins	✓
Mr. Kelly	✓	Ms. Sewell	✓
Mr. Renacci	Ms. DelBene	✓
Mr. Meehan	Ms. Chu	✓
Ms. Noem	✓				
Mr. Holding	✓				
Mr. Smith (MO)	✓				
Mr. Rice	✓				
Mr. Schweikert	✓				
Ms. Walorski	✓				
Mr. Curbelo	✓				
Mr. Bishop	✓				

The bill, H.R. 3178, was ordered favorably reported as amended by voice vote (with a quorum being present).

IV. BUDGET EFFECTS OF THE BILL

A. COMMITTEE ESTIMATE OF BUDGETARY EFFECTS

In compliance with clause 3(d) of rule XIII of the Rules of the House of Representatives, the following statement is made concerning the effects on the budget of the bill, H.R. 3178, as reported. The Committee agrees with the estimate prepared by the Congressional Budget Office (CBO), which is included below.

B. STATEMENT REGARDING NEW BUDGET AUTHORITY AND TAX EXPENDITURES BUDGET AUTHORITY

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee states that the bill involves no new or increased budget authority. The Committee states further that the bill involves no new or increased tax expenditures.

C. COST ESTIMATE PREPARED BY THE CONGRESSIONAL BUDGET OFFICE

In compliance with clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, requiring a cost estimate prepared by the CBO, the following statement by CBO is provided.

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, July 24, 2017.

Hon. KEVIN BRADY,
*Chairman, Committee on Ways and Means,
House of Representatives, Washington, DC.*

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 3178, the Medicare Part B Improvement Act of 2017.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Lara Robillard.

Sincerely,

MARK P. HADLEY
(For Keith Hall, Director).

Enclosure.

H.R. 3178—Medicare Part B Improvement Act of 2017

Summary: H.R. 3178 would modify several Medicare policies related to coverage and payment for services under Part B of the program. CBO estimates that enacting H.R. 3178 would reduce direct spending by \$4 million over the 2018–2027 period.

Pay-as-you-go procedures apply because enacting the legislation would affect direct spending. The legislation would not affect revenues.

CBO estimates that enacting the legislation would not increase net direct spending or on-budget deficits in any of the four consecutive 10-year periods beginning in 2028.

H.R. 3178 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA) and would impose no costs on state, local, or tribal governments.

Estimated Cost to the Federal Government: The estimated budgetary effect of H.R. 3178 is shown in the following table. The costs of this legislation fall within budget function 570 (Medicare).

	By fiscal year, in millions of dollars—												
	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2017–2022	2017–2027
INCREASES OR DECREASES (–) IN DIRECT SPENDING													
Estimated Budget Authority	0	23	77	–17	–55	–12	0	0	0	0	0	–4	–4
Estimated Outlays	0	23	77	–17	–55	–12	0	0	0	0	0	–4	–4

Basis of Estimate: For this estimate, CBO assumes that H.R. 3178 will be enacted near the end of fiscal year 2017. CBO estimates that enacting H.R. 3178 would affect direct spending in fiscal years 2018 through 2022 and would decrease direct spending by \$4 million over that period. The bill would make a number of changes to Medicare, including changes to rules related to self-referral by physicians and modifications to telehealth utilization by

beneficiaries with end-stage renal disease. The provisions that would affect direct spending are discussed below.

Transitional payment for home infusion therapy services. Currently, the Medicare program does not pay for nursing and administration services when beneficiaries receive a drug infusion in the home setting. Many drugs that beneficiaries receive in that setting are delivered via a pump, which Medicare does cover as part of the durable medical equipment (DME) benefit. Medicare also pays for covered drugs administered through a pump for beneficiaries in the home setting.

The 21st Century Cures Act of 2016 (Public Law 114–255) added a home infusion benefit to Medicare, but that benefit will not become available until January 1, 2021. That act also modified, as of January 1, 2017, the payment rate for drugs delivered through DME, which lowered the payment rate significantly for several infused drugs. According to stakeholders, suppliers had used the difference between their cost to purchase infused drugs and the Medicare payment rate to pay for administration services for beneficiaries receiving infused drugs in the home setting. After that reduction in payment rates for drugs administered through DME was implemented, evidence suggests that many beneficiaries now receive their infusions in physicians' offices or hospital outpatient departments instead of at home.

H.R. 3178 would add a temporary home infusion benefit to Medicare, beginning on January 1, 2019, and ending on December 31, 2020. Payment for home infusion services under the new benefit would be based on payment rates for infusion services under the Medicare physician fee schedule (PFS). The payment would vary depending on the drug being administered, and would be set based on the PFS rate for a five-hour infusion.

CBO analyzed how drugs that would be included in the temporary benefit were utilized across settings prior to the enactment of the 21st Century Cures Act, to understand where beneficiaries typically had received drug infusions. CBO also assessed how those utilization patterns likely changed since the enactment of the 21st Century Cures Act and how the distribution across settings would change if H.R. 3178 is enacted.

Some beneficiaries who now receive infusions at home would continue to do so if the legislation is enacted. For those beneficiaries, the bill would increase Medicare spending for drug administration services. Other beneficiaries currently receive infusion services in the physician office setting and some would choose to receive infusions at home if H.R. 3178 becomes law. In that case, Medicare spending would increase slightly, because CBO estimates that the average duration of a physician-administered infusion is shorter than the five hours allowed for in H.R. 3178. For beneficiaries currently receiving infusions in the hospital outpatient setting who would switch to the home setting, H.R. 3178 would reduce spending, as the temporary rate would be lower than the equivalent rate in the outpatient setting.

Based on CBO's expectation that Medicare would pay for about 25 million infusions per year in the home setting, CBO estimates that on net, the home infusion provision would increase direct spending by \$15 million over the 2018–2027 period.

Extension of Medicare Patient IVIG Access Demonstration Project. The Medicare IVIG Access and Strengthening Medicare and Repaying Taxpayers Act of 2012 (Public Law 112–242) authorized a three-year demonstration project under which Medicare pays for services related to the infusion of intravenous immune globulin (IVIG) to certain beneficiaries. Under the demonstration Medicare makes a per-visit payment for items and services needed for the in-home administration of IVIG. The demonstration is scheduled to end on September 30, 2017.

H.R. 3178 would extend the existing demonstration through December 31, 2020. Public Law 112–242 appropriated \$45 million for the project; as of January 2017, about \$5 million has been spent. Although the funding made available for the demonstration has not been exhausted, the authority to spend that money will lapse as of October 1, 2017. As a result, extending the demonstration would result in new direct spending. Based on historical enrollment and spending patterns for the demonstration, CBO estimates that the extension in H.R. 3178 would increase direct spending by about \$16 million over the 2018–2027 period.

Rescission. H.R. 3178 would rescind \$25 million earmarked under current law for making improvements to the Medicare fee-for-service program. Changes in spending in the fee-for-service sector affect both payment to Medicare Advantage plans and collections of Part B premiums. Taking those effects into account, CBO estimates that rescission would reduce direct spending for Medicare by \$35 million over the 2017–2027 period.

Pay-As-You-Go Considerations: The Statutory Pay-As-You-Go Act of 2010 establishes budget-reporting and enforcement procedures for legislation affecting direct spending or revenues. The net changes in outlays that are subject to those pay-as-you-go procedures are shown in the following table.

CBO ESTIMATE OF PAY-AS-YOU-GO EFFECTS FOR H.R. 3178, AS ORDERED REPORTED BY THE HOUSE COMMITTEE ON WAYS AND MEANS ON JULY 13, 2017

	By fiscal year, in millions of dollars—													2017–2022	2017–2027
	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027				
	NET DECREASE (–) IN THE DEFICIT														
Statutory Pay-As-You-Go Impact	0	3	77	–17	–55	–12	0	0	0	0	0	0	–4	–4	

Increase in long-term direct spending and deficits: CBO estimates that enacting the legislation would not increase net direct spending or on-budget deficits in any of the four consecutive 10-year periods beginning in 2028.

Intergovernmental and private-sector impact: H.R. 3178 contains no intergovernmental or private-sector mandates as defined in UMRA and would impose no costs on state, local, or tribal governments.

Estimate prepared by: Federal costs: Lara Robillard and Rebecca Yip; Impact on state, local, and tribal governments: Zachary Byrum; Impact on the private sector: Amy Petz.

Estimate approved by: Holly Harvey, Deputy Assistant Director for Budget Analysis.

V. OTHER MATTERS TO BE DISCUSSED UNDER THE RULES OF THE HOUSE

A. COMMITTEE OVERSIGHT FINDINGS AND RECOMMENDATIONS

With respect to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee made findings and recommendations that are reflected in this report.

B. STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

With respect to clause 3(c)(4) of rule XIII of the Rules of the House of Representatives, the Committee advises that the bill does not authorize funding, so no statement of general performance goals and objectives is required.

C. INFORMATION RELATING TO UNFUNDED MANDATES

This information is provided in accordance with section 423 of the Unfunded Mandates Reform Act of 1995 (Pub. L. No. 104-4).

The Committee has determined that the bill does not contain Federal mandates on the private sector. The Committee has determined that the bill does not impose a Federal intergovernmental mandate on State, local, or tribal governments.

D. CONGRESSIONAL EARMARKS, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

With respect to clause 9 of rule XXI of the Rules of the House of Representatives, the Committee has carefully reviewed the provisions of the bill, and states that the provisions of the bill do not contain any congressional earmarks, limited tax benefits, or limited tariff benefits within the meaning of the rule.

E. DUPLICATION OF FEDERAL PROGRAMS

In compliance with clause 3(c)(5) of rule XIII of the Rules of the House of Representatives, the Committee states that no provision of the bill establishes or reauthorizes: (1) a program of the Federal Government known to be duplicative of another Federal program; (2) a program included in any report from the Government Accountability Office to Congress pursuant to section 21 of Public Law 111-139; or (3) a program related to a program identified in the most recent Catalog of Federal Domestic Assistance, published pursuant to the Federal Program Information Act (Pub. L. No. 95-220, as amended by Pub. L. No. 98-169).

F. DISCLOSURE OF DIRECTED RULE MAKINGS

In compliance with Sec. 3(i) of H. Res. 5 (115th Congress), the following statement is made concerning directed rule makings:

The Committee advises that the bill requires no directed rulemakings within the meaning of such section.

VI. CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill,

as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, and existing law in which no change is proposed is shown in roman):

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, and existing law in which no change is proposed is shown in roman):

SOCIAL SECURITY ACT

* * * * *

TITLE XI—GENERAL PROVISIONS, PEER REVIEW, AND ADMINISTRATIVE SIMPLIFICATION

* * * * *

PART A—GENERAL PROVISIONS

* * * * *

CIVIL MONETARY PENALTIES

SEC. 1128A. (a) Any person (including an organization, agency, or other entity, but excluding a beneficiary, as defined in subsection (i)(5)) that—

(1) knowingly presents or causes to be presented to an officer, employee, or agent of the United States, or of any department or agency thereof, or of any State agency (as defined in subsection (i)(1)), a claim (as defined in subsection (i)(2)) that the Secretary determines—

(A) is for a medical or other item or service that the person knows or should know was not provided as claimed, including any person who engages in a pattern or practice of presenting or causing to be presented a claim for an item or service that is based on a code that the person knows or should know will result in a greater payment to the person than the code the person knows or should know is applicable to the item or service actually provided,

(B) is for a medical or other item or service and the person knows or should know the claim is false or fraudulent,

(C) is presented for a physician's service (or an item or service incident to a physician's service) by a person who knows or should know that the individual who furnished (or supervised the furnishing of) the service—

- (i) was not licensed as a physician,
- (ii) was licensed as a physician, but such license had been obtained through a misrepresentation of material fact (including cheating on an examination required for licensing), or
- (iii) represented to the patient at the time the service was furnished that the physician was certified in

a medical specialty by a medical specialty board when the individual was not so certified,

(D) is for a medical or other item or service furnished during a period in which the person was excluded from the program under which the claim was made pursuant to a determination by the Secretary under this section or under section 1128, 1156, 1160(b) (as in effect on September 2, 1982), 1862(d) (as in effect on the date of the enactment of the Medicare and Medicaid Patient and Program Protection Act of 1987), or 1866(b) or as a result of the application of the provisions of section 1842(j)(2), or

(E) is for a pattern of medical or other items or services that a person knows or should know are not medically necessary;

(2) knowingly presents or causes to be presented to any person a request for payment which is in violation of the terms of (A) an assignment under section 1842(b)(3)(B)(ii), or (B) an agreement with a State agency (or other requirement of a State plan under title XIX) not to charge a person for an item or service in excess of the amount permitted to be charged, or (C) an agreement to be a participating physician or supplier under section 1842(h)(1), or (D) an agreement pursuant to section 1866(a)(1)(G);

(3) knowingly gives or causes to be given to any person, with respect to coverage under title XVIII of inpatient hospital services subject to the provisions of section 1886, information that he knows or should know is false or misleading, and that could reasonably be expected to influence the decision when to discharge such person or another individual from the hospital;

(4) in the case of a person who is not an organization, agency, or other entity, is excluded from participating in a program under title XVIII or a State health care program in accordance with this subsection or under section 1128 and who, at the time of a violation of this subsection—

(A) retains a direct or indirect ownership or control interest in an entity that is participating in a program under title XVIII or a State health care program, and who knows or should know of the action constituting the basis for the exclusion; or

(B) is an officer or managing employee (as defined in section 1126(b)) of such an entity;

(5) offers to or transfers remuneration to any individual eligible for benefits under title XVIII of this Act, or under a State health care program (as defined in section 1128(h)) that such person knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, under title XVIII, or a State health care program (as so defined);

(6) arranges or contracts (by employment or otherwise) with an individual or entity that the person knows or should know is excluded from participation in a Federal health care program (as defined in section 1128B(f)), for the provision of items or services for which payment may be made under such a program;

(7) commits an act described in paragraph (1) or (2) of section 1128B(b);

(8) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim for payment for items and services furnished under a Federal health care program; or

(9) fails to grant timely access, upon reasonable request (as defined by the Secretary in regulations), to the Inspector General of the Department of Health and Human Services, for the purpose of audits, investigations, evaluations, or other statutory functions of the Inspector General of the Department of Health and Human Services;

(8) orders or prescribes a medical or other item or service during a period in which the person was excluded from a Federal health care program (as so defined), in the case where the person knows or should know that a claim for such medical or other item or service will be made under such a program;

(9) knowingly makes or causes to be made any false statement, omission, or misrepresentation of a material fact in any application, bid, or contract to participate or enroll as a provider of services or a supplier under a Federal health care program (as so defined), including Medicare Advantage organizations under part C of title XVIII, prescription drug plan sponsors under part D of title XVIII, medicaid managed care organizations under title XIX, and entities that apply to participate as providers of services or suppliers in such managed care organizations and such plans;

(10) knows of an overpayment (as defined in paragraph (4) of section 1128J(d)) and does not report and return the overpayment in accordance with such section;

shall be subject, in addition to any other penalties that may be prescribed by law, to a civil money penalty of not more than \$10,000 for each item or service (or, in cases under paragraph (3), \$15,000 for each individual with respect to whom false or misleading information was given; in cases under paragraph (4), \$10,000 for each day the prohibited relationship occurs; in cases under paragraph (7), \$50,000 for each such act; or in cases under paragraph (9), \$50,000 for each false statement or misrepresentation of a material fact). In addition, such a person shall be subject to an assessment of not more than 3 times the amount claimed for each such item or service in lieu of damages sustained by the United States or a State agency because of such claim (or, in cases under paragraph (7), damages of not more than 3 times the total amount of remuneration offered, paid, solicited, or received, without regard to whether a portion of such remuneration was offered, paid, solicited, or received for a lawful purpose; or in cases under paragraph (9), an assessment of not more than 3 times the total amount claimed for each item or service for which payment was made based upon the application containing the false statement or misrepresentation of a material fact). In addition the Secretary may make a determination in the same proceeding to exclude the person from participation in the Federal health care programs (as defined in section 1128B(f)(1)) and to direct the appropriate State agency to exclude the person from participation in any State health care program.

(b)(1) If a hospital or a critical access hospital knowingly makes a payment, directly or indirectly, to a physician as an inducement to reduce or limit medically necessary services provided with respect to individuals who—

(A) are entitled to benefits under part A or part B of title XVIII or to medical assistance under a State plan approved under title XIX, and

(B) are under the direct care of the physician, the hospital or a critical access hospital shall be subject, in addition to any other penalties that may be prescribed by law, to a civil money penalty of not more than \$2,000 for each such individual with respect to whom the payment is made.

(2) Any physician who knowingly accepts receipt of a payment described in paragraph (1) shall be subject, in addition to any other penalties that may be prescribed by law, to a civil money penalty of not more than \$2,000 for each individual described in such paragraph with respect to whom the payment is made.

(3)(A) Any physician who executes a document described in subparagraph (B) with respect to an individual knowing that all of the requirements referred to in such subparagraph are not met with respect to the individual shall be subject to a civil monetary penalty of not more than the greater of—

(i) \$5,000, or

(ii) three times the amount of the payments under title XVIII for home health services which are made pursuant to such certification.

(B) A document described in this subparagraph is any document that certifies, for purposes of title XVIII, that an individual meets the requirements of section 1814(a)(2)(C) or 1835(a)(2)(A) in the case of home health services furnished to the individual.

(c)(1) The Secretary may initiate a proceeding to determine whether to impose a civil money penalty, assessment, or exclusion under subsection (a) or (b) only as authorized by the Attorney General pursuant to procedures agreed upon by them. The Secretary may not initiate an action under this section with respect to any claim, request for payment, or other occurrence described in this section later than six years after the date the claim was presented, the request for payment was made, or the occurrence took place. The Secretary may initiate an action under this section by serving notice of the action in any manner authorized by Rule 4 of the Federal Rules of Civil Procedure.

(2) The Secretary shall not make a determination adverse to any person under subsection (a) or (b) until the person has been given written notice and an opportunity for the determination to be made on the record after a hearing at which the person is entitled to be represented by counsel, to present witnesses, and to cross-examine witnesses against the person.

(3) In a proceeding under subsection (a) or (b) which—

(A) is against a person who has been convicted (whether upon a verdict after trial or upon a plea of guilty or nolo contendere) of a Federal crime charging fraud or false statements, and

(B) involves the same transaction as in the criminal action, the person is estopped from denying the essential elements of the criminal offense.

(4) The official conducting a hearing under this section may sanction a person, including any party or attorney, for failing to comply with an order or procedure, failing to defend an action, or other misconduct as would interfere with the speedy, orderly, or fair conduct of the hearing. Such sanction shall reasonably relate to the severity and nature of the failure or misconduct. Such sanction may include—

(A) in the case of refusal to provide or permit discovery, drawing negative factual inferences or treating such refusal as an admission by deeming the matter, or certain facts, to be established,

(B) prohibiting a party from introducing certain evidence or otherwise supporting a particular claim or defense,

(C) striking pleadings, in whole or in part,

(D) staying the proceedings,

(E) dismissal of the action,

(F) entering a default judgment,

(G) ordering the party or attorney to pay attorneys' fees and other costs caused by the failure or misconduct, and

(H) refusing to consider any motion or other action which is not filed in a timely manner.

(d) In determining the amount or scope of any penalty, assessment, or exclusion imposed pursuant to subsection (a) or (b), the Secretary shall take into account—

(1) the nature of claims and the circumstances under which they were presented,

(2) the degree of culpability, history of prior offenses, and financial condition of the person presenting the claims, and

(3) such other matters as justice may require.

(e) Any person adversely affected by a determination of the Secretary under this section may obtain a review of such determination in the United States Court of Appeals for the circuit in which the person resides, or in which the claim or specified claim was presented, by filing in such court (within sixty days following the date the person is notified of the Secretary's determination) a written petition requesting that the determination be modified or set aside. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary, and thereupon the Secretary shall file in the Court the record in the proceeding as provided in section 2112 of title 28, United States Code. Upon such filing, the court shall have jurisdiction of the proceeding and of the question determined therein, and shall have the power to make and enter upon the pleadings, testimony, and proceedings set forth in such record a decree affirming, modifying, remanding for further consideration, or setting aside, in whole or in part, the determination of the Secretary and enforcing the same to the extent that such order is affirmed or modified. No objection that has not been urged before the Secretary shall be considered by the court, unless the failure or neglect to urge such objection shall be excused because of extraordinary circumstances. The findings of the Secretary with respect to questions of fact, if supported by substantial evidence on the record considered as a whole, shall be conclusive. If any party shall apply to the court for leave to adduce additional evidence and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the

failure to adduce such evidence in the hearing before the Secretary, the court may order such additional evidence to be taken before the Secretary and to be made a part of the record. The Secretary may modify his findings as to the facts, or make new findings, by reason of additional evidence so taken and filed, and he shall file with the court such modified or new findings, which findings with respect to questions of fact, if supported by substantial evidence on the record considered as a whole, shall be conclusive, and his recommendations, if any, for the modification or setting aside of his original order. Upon the filing of the record with it, the jurisdiction of the court shall be exclusive and its judgment and decree shall be final, except that the same shall be subject to review by the Supreme Court of the United States, as provided in section 1254 of title 28, United States Code.

(f) Civil money penalties and assessments imposed under this section may be compromised by the Secretary and may be recovered in a civil action in the name of the United States brought in United States district court for the district where the claim or specified claim (as defined in subsection (r)) was presented, or where the claimant (or, with respect to a person described in subsection (o), the person) resides, as determined by the Secretary. Amounts recovered under this section shall be paid to the Secretary and disposed of as follows:

(1)(A) In the case of amounts recovered arising out of a claim under title XIX, there shall be paid to the State agency an amount bearing the same proportion to the total amount recovered as the State's share of the amount paid by the State agency for such claim bears to the total amount paid for such claim.

(B) In the case of amounts recovered arising out of a claim under an allotment to a State under title V, there shall be paid to the State agency an amount equal to three-sevenths of the amount recovered.

(2) Such portion of the amounts recovered as is determined to have been paid out of the trust funds under sections 1817 and 1841 shall be repaid to such trust funds.

(3) With respect to amounts recovered arising out of a claim under a Federal health care program (as defined in section 1128B(f)), the portion of such amounts as is determined to have been paid by the program shall be repaid to the program, and the portion of such amounts attributable to the amounts recovered under this section by reason of the amendments made by the Health Insurance Portability and Accountability Act of 1996 (as estimated by the Secretary) shall be deposited into the Federal Hospital Insurance Trust Fund pursuant to section 1817(k)(2)(C).

(4) The remainder of the amounts recovered shall be deposited as miscellaneous receipts of the Treasury of the United States.

The amount of such penalty or assessment, when finally determined, or the amount agreed upon in compromise, may be deducted from any sum then or later owing by the United States or a State agency (or, in the case of a penalty or assessment under subsection (o), by a specified State agency (as defined in subsection (q)(6)), to the person against whom the penalty or assessment has been assessed.

(g) A determination by the Secretary to impose a penalty, assessment, or exclusion under subsection (a) or (b) shall be final upon the expiration of the sixty-day period referred to in subsection (e). Matters that were raised or that could have been raised in a hearing before the Secretary or in an appeal pursuant to subsection (e) may not be raised as a defense to a civil action by the United States to collect a penalty, assessment, or exclusion assessed under this section.

(h) Whenever the Secretary's determination to impose a penalty, assessment, or exclusion under subsection (a) or (b) becomes final, he shall notify the appropriate State or local medical or professional organization, the appropriate State agency or agencies administering or supervising the administration of State health care programs (as defined in section 1128(h)), and the appropriate utilization and quality control peer review organization, and the appropriate State or local licensing agency or organization (including the agency specified in section 1864(a) and 1902(a)(33)) that such a penalty, assessment, or exclusion has become final and the reasons therefor.

(i) For the purposes of this section:

(1) The term "State agency" means the agency established or designated to administer or supervise the administration of the State plan under title XIX of this Act or designated to administer the State's program under title V or subtitle 1 of title XX of this Act.

(2) The term "claim" means an application for payments for items and services under a Federal health care program (as defined in section 1128B(f)).

(3) The term "item or service" includes (A) any particular item, device, medical supply, or service claimed to have been provided to a patient and listed in an itemized claim for payment, and (B) in the case of a claim based on costs, any entry in the cost report, books of account or other documents supporting such claim.

(4) The term "agency of the United States" includes any contractor acting as a fiscal intermediary, carrier, or fiscal agent or any other claims processing agent for a Federal health care program (as so defined).

(5) The term "beneficiary" means an individual who is eligible to receive items or services for which payment may be made under a Federal health care program (as so defined) but does not include a provider, supplier, or practitioner.

(6) The term "remuneration" includes the waiver of coinsurance and deductible amounts (or any part thereof), and transfers of items or services for free or for other than fair market value. The term "remuneration" does not include—

(A) the waiver of coinsurance and deductible amounts by a person, if—

(i) the waiver is not offered as part of any advertisement or solicitation;

(ii) the person does not routinely waive coinsurance or deductible amounts; and

(iii) the person—

(I) waives the coinsurance and deductible amounts after determining in good faith that the individual is in financial need; or

(II) fails to collect coinsurance or deductible amounts after making reasonable collection efforts;

(B) subject to subsection (n), any permissible practice described in any subparagraph of section 1128B(b)(3) or in regulations issued by the Secretary;

(C) differentials in coinsurance and deductible amounts as part of a benefit plan design as long as the differentials have been disclosed in writing to all beneficiaries, third party payers, and providers, to whom claims are presented and as long as the differentials meet the standards as defined in regulations promulgated by the Secretary not later than 180 days after the date of the enactment of the Health Insurance Portability and Accountability Act of 1996;

(D) incentives given to individuals to promote the delivery of preventive care as determined by the Secretary in regulations so promulgated;

(E) a reduction in the copayment amount for covered OPD services under section 1833(t)(5)(B);

(F) any other remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs (as defined in section 1128B(f) and designated by the Secretary under regulations);

(G) the offer or transfer of items or services for free or less than fair market value by a person, if—

(i) the items or services consist of coupons, rebates, or other rewards from a retailer;

(ii) the items or services are offered or transferred on equal terms available to the general public, regardless of health insurance status; and

(iii) the offer or transfer of the items or services is not tied to the provision of other items or services reimbursed in whole or in part by the program under title XVIII or a State health care program (as defined in section 1128(h));

(H) the offer or transfer of items or services for free or less than fair market value by a person, if—

(i) the items or services are not offered as part of any advertisement or solicitation;

(ii) the items or services are not tied to the provision of other services reimbursed in whole or in part by the program under title XVIII or a State health care program (as so defined);

(iii) there is a reasonable connection between the items or services and the medical care of the individual; and

(iv) the person provides the items or services after determining in good faith that the individual is in financial need[; or];

(I) effective on a date specified by the Secretary (but not earlier than January 1, 2011), the waiver by a PDP spon-

sor of a prescription drug plan under part D of title XVIII or an MA organization offering an MA PD plan under part C of such title of any copayment for the first fill of a covered part D drug (as defined in section 1860D 2(e)) that is a generic drug for individuals enrolled in the prescription drug plan or MA PD plan, respectively[.]; or

(J) the provision of telehealth on or after January 1, 2019, to individuals with end stage renal disease under title XVIII by a health care provider for the purpose of furnishing of telehealth.

(7) The term “should know” means that a person, with respect to information—

(A) acts in deliberate ignorance of the truth or falsity of the information; or

(B) acts in reckless disregard of the truth or falsity of the information,

and no proof of specific intent to defraud is required.

(j)(1) The provisions of subsections (d) and (e) of section 205 shall apply with respect to this section to the same extent as they are applicable with respect to title II. The Secretary may delegate the authority granted by section 205(d) (as made applicable to this section) to the Inspector General of the Department of Health and Human Services for purposes of any investigation under this section.

(2) The Secretary may delegate authority granted under this section and under section 1128 to the Inspector General of the Department of Health and Human Services.

(k) Whenever the Secretary has reason to believe that any person has engaged, is engaging, or is about to engage in any activity which makes the person subject to a civil monetary penalty under this section, the Secretary may bring an action in an appropriate district court of the United States (or, if applicable, a United States court of any territory) to enjoin such activity, or to enjoin the person from concealing, removing, encumbering, or disposing of assets which may be required in order to pay a civil monetary penalty if any such penalty were to be imposed or to seek other appropriate relief.

(l) A principal is liable for penalties, assessments, and an exclusion under this section for the actions of the principal’s agent acting within the scope of the agency.

(m)(1) For purposes of this section, with respect to a Federal health care program not contained in this Act, references to the Secretary in this section shall be deemed to be references to the Secretary or Administrator of the department or agency with jurisdiction over such program and references to the Inspector General of the Department of Health and Human Services in this section shall be deemed to be references to the Inspector General of the applicable department or agency.

(2)(A) The Secretary and Administrator of the departments and agencies referred to in paragraph (1) may include in any action pursuant to this section, claims within the jurisdiction of other Federal departments or agencies as long as the following conditions are satisfied:

(i) The case involves primarily claims submitted to the Federal health care programs of the department or agency initiating the action.

(ii) The Secretary or Administrator of the department or agency initiating the action gives notice and an opportunity to participate in the investigation to the Inspector General of the department or agency with primary jurisdiction over the Federal health care programs to which the claims were submitted.

(B) If the conditions specified in subparagraph (A) are fulfilled, the Inspector General of the department or agency initiating the action is authorized to exercise all powers granted under the Inspector General Act of 1978 (5 U.S.C. App.) with respect to the claims submitted to the other departments or agencies to the same manner and extent as provided in that Act with respect to claims submitted to such departments or agencies.

(n)(1) Subparagraph (B) of subsection (i)(6) shall not apply to a practice described in paragraph (2) unless—

(A) the Secretary, through the Inspector General of the Department of Health and Human Services, promulgates a rule authorizing such a practice as an exception to remuneration; and

(B) the remuneration is offered or transferred by a person under such rule during the 2-year period beginning on the date the rule is first promulgated.

(2) A practice described in this paragraph is a practice under which a health care provider or facility pays, in whole or in part, premiums for medicare supplemental policies for individuals entitled to benefits under part A of title XVIII pursuant to section 226A.

(o) Any person (including an organization, agency, or other entity, but excluding a program beneficiary, as defined in subsection (q)(4)) that, with respect to a grant, contract, or other agreement for which the Secretary provides funding—

(1) knowingly presents or causes to be presented a specified claim (as defined in subsection (r)) under such grant, contract, or other agreement that the person knows or should know is false or fraudulent;

(2) knowingly makes, uses, or causes to be made or used any false statement, omission, or misrepresentation of a material fact in any application, proposal, bid, progress report, or other document that is required to be submitted in order to directly or indirectly receive or retain funds provided in whole or in part by such Secretary pursuant to such grant, contract, or other agreement;

(3) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent specified claim under such grant, contract, or other agreement;

(4) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation (as defined in subsection (s)) to pay or transmit funds or property to such Secretary with respect to such grant, contract, or other agreement, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit funds or property to such Secretary with respect to such grant, contract, or other agreement; or

(5) fails to grant timely access, upon reasonable request (as defined by such Secretary in regulations), to the Inspector General of the Department, for the purpose of audits, investigations, evaluations, or other statutory functions of such Inspector General in matters involving such grants, contracts, or other agreements;

shall be subject, in addition to any other penalties that may be prescribed by law, to a civil money penalty in cases under paragraph (1), of not more than \$10,000 for each specified claim; in cases under paragraph (2), not more than \$50,000 for each false statement, omission, or misrepresentation of a material fact; in cases under paragraph (3), not more than \$50,000 for each false record or statement; in cases under paragraph (4), not more than \$50,000 for each false record or statement or \$10,000 for each day that the person knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay; or in cases under paragraph (5), not more than \$15,000 for each day of the failure described in such paragraph. In addition, in cases under paragraphs (1) and (3), such a person shall be subject to an assessment of not more than 3 times the amount claimed in the specified claim described in such paragraph in lieu of damages sustained by the United States or a specified State agency because of such specified claim, and in cases under paragraphs (2) and (4), such a person shall be subject to an assessment of not more than 3 times the total amount of the funds described in paragraph (2) or (4), respectively (or, in the case of an obligation to transmit property to the Secretary described in paragraph (4), of the value of the property described in such paragraph) in lieu of damages sustained by the United States or a specified State agency because of such case. In addition, the Secretary may make a determination in the same proceeding to exclude the person from participation in the Federal health care programs (as defined in section 1128B(f)(1)) and to direct the appropriate State agency to exclude the person from participation in any State health care program.

(p) The provisions of subsections (c), (d), (g), and (h) shall apply to a civil money penalty or assessment under subsection (o) in the same manner as such provisions apply to a penalty, assessment, or proceeding under subsection (a). In applying subsection (d), each reference to a claim under such subsection shall be treated as including a reference to a specified claim (as defined in subsection (r)).

(q) For purposes of this subsection and subsections (o) and (p):

(1) The term "Department" means the Department of Health and Human Services.

(2) The term "material" means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.

(3) The term "other agreement" includes a cooperative agreement, scholarship, fellowship, loan, subsidy, payment for a specified use, donation agreement, award, or subaward (regardless of whether one or more of the persons entering into the agreement is a contractor or subcontractor).

(4) The term "program beneficiary" means, in the case of a grant, contract, or other agreement designed to accomplish the objective of awarding or otherwise furnishing benefits or assist-

ance to individuals and for which the Secretary provides funding, an individual who applies for, or who receives, such benefits or assistance from such grant, contract, or other agreement. Such term does not include, with respect to such grant, contract, or other agreement, an officer, employee, or agent of a person or entity that receives such grant or that enters into such contract or other agreement.

(5) The term “recipient” includes a subrecipient or subcontractor.

(6) The term “specified State agency” means an agency of a State government established or designated to administer or supervise the administration of a grant, contract, or other agreement funded in whole or in part by the Secretary.

(r) For purposes of this section, the term “specified claim” means any application, request, or demand under a grant, contract, or other agreement for money or property, whether or not the United States or a specified State agency has title to the money or property, that is not a claim (as defined in subsection (i)(2)) and that—

(1) is presented or caused to be presented to an officer, employee, or agent of the Department or agency thereof, or of any specified State agency; or

(2) is made to a contractor, grantee, or any other recipient if the money or property is to be spent or used on the Department’s behalf or to advance a Department program or interest, and if the Department—

(A) provides or has provided any portion of the money or property requested or demanded; or

(B) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded.

(s) For purposes of subsection (o), the term “obligation” means an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, for a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment.

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TITLE XVIII—HEALTH INSURANCE FOR THE AGED AND DISABLED

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PART B—SUPPLEMENTARY MEDICAL INSURANCE BENEFITS FOR THE AGED AND DISABLED

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SPECIAL PAYMENT RULES FOR PARTICULAR ITEMS AND SERVICES

SEC. 1834. (a) PAYMENT FOR DURABLE MEDICAL EQUIPMENT.—

(1) GENERAL RULE FOR PAYMENT.—

(A) **IN GENERAL.**—With respect to a covered item (as defined in paragraph (13)) for which payment is determined under this subsection, payment shall be made in the frequency specified in paragraphs (2) through (7) and in an amount equal to 80 percent of the payment basis described in subparagraph (B).

(B) PAYMENT BASIS.—Subject to subparagraph (F)(i), the payment basis described in this subparagraph is the lesser of—

(i) the actual charge for the item, or
(ii) the payment amount recognized under paragraphs (2) through (7) of this subsection for the item; except that clause (i) shall not apply if the covered item is furnished by a public home health agency (or by another home health agency which demonstrates to the satisfaction of the Secretary that a significant portion of its patients are low income) free of charge or at nominal charges to the public.

(C) EXCLUSIVE PAYMENT RULE.—Subject to subparagraph (F)(ii), this subsection shall constitute the exclusive provision of this title for payment for covered items under this part or under part A to a home health agency.

(D) REDUCTION IN FEE SCHEDULES FOR CERTAIN ITEMS.—With respect to a seat-lift chair or transcutaneous electrical nerve stimulator furnished on or after April 1, 1990, the Secretary shall reduce the payment amount applied under subparagraph (B)(ii) for such an item by 15 percent, and, in the case of a transcutaneous electrical nerve stimulator furnished on or after January 1, 1991, the Secretary shall further reduce such payment amount (as previously reduced) by 45 percent.

(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)), 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.

(F) APPLICATION OF COMPETITIVE ACQUISITION; LIMITATION OF INHERENT REASONABLENESS AUTHORITY.— In the case of covered items furnished on or after January 1, 2011, subject to subparagraphs (G) and (H), 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;

(ii) the Secretary may (and, in the case of covered items furnished on or after January 1, 2016, subject to clause (iii), shall) 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

(iii) in the case of covered items furnished on or after January 1, 2016, the Secretary shall continue to make such adjustments described in clause (ii) as, under such competitive acquisition programs, additional covered items are phased in or information is updated as contracts under section 1847 are re-competed in accordance with section 1847(b)(3)(B).

(G) USE OF INFORMATION ON COMPETITIVE BID RATES.— The Secretary shall specify by regulation the methodology to be used in applying the provisions of subparagraph (F)(ii) and subsection (h)(1)(H)(ii). In promulgating such regulation, the Secretary shall consider the costs of items and services in areas in which such provisions would be applied compared to the payment rates for such items and services in competitive acquisition areas. In the case of items and services furnished on or after January 1, 2019, in making any adjustments under clause (ii) or (iii) of subparagraph (F), under subsection (h)(1)(H)(ii), or under section 1842(s)(3)(B), the Secretary shall—

(i) solicit and take into account stakeholder input; and

(ii) take into account the highest amount bid by a winning supplier in a competitive acquisition area and a comparison of each of the following with respect to non-competitive acquisition areas and competitive acquisition areas:

(I) The average travel distance and cost associated with furnishing items and services in the area.

(II) The average volume of items and services furnished by suppliers in the area.

(III) The number of suppliers in the area.

(H) DIABETIC SUPPLIES.—

(i) IN GENERAL.—On or after the date described in clause (ii), the payment amount under this part for diabetic supplies, including testing strips, that are non-mail order items (as defined by the Secretary) shall be equal to the single payment amounts established under the national mail order competition for diabetic supplies under section 1847.

(ii) DATE DESCRIBED.—The date described in this clause is the date of the implementation of the single payment amounts under the national mail order competition for diabetic supplies under section 1847.

(I) TREATMENT OF VACUUM ERECTION SYSTEMS.—Effective for items and services furnished on and after July 1, 2015, vacuum erection systems described as prosthetic devices described in section 1861(s)(8) shall be treated in the same manner as erectile dysfunction drugs are treated for purposes of section 1860D–2(e)(2)(A).

(2) PAYMENT FOR INEXPENSIVE AND OTHER ROUTINELY PURCHASED DURABLE MEDICAL EQUIPMENT.—

(A) IN GENERAL.—Payment for an item of durable medical equipment (as defined in paragraph (13))—

(i) the purchase price of which does not exceed \$150,

(ii) which the Secretary determines is acquired at least 75 percent of the time by purchase,

(iii) which is an accessory used in conjunction with a nebulizer, aspirator, or a ventilator excluded under paragraph (3)(A), or

(iv) in the case of devices furnished on or after October 1, 2015, and before October 1, 2018, which serves as a speech generating device or which is an accessory that is needed for the individual to effectively utilize such a device,

shall be made on a rental basis or in a lump-sum amount for the purchase of the item. The payment amount recognized for purchase or rental of such equipment is the amount specified in subparagraph (B) for purchase or rental, except that the total amount of payments with respect to an item may not exceed the payment amount specified in subparagraph (B) with respect to the purchase of the item.

(B) PAYMENT AMOUNT.—For purposes of subparagraph (A), the amount specified in this subparagraph, with respect to the purchase or rental of an item furnished in a carrier service area—

(i) in 1989 and in 1990 is the average reasonable charge in the area for the purchase or rental, respectively, of the item for the 12-month period ending on June 30, 1987, increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 6-month period ending with December 1987;

(ii) in 1991 is the sum of (I) 67 percent of the local payment amount for the item or device computed under subparagraph (C)(i)(I) for 1991, and (II) 33 percent of the national limited payment amount for the item or device computed under subparagraph (C)(ii) for 1991;

(iii) in 1992 is the sum of (I) 33 percent of the local payment amount for the item or device computed under subparagraph (C)(i)(II) for 1992, and (II) 67 percent of the national limited payment amount for the item or device computed under subparagraph (C)(ii) for 1992; and

(iv) in 1993 and each subsequent year is the national limited payment amount for the item or device computed under subparagraph (C)(ii) for that year (reduced by 10 percent, in the case of a blood glucose testing strip furnished after 1997 for an individual with diabetes).

(C) COMPUTATION OF LOCAL PAYMENT AMOUNT AND NATIONAL LIMITED PAYMENT AMOUNT.—For purposes of subparagraph (B)—

(i) the local payment amount for an item or device for a year is equal to—

(I) for 1991, the amount specified in subparagraph (B)(i) for 1990 increased by the covered item update for 1991, and

(II) for 1992, 1993, and 1994 the amount determined under this clause for the preceding year increased by the covered item update for the year; and

(ii) the national limited payment amount for an item or device for a year is equal to—

(I) for 1991, the local payment amount determined under clause (i) for such item or device for that year, except that the national limited payment amount may not exceed 100 percent of the weighted average of all local payment amounts determined under such clause for such item for that year and may not be less than 85 percent of the weighted average of all local payment amounts determined under such clause for such item,

(II) for 1992 and 1993, the amount determined under this clause for the preceding year increased by the covered item update for such subsequent year,

(III) for 1994, the local payment amount determined under clause (i) for such item or device for that year, except that the national limited payment amount may not exceed 100 percent of the median of all local payment amounts determined under such clause for such item for that year and may not be less than 85 percent of the median of all local payment amounts determined under such clause for such item or device for that year, and

(IV) for each subsequent year, the amount determined under this clause for the preceding year increased by the covered item update for such subsequent year.

(3) PAYMENT FOR ITEMS REQUIRING FREQUENT AND SUBSTANTIAL SERVICING.—

(A) IN GENERAL.—Payment for a covered item (such as IPPB machines and ventilators, excluding ventilators that are either continuous airway pressure devices or intermittent assist devices with continuous airway pressure devices) for which there must be frequent and substantial servicing in order to avoid risk to the patient's health shall be made on a monthly basis for the rental of the item and the amount recognized is the amount specified in subparagraph (B).

(B) PAYMENT AMOUNT.—For purposes of subparagraph (A), the amount specified in this subparagraph, with respect to an item or device furnished in a carrier service area—

(i) in 1989 and in 1990 is the average reasonable charge in the area for the rental of the item or device for the 12-month period ending with June 1987, increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 6-month period ending with December 1987;

(ii) in 1991 is the sum of (I) 67 percent of the local payment amount for the item or device computed under subparagraph (C)(i)(I) for 1991, and (II) 33 percent of the national limited payment amount for the item or device computed under subparagraph (C)(ii) for 1991;

(iii) in 1992 is the sum of (I) 33 percent of the local payment amount for the item or device computed under subparagraph (C)(i)(II) for 1992, and (II) 67 percent of the national limited payment amount for the item or device computed under subparagraph (C)(ii) for 1992; and

(iv) in 1993 and each subsequent year is the national limited payment amount for the item or device computed under subparagraph (C)(ii) for that year.

(C) COMPUTATION OF LOCAL PAYMENT AMOUNT AND NATIONAL LIMITED PAYMENT AMOUNT.—For purposes of subparagraph (B)—

(i) the local payment amount for an item or device for a year is equal to—

(I) for 1991, the amount specified in subparagraph (B)(i) for 1990 increased by the covered item update for 1991, and

(II) for 1992, 1993, and 1994 the amount determined under this clause for the preceding year increased by the covered item update for the year; and

(ii) the national limited payment amount for an item or device for a year is equal to—

(I) for 1991, the local payment amount determined under clause (i) for such item or device for that year, except that the national limited payment amount may not exceed 100 percent of the weighted average of all local payment amounts determined under such clause for such item for that year and may not be less than 85 percent of the weighted average of all local payment amounts determined under such clause for such item,

(II) for 1992 and 1993, the amount determined under this clause for the preceding year increased by the covered item update for such subsequent year,

(III) for 1994, the local payment amount determined under clause (i) for such item or device for that year, except that the national limited payment amount may not exceed 100 percent of the median of all local payment amounts determined under such clause for such item for that year and may not be less than 85 percent of the median of all local payment amounts determined under such clause for such item or device for that year, and

(IV) for each subsequent year, the amount determined under this clause for the preceding year increased by the covered item update for such subsequent year.

(4) PAYMENT FOR CERTAIN CUSTOMIZED ITEMS.—Payment with respect to a covered item that is uniquely constructed or substantially modified to meet the specific needs of an individual patient, and for that reason cannot be grouped with similar items for purposes of payment under this title, shall be made in a lump-sum amount (A) for the purchase of the item in a payment amount based upon the carrier's individual consideration for that item, and (B) for the reasonable and necessary maintenance and servicing for parts and labor not covered by the supplier's or manufacturer's warranty, when necessary during the period of medical need, and the amount recognized for such maintenance and servicing shall be paid on a lump-sum, as needed basis based upon the carrier's individual consideration for that item. In the case of a wheelchair furnished on or after January 1, 1992, the wheelchair shall be treated as a customized item for purposes of this paragraph if the wheelchair has been measured, fitted, or adapted in consideration of the patient's body size, disability, period of need, or intended use, and has been assembled by a supplier or ordered from a manufacturer who makes available customized features, modifications, or components for wheelchairs that are intended for an individual patient's use in accordance with instructions from the patient's physician.

(5) PAYMENT FOR OXYGEN AND OXYGEN EQUIPMENT.—

(A) IN GENERAL.—Payment for oxygen and oxygen equipment shall be made on a monthly basis in the monthly payment amount recognized under paragraph (9) for oxygen and oxygen equipment (other than portable oxygen equipment), subject to subparagraphs (B), (C), (E), and (F).

(B) ADD-ON FOR PORTABLE OXYGEN EQUIPMENT.—When portable oxygen equipment is used, but subject to subparagraph (D), the payment amount recognized under subparagraph (A) shall be increased by the monthly payment amount recognized under paragraph (9) for portable oxygen equipment.

(C) VOLUME ADJUSTMENT.—When the attending physician prescribes an oxygen flow rate—

- (i) exceeding 4 liters per minute, the payment amount recognized under subparagraph (A), subject to subparagraph (D), shall be increased by 50 percent, or
- (ii) of less than 1 liter per minute, the payment amount recognized under subparagraph (A) shall be decreased by 50 percent.

(D) LIMIT ON ADJUSTMENT.—When portable oxygen equipment is used and the attending physician prescribes an oxygen flow rate exceeding 4 liters per minute, there shall only be an increase under either subparagraph (B) or (C), whichever increase is larger, and not under both such subparagraphs.

(E) RECERTIFICATION FOR PATIENTS RECEIVING HOME OXYGEN THERAPY.—In the case of a patient receiving home oxygen therapy services who, at the time such services are initiated, has an initial arterial blood gas value at or above a partial pressure of 56 or an arterial oxygen saturation at or above 89 percent (or such other values, pressures, or criteria as the Secretary may specify) no payment may be made under this part for such services after the expiration of the 90-day period that begins on the date the patient first receives such services unless the patient's attending physician certifies that, on the basis of a follow-up test of the patient's arterial blood gas value or arterial oxygen saturation conducted during the final 30 days of such 90-day period, there is a medical need for the patient to continue to receive such services.

(F) RENTAL CAP.—

(i) IN GENERAL.—Payment for oxygen equipment (including portable oxygen equipment) under this paragraph may not extend over a period of continuous use (as determined by the Secretary) of longer than 36 months.

(ii) PAYMENTS AND RULES AFTER RENTAL CAP.—After the 36th continuous month during which payment is made for the equipment under this paragraph—

(I) the supplier furnishing such equipment under this subsection shall continue to furnish the equipment during any period of medical need for the remainder of the reasonable useful lifetime of the equipment, as determined by the Secretary;

(II) payments for oxygen shall continue to be made in the amount recognized for oxygen under paragraph (9) for the period of medical need; and

(III) maintenance and servicing payments shall, if the Secretary determines such payments are reasonable and necessary, be made (for parts and

labor not covered by the supplier's or manufacturer's warranty, as determined by the Secretary to be appropriate for the equipment), and such payments shall be in an amount determined to be appropriate by the Secretary.

(6) PAYMENT FOR OTHER COVERED ITEMS (OTHER THAN DURABLE MEDICAL EQUIPMENT).—Payment for other covered items (other than durable medical equipment and other covered items described in paragraph (3), (4), or (5)) shall be made in a lump-sum amount for the purchase of the item in the amount of the purchase price recognized under paragraph (8).

(7) PAYMENT FOR OTHER ITEMS OF DURABLE MEDICAL EQUIPMENT.—

(A) PAYMENT.—In the case of an item of durable medical equipment not described in paragraphs (2) through (6), the following rules shall apply:

(i) RENTAL.—

(I) IN GENERAL.—Except as provided in clause (iii), payment for the item shall be made on a monthly basis for the rental of the item during the period of medical need (but payments under this clause may not extend over a period of continuous use (as determined by the Secretary) of longer than 13 months).

(II) PAYMENT AMOUNT.—Subject to subclause (III) and subparagraph (B), the amount recognized for the item, for each of the first 3 months of such period, is 10 percent of the purchase price recognized under paragraph (8) with respect to the item, and, for each of the remaining months of such period, is 7.5 percent of such purchase price.

(III) SPECIAL RULE FOR POWER-DRIVEN WHEELCHAIRS.—For purposes of payment for power-driven wheelchairs, subclause (II) shall be applied by substituting “15 percent” and “6 percent” for “10 percent” and “7.5 percent”, respectively.

(ii) OWNERSHIP AFTER RENTAL.—On the first day that begins after the 13th continuous month during which payment is made for the rental of an item under clause (i), the supplier of the item shall transfer title to the item to the individual.

(iii) PURCHASE AGREEMENT OPTION FOR COMPLEX, REHABILITATIVE POWER-DRIVEN WHEELCHAIRS.—In the case of a complex, rehabilitative power-driven wheelchair, at the time the supplier furnishes the item, the supplier shall offer the individual the option to purchase the item, and payment for such item shall be made on a lump-sum basis if the individual exercises such option.

(iv) MAINTENANCE AND SERVICING.—After the supplier transfers title to the item under clause (ii) or in the case of a power-driven wheelchair for which a purchase agreement has been entered into under clause (iii), maintenance and servicing payments shall, if the Secretary determines such payments are reasonable

and necessary, be made (for parts and labor not covered by the supplier's or manufacturer's warranty, as determined by the Secretary to be appropriate for the particular type of durable medical equipment), and such payments shall be in an amount determined to be appropriate by the Secretary.

(B) RANGE FOR RENTAL AMOUNTS.—

(i) FOR 1989.—For items furnished during 1989, the payment amount recognized under subparagraph (A)(i) shall not be more than 115 percent, and shall not be less than 85 percent, of the prevailing charge established for rental of the item in January 1987, increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 6-month period ending with December 1987.

(ii) FOR 1990.—For items furnished during 1990, clause (i) shall apply in the same manner as it applies to items furnished during 1989.

(C) REPLACEMENT OF ITEMS.—

(i) ESTABLISHMENT OF REASONABLE USEFUL LIFETIME.—In accordance with clause (iii), the Secretary shall determine and establish a reasonable useful lifetime for items of durable medical equipment for which payment may be made under this paragraph.

(ii) PAYMENT FOR REPLACEMENT ITEMS.—If the reasonable lifetime of such an item, as so established, has been reached during a continuous period of medical need, or the carrier determines that the item is lost or irreparably damaged, the patient may elect to have payment for an item serving as a replacement for such item made—

(I) on a monthly basis for the rental of the replacement item in accordance with subparagraph (A); or

(II) in the case of an item for which a purchase agreement has been entered into under subparagraph (A)(iii), in a lump-sum amount for the purchase of the item.

(iii) LENGTH OF REASONABLE USEFUL LIFETIME.—The reasonable useful lifetime of an item of durable medical equipment under this subparagraph shall be equal to 5 years, except that, if the Secretary determines that, on the basis of prior experience in making payments for such an item under this title, a reasonable useful lifetime of 5 years is not appropriate with respect to a particular item, the Secretary shall establish an alternative reasonable lifetime for such item.

(8) PURCHASE PRICE RECOGNIZED FOR MISCELLANEOUS DEVICES AND ITEMS.—For purposes of paragraphs (6) and (7), the amount that is recognized under this paragraph as the purchase price for a covered item is the amount described in subparagraph (C) of this paragraph, determined as follows:

(A) COMPUTATION OF LOCAL PURCHASE PRICE.—Each carrier under section 1842 shall compute a base local purchase price for the item as follows:

(i) The carrier shall compute a base local purchase price, for each item described—

(I) in paragraph (6) equal to the average reasonable charge in the locality for the purchase of the item for the 12-month period ending with June 1987, or

(II) in paragraph (7) equal to the average of the purchase prices on the claims submitted on an assignment-related basis for the unused item supplied during the 6-month period ending with December 1986.

(ii) The carrier shall compute a local purchase price, with respect to the furnishing of each particular item—

(I) in 1989 and 1990, equal to the base local purchase price computed under clause (i) increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 6-month period ending with December 1987,

(II) in 1991, equal to the local purchase price computed under this clause for the previous year, increased by the covered item update for 1991, and decreased by the percentage by which the average of the reasonable charges for claims paid for all items described in paragraph (7) is lower than the average of the purchase prices submitted for such items during the final 9 months of 1988; or

(III) in 1992, 1993, and 1994 equal to the local purchase price computed under this clause for the previous year increased by the covered item update for the year.

(B) COMPUTATION OF NATIONAL LIMITED PURCHASE PRICE.—With respect to the furnishing of a particular item in a year, the Secretary shall compute a national limited purchase price—

(i) for 1991, equal to the local purchase price computed under subparagraph (A)(ii) for the item for the year, except that such national limited purchase price may not exceed 100 percent of the weighted average of all local purchase prices for the item computed under such subparagraph for the year, and may not be less than 85 percent of the weighted average of all local purchase prices for the item computed under such subparagraph for the year;

(ii) for 1992 and 1993, the amount determined under this subparagraph for the preceding year increased by the covered item update for such subsequent year;

(iii) for 1994, the local purchase price computed under subparagraph (A)(ii) for the item for the year, except that such national limited purchase price may not exceed 100 percent of the median of all local purchase prices computed for the item under such subparagraph for the year and may not be less than 85 percent of the median of all local purchase prices com-

puted under such subparagraph for the item for the year; and

(iv) for each subsequent year, equal to the amount determined under this subparagraph for the preceding year increased by the covered item update for such subsequent year.

(C) PURCHASE PRICE RECOGNIZED.—For purposes of paragraphs (6) and (7), the amount that is recognized under this paragraph as the purchase price for each item furnished—

(i) in 1989 or 1990, is 100 percent of the local purchase price computed under subparagraph (A)(ii)(I);

(ii) in 1991, is the sum of (I) 67 percent of the local purchase price computed under subparagraph (A)(ii)(II) for 1991, and (II) 33 percent of the national limited purchase price computed under subparagraph (B) for 1991;

(iii) in 1992, is the sum of (I) 33 percent of the local purchase price computed under subparagraph (A)(ii)(III) for 1992, and (II) 67 percent of the national limited purchase price computed under subparagraph (B) for 1992; and

(iv) in 1993 or a subsequent year, is the national limited purchase price computed under subparagraph (B) for that year.

(9) MONTHLY PAYMENT AMOUNT RECOGNIZED WITH RESPECT TO OXYGEN AND OXYGEN EQUIPMENT.—For purposes of paragraph (5), the amount that is recognized under this paragraph for payment for oxygen and oxygen equipment is the monthly payment amount described in subparagraph (C) of this paragraph. Such amount shall be computed separately (i) for all items of oxygen and oxygen equipment (other than portable oxygen equipment) and (ii) for portable oxygen equipment (each such group referred to in this paragraph as an “item”).

(A) COMPUTATION OF LOCAL MONTHLY PAYMENT RATE.—

Each carrier under this section shall compute a base local payment rate for each item as follows:

(i) The carrier shall compute a base local average monthly payment rate per beneficiary as an amount equal to (I) the total reasonable charges for the item during the 12-month period ending with December 1986, divided by (II) the total number of months for all beneficiaries receiving the item in the area during the 12-month period for which the carrier made payment for the item under this title.

(ii) The carrier shall compute a local average monthly payment rate for the item applicable—

(I) to 1989 and 1990, equal to 95 percent of the base local average monthly payment rate computed under clause (i) for the item increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 6-month period ending with December 1987, or

(II) to 1991, 1992, 1993, and 1994 equal to the local average monthly payment rate computed under this clause for the item for the previous year increased by the covered item increase for the year.

(B) COMPUTATION OF NATIONAL LIMITED MONTHLY PAYMENT RATE.—With respect to the furnishing of an item in a year, the Secretary shall compute a national limited monthly payment rate equal to—

(i) for 1991, the local monthly payment rate computed under subparagraph (A)(ii)(II) for the item for the year, except that such national limited monthly payment rate may not exceed 100 percent of the weighted average of all local monthly payment rates computed for the item under such subparagraph for the year, and may not be less than 85 percent of the weighted average of all local monthly payment rates computed for the item under such subparagraph for the year;

(ii) for 1992 and 1993, the amount determined under this subparagraph for the preceding year increased by the covered item update for such subsequent year;

(iii) for 1994, the local monthly payment rate computed under subparagraph (A)(ii) for the item for the year, except that such national limited monthly payment rate may not exceed 100 percent of the median of all local monthly payment rates computed for the item under such subparagraph for the year and may not be less than 85 percent of the median of all local monthly payment rates computed for the item under such subparagraph for the year;

(iv) for 1995, 1996, and 1997, equal to the amount determined under this subparagraph for the preceding year increased by the covered item update for such subsequent year;

(v) for 1998, 75 percent of the amount determined under this subparagraph for 1997; and

(vi) for 1999 and each subsequent year, 70 percent of the amount determined under this subparagraph for 1997.

(C) MONTHLY PAYMENT AMOUNT RECOGNIZED.—For purposes of paragraph (5), the amount that is recognized under this paragraph as the base monthly payment amount for each item furnished—

(i) in 1989 and in 1990, is 100 percent of the local average monthly payment rate computed under subparagraph (A)(ii) for the item;

(ii) in 1991, is the sum of (I) 67 percent of the local average monthly payment rate computed under subparagraph (A)(ii)(II) for the item for 1991, and (II) 33 percent of the national limited monthly payment rate computed under subparagraph (B)(i) for the item for 1991;

(iii) in 1992, is the sum of (I) 33 percent of the local average monthly payment rate computed under sub-

paragraph (A)(ii)(II) for the item for 1992, and (II) 67 percent of the national limited monthly payment rate computed under subparagraph (B)(ii) for the item for 1992; and

(iv) in a subsequent year, is the national limited monthly payment rate computed under subparagraph (B) for the item for that year.

(10) EXCEPTIONS AND ADJUSTMENTS.—

(A) AREAS OUTSIDE CONTINENTAL UNITED STATES.—Exceptions to the amounts recognized under the previous provisions of this subsection shall be made to take into account the unique circumstances of covered items furnished in Alaska, Hawaii, or Puerto Rico.

(B) ADJUSTMENT FOR INHERENT REASONABLENESS.—The Secretary is authorized to apply the provisions of paragraphs (8) and (9) of section 1842(b) to covered items and suppliers of such items and payments under this subsection 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).

(C) TRANSCUTANEOUS ELECTRICAL NERVE STIMULATOR (TENS).—In order to permit an attending physician time to determine whether the purchase of a transcutaneous electrical nerve stimulator is medically appropriate for a particular patient, the Secretary may determine an appropriate payment amount for the initial rental of such item for a period of not more than 2 months. If such item is subsequently purchased, the payment amount with respect to such purchase is the payment amount determined under paragraph (2).

(11) IMPROPER BILLING AND REQUIREMENT OF PHYSICIAN ORDER.—

(A) IMPROPER BILLING FOR CERTAIN RENTAL ITEMS.—Notwithstanding any other provision of this title, a supplier of a covered item for which payment is made under this subsection and which is furnished on a rental basis shall continue to supply the item without charge (other than a charge provided under this subsection for the maintenance and servicing of the item) after rental payments may no longer be made under this subsection. If a supplier knowingly and willfully violates the previous sentence, the Secretary may apply sanctions against the supplier under section 1842(j)(2) in the same manner such sanctions may apply with respect to a physician.

(B) REQUIREMENT OF PHYSICIAN ORDER.—

(i) IN GENERAL.—The Secretary is authorized to require, for specified covered items, that payment may be made under this subsection with respect to the item only if a physician enrolled under section 1866(j) or an eligible professional under section 1848(k)(3)(B) that is enrolled under section 1866(j) has communicated to the supplier, before delivery of the item, a written order for the item.

(ii) REQUIREMENT FOR FACE TO FACE ENCOUNTER.—The Secretary shall require that such an order be

written pursuant to a physician, a physician assistant, a nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1861(aa)(5)) documenting such physician, physician assistant, practitioner, or specialist has had a face-to-face encounter (including through use of telehealth under subsection (m) and other than with respect to encounters that are incident to services involved) with the individual involved during the 6-month period preceding such written order, or other reasonable timeframe as determined by the Secretary.

(12) REGIONAL CARRIERS.—The Secretary may designate, by regulation under section 1842, one carrier for one or more entire regions to process all claims within the region for covered items under this section.

(13) COVERED ITEM.—In this subsection, the term “covered item” means durable medical equipment (as defined in section 1861(n)), including such equipment described in section 1861(m)(5), but not including implantable items for which payment may be made under section 1833(t).

(14) COVERED ITEM UPDATE.—In this subsection, the term “covered item update” means, with respect to a year—

(A) for 1991 and 1992, the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June of the previous year reduced by 1 percentage point;

(B) for 1993, 1994, 1995, 1996, and 1997, the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June of the previous year;

(C) for each of the years 1998 through 2000, 0 percentage points;

(D) for 2001, the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June 2000;

(E) for 2002, 0 percentage points;

(F) for 2003, 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 2002;

(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;

(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;

(J) for 2009—

(i) in the case of items and services furnished in any geographic area, if such items or services were selected for competitive acquisition in any area under the competitive acquisition program under section 1847(a)(1)(B)(i)(I) before July 1, 2008, including related accessories but only if furnished with such items and services selected for such competition and diabetic supplies but only if furnished through mail order,—9.5 percent; or

(ii) in the case of other items and services, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June 2008;

(K) for 2010, 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; and

(L) for 2011 and each subsequent year—

(i) 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, reduced by—

(ii) the productivity adjustment described in section 1886(b)(3)(B)(xi)(II).

The application of subparagraph (L)(ii) may result in the covered item update under this paragraph being less than 0.0 for a year, and may result in payment rates under this subsection for a year being less than such payment rates for the preceding year.

(15) ADVANCE DETERMINATIONS OF COVERAGE FOR CERTAIN ITEMS.—

(A) DEVELOPMENT OF LISTS OF ITEMS BY SECRETARY.—

The Secretary may develop and periodically update a list of items for which payment may be made under this subsection that the Secretary determines, on the basis of prior payment experience, are frequently subject to unnecessary utilization throughout a carrier's entire service area or a portion of such area.

(B) DEVELOPMENT OF LISTS OF SUPPLIERS BY SECRETARY.—The Secretary may develop and periodically up-

date a list of suppliers of items for which payment may be made under this subsection with respect to whom—

(i) the Secretary has found that a substantial number of claims for payment under this part for items furnished by the supplier have been denied on the basis of the application of section 1862(a)(1); or

(ii) the Secretary has identified a pattern of overutilization resulting from the business practice of the supplier.

(C) DETERMINATIONS OF COVERAGE IN ADVANCE.—A carrier shall determine in advance of delivery of an item whether payment for the item may not be made because the item is not covered or because of the application of section 1862(a)(1) if—

(i) the item is included on the list developed by the Secretary under subparagraph (A);

(ii) the item is furnished by a supplier included on the list developed by the Secretary under subparagraph (B); or

(iii) the item is a customized item (other than inexpensive items specified by the Secretary) and the patient to whom the item is to be furnished or the supplier requests that such advance determination be made.

(16) DISCLOSURE OF INFORMATION AND SURETY BOND.—The Secretary shall not provide for the issuance (or renewal) of a provider number for a supplier of durable medical equipment, for purposes of payment under this part for durable medical equipment furnished by the supplier, unless the supplier provides the Secretary on a continuing basis—

(A) with—

(i) full and complete information as to the identity of each person with an ownership or control interest (as defined in section 1124(a)(3)) in the supplier or in any subcontractor (as defined by the Secretary in regulations) in which the supplier directly or indirectly has a 5 percent or more ownership interest; and

(ii) to the extent determined to be feasible under regulations of the Secretary, the name of any disclosing entity (as defined in section 1124(a)(2)) with respect to which a person with such an ownership or control interest in the supplier is a person with such an ownership or control interest in the disclosing entity; and

(B) with a surety bond in a form specified by the Secretary and in an amount that is not less than \$50,000 that the Secretary determines is commensurate with the volume of the billing of the supplier.

The Secretary may waive the requirement of a bond under subparagraph (B) in the case of a supplier that provides a comparable surety bond under State law. The Secretary, at the Secretary's discretion, may impose the requirements of the first sentence with respect to some or all providers of items or services under part A or some or all suppliers or other persons (other than physicians or other practitioners, as defined in sec-

tion 1842(b)(18)(C)) who furnish items or services under this part.

(17) PROHIBITION AGAINST UNSOLICITED TELEPHONE CONTACTS BY SUPPLIERS.—

(A) IN GENERAL.—A supplier of a covered item under this subsection may not contact an individual enrolled under this part by telephone regarding the furnishing of a covered item to the individual unless 1 of the following applies:

(i) The individual has given written permission to the supplier to make contact by telephone regarding the furnishing of a covered item.

(ii) The supplier has furnished a covered item to the individual and the supplier is contacting the individual only regarding the furnishing of such covered item.

(iii) If the contact is regarding the furnishing of a covered item other than a covered item already furnished to the individual, the supplier has furnished at least 1 covered item to the individual during the 15-month period preceding the date on which the supplier makes such contact.

(B) PROHIBITING PAYMENT FOR ITEMS FURNISHED SUBSEQUENT TO UNSOLICITED CONTACTS.—If a supplier knowingly contacts an individual in violation of subparagraph (A), no payment may be made under this part for any item subsequently furnished to the individual by the supplier.

(C) EXCLUSION FROM PROGRAM FOR SUPPLIERS ENGAGING IN PATTERN OF UNSOLICITED CONTACTS.—If a supplier knowingly contacts individuals in violation of subparagraph (A) to such an extent that the supplier's conduct establishes a pattern of contacts in violation of such subparagraph, the Secretary shall exclude the supplier from participation in the programs under this Act, in accordance with the procedures set forth in subsections (c), (f), and (g) of section 1128.

(18) REFUND OF AMOUNTS COLLECTED FOR CERTAIN DISALLOWED ITEMS.—

(A) IN GENERAL.—If a nonparticipating supplier furnishes to an individual enrolled under this part a covered item for which no payment may be made under this part by reason of paragraph (17)(B), the supplier shall refund on a timely basis to the patient (and shall be liable to the patient for) any amounts collected from the patient for the item, unless—

(i) the supplier establishes that the supplier did not know and could not reasonably have been expected to know that payment may not be made for the item by reason of paragraph (17)(B), or

(ii) before the item was furnished, the patient was informed that payment under this part may not be made for that item and the patient has agreed to pay for that item.

(B) SANCTIONS.—If a supplier knowingly and willfully fails to make refunds in violation of subparagraph (A), the

Secretary may apply sanctions against the supplier in accordance with section 1842(j)(2).

(C) NOTICE.—Each carrier with a contract in effect under this part with respect to suppliers of covered items shall send any notice of denial of payment for covered items by reason of paragraph (17)(B) and for which payment is not requested on an assignment-related basis to the supplier and the patient involved.

(D) TIMELY BASIS DEFINED.—A refund under subparagraph (A) is considered to be on a timely basis only if—

(i) in the case of a supplier who does not request reconsideration or seek appeal on a timely basis, the refund is made within 30 days after the date the supplier receives a denial notice under subparagraph (C), or

(ii) in the case in which such a reconsideration or appeal is taken, the refund is made within 15 days after the date the supplier receives notice of an adverse determination on reconsideration or appeal.

(19) CERTAIN UPGRADED ITEMS.—

(A) INDIVIDUAL'S RIGHT TO CHOOSE UPGRADED ITEM.—Notwithstanding any other provision of this title, the Secretary may issue regulations under which an individual may purchase or rent from a supplier an item of upgraded durable medical equipment for which payment would be made under this subsection if the item were a standard item.

(B) PAYMENTS TO SUPPLIER.—In the case of the purchase or rental of an upgraded item under subparagraph (A)—

(i) the supplier shall receive payment under this subsection with respect to such item as if such item were a standard item; and

(ii) the individual purchasing or renting the item shall pay the supplier an amount equal to the difference between the supplier's charge and the amount under clause (i).

In no event may the supplier's charge for an upgraded item exceed the applicable fee schedule amount (if any) for such item.

(C) CONSUMER PROTECTION SAFEGUARDS.—Any regulations under subparagraph (A) shall provide for consumer protection standards with respect to the furnishing of upgraded equipment under subparagraph (A). Such regulations shall provide for—

(i) determination of fair market prices with respect to an upgraded item;

(ii) full disclosure of the availability and price of standard items and proof of receipt of such disclosure information by the beneficiary before the furnishing of the upgraded item;

(iii) conditions of participation for suppliers in the billing arrangement;

(iv) sanctions of suppliers who are determined to engage in coercive or abusive practices, including exclusion; and

(v) such other safeguards as the Secretary determines are necessary.

(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(a), 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, including subparagraph (F), 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.

(F) APPLICATION OF ACCREDITATION REQUIREMENT.—In implementing quality standards under this paragraph—

(i) subject to clause (ii) and subparagraph (G), the Secretary shall require suppliers furnishing items and services described in subparagraph (D) on or after October 1, 2009, directly or as a subcontractor for another entity, to have submitted to the Secretary evidence of accreditation by an accreditation organization designated under subparagraph (B) as meeting appli-

cable quality standards, except that the Secretary shall not require under this clause pharmacies to obtain such accreditation before January 1, 2010, except that the Secretary shall not require a pharmacy to have submitted to the Secretary such evidence of accreditation prior to January 1, 2011; and

(ii) in applying such standards and the accreditation requirement of clause (i) with respect to eligible professionals (as defined in section 1848(k)(3)(B)), and including such other persons, such as orthotists and prosthetists, as specified by the Secretary, furnishing such items and services—

(I) such standards and accreditation requirement shall not apply to such professionals and persons unless the Secretary determines that the standards being applied are designed specifically to be applied to such professionals and persons; and

(II) the Secretary may exempt such professionals and persons from such standards and requirement if the Secretary determines that licensing, accreditation, or other mandatory quality requirements apply to such professionals and persons with respect to the furnishing of such items and services.

(G) APPLICATION OF ACCREDITATION REQUIREMENT TO CERTAIN PHARMACIES.—

(i) IN GENERAL.—With respect to items and services furnished on or after January 1, 2011, in implementing quality standards under this paragraph—

(I) subject to subclause (II), in applying such standards and the accreditation requirement of subparagraph (F)(i) with respect to pharmacies described in clause (ii) furnishing such items and services, such standards and accreditation requirement shall not apply to such pharmacies; and

(II) the Secretary may apply to such pharmacies an alternative accreditation requirement established by the Secretary if the Secretary determines such alternative accreditation requirement is more appropriate for such pharmacies.

(ii) PHARMACIES DESCRIBED.—A pharmacy described in this clause is a pharmacy that meets each of the following criteria:

(I) The total billings by the pharmacy for such items and services under this title are less than 5 percent of total pharmacy sales, as determined based on the average total pharmacy sales for the previous 3 calendar years, 3 fiscal years, or other yearly period specified by the Secretary.

(II) The pharmacy has been enrolled under section 1866(j) as a supplier of durable medical equipment, prosthetics, orthotics, and supplies, has been issued (which may include the renewal

of) a provider number for at least 5 years, and for which a final adverse action (as defined in section 424.57(a) of title 42, Code of Federal Regulations) has not been imposed in the past 5 years.

(III) The pharmacy submits to the Secretary an attestation, in a form and manner, and at a time, specified by the Secretary, that the pharmacy meets the criteria described in subclauses (I) and (II). Such attestation shall be subject to section 1001 of title 18, United States Code.

(IV) The pharmacy agrees to submit materials as requested by the Secretary, or during the course of an audit conducted on a random sample of pharmacies selected annually, to verify that the pharmacy meets the criteria described in subclauses (I) and (II). Materials submitted under the preceding sentence shall include a certification by an accountant on behalf of the pharmacy or the submission of tax returns filed by the pharmacy during the relevant periods, as requested by the Secretary.

(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.

(22) SPECIAL PAYMENT RULE FOR DIABETIC SUPPLIES.—Notwithstanding the preceding provisions of this subsection, for purposes of determining the payment amount under this subsection for diabetic supplies furnished on or after the first day of the calendar quarter during 2013 that is at least 30 days after the date of the enactment of this paragraph and before the date described in paragraph (1)(H)(ii), the Secretary shall recalculate and apply the covered item update under paragraph (14) as if subparagraph (J)(i) of such paragraph was amended by striking “but only if furnished through mail order”.

(b) FEE SCHEDULES FOR RADIOLOGIST SERVICES.—

(1) DEVELOPMENT.—The Secretary shall develop—

(A) a relative value scale to serve as the basis for the payment for radiologist services under this part, and

(B) using such scale and appropriate conversion factors and subject to subsection (c)(1)(A), fee schedules (on a regional, statewide, locality, or carrier service area basis) for payment for radiologist services under this part, to be implemented for such services furnished during 1989.

(2) CONSULTATION.—In carrying out paragraph (1), the Secretary shall regularly consult closely with the Physician Payment Review Commission, the American College of Radiology, and other organizations representing physicians or suppliers who furnish radiologist services and shall share with them the data and data analysis being used to make the determinations under paragraph (1), including data on variations in current medicare payments by geographic area, and by service and physician specialty.

(3) CONSIDERATIONS.—In developing the relative value scale and fee schedules under paragraph (1), the Secretary—

(A) shall take into consideration variations in the cost of furnishing such services among geographic areas and among different sites where services are furnished, and

(B) may also take into consideration such other factors respecting the manner in which physicians in different specialties furnish such services as may be appropriate to assure that payment amounts are equitable and designed to promote effective and efficient provision of radiologist services by physicians in the different specialties.

(4) SAVINGS.—

(A) BUDGET NEUTRAL FEE SCHEDULES.—The Secretary shall develop preliminary fee schedules for 1989, which are designed to result in the same amount of aggregate payments (net of any coinsurance and deductibles under sections 1833(a)(1)(J) and 1833(b)) for radiologist services furnished in 1989 as would have been made if this subsection had not been enacted.

(B) INITIAL SAVINGS.—The fee schedules established for payment purposes under this subsection for services furnished in 1989 shall be 97 percent of the amounts permitted under these preliminary fee schedules developed under subparagraph (A).

(C) 1990 FEE SCHEDULES.—For radiologist services (other than portable X-ray services) furnished under this part

during 1990, after March 31 of such year, the conversion factors used under this subsection shall be 96 percent of the conversion factors that applied under this subsection as of December 31, 1989.

(D) 1991 FEE SCHEDULES.—For radiologist services (other than portable X-ray services) furnished under this part during 1991, the conversion factors used in a locality under this subsection shall, subject to clause (vii), be reduced to the adjusted conversion factor for the locality determined as follows:

(i) NATIONAL WEIGHTED AVERAGE CONVERSION FACTOR.—The Secretary shall estimate the national weighted average of the conversion factors used under this subsection for services furnished during 1990 beginning on April 1, using the best available data.

(ii) REDUCED NATIONAL WEIGHTED AVERAGE.—The national weighted average estimated under clause (i) shall be reduced by 13 percent.

(iii) COMPUTATION OF 1990 LOCALITY INDEX RELATIVE TO NATIONAL AVERAGE.—The Secretary shall establish an index which reflects, for each locality, the ratio of the conversion factor used in the locality under this subsection to the national weighted average estimated under clause (i).

(iv) ADJUSTED CONVERSION FACTOR.—The adjusted conversion factor for the professional or technical component of a service in a locality is the sum of $\frac{1}{2}$ of the locally-adjusted amount determined under clause (v) and $\frac{1}{2}$ of the GPCI-adjusted amount determined under clause (vi).

(v) LOCALLY-ADJUSTED AMOUNT.—For purposes of clause (iv), the locally adjusted amount determined under this clause is the product of (I) the national weighted average conversion factor computed under clause (ii), and (II) the index value established under clause (iii) for the locality.

(vi) GPCI-ADJUSTED AMOUNT.—For purposes of clause (iv), the GPCI-adjusted amount determined under this clause is the sum of—

(I) the product of (a) the portion of the reduced national weighted average conversion factor computed under clause (ii) which is attributable to physician work and (b) the geographic work index value for the locality (specified in Addendum C to the Model Fee Schedule for Physician Services (published on September 4, 1990, 55 Federal Register pp. 36238 36243)); and

(II) the product of (a) the remaining portion of the reduced national weighted average conversion factor computed under clause (ii), and (b) the geographic practice cost index value specified in section 1842(b)(14)(C)(iv) for the locality.

In applying this clause with respect to the professional component of a service, 80 percent of the conversion factor shall be considered to be attributable to physi-

cian work and with respect to the technical component of the service, 0 percent shall be considered to be attributable to physician work.

(vii) LIMITS ON CONVERSION FACTOR.—The conversion factor to be applied to a locality to the professional or technical component of a service shall not be reduced under this subparagraph by more than 9.5 percent below the conversion factor applied in the locality under subparagraph (C) to such component, but in no case shall the conversion factor be less than 60 percent of the national weighted average of the conversion factors (computed under clause (i)).

(E) RULE FOR CERTAIN SCANNING SERVICES.—In the case of the technical components of magnetic resonance imaging (MRI) services and computer assisted tomography (CAT) services furnished after December 31, 1990, the amount otherwise payable shall be reduced by 10 percent.

(F) SUBSEQUENT UPDATING.—For radiologist services furnished in subsequent years, the fee schedules shall be the schedules for the previous year updated by the percentage increase in the MEI (as defined in section 1842(i)(3)) for the year.

(G) NONPARTICIPATING PHYSICIANS AND SUPPLIERS.—Each fee schedule so established shall provide that the payment rate recognized for nonparticipating physicians and suppliers is equal to the appropriate percent (as defined in section 1842(b)(4)(A)(iv)) of the payment rate recognized for participating physicians and suppliers.

(5) LIMITING CHARGES OF NONPARTICIPATING PHYSICIANS AND SUPPLIERS.—

(A) IN GENERAL.—In the case of radiologist services furnished after January 1, 1989, for which payment is made under a fee schedule under this subsection, if a nonparticipating physician or supplier furnishes the service to an individual entitled to benefits under this part, the physician or supplier may not charge the individual more than the limiting charge (as defined in subparagraph (B)).

(B) LIMITING CHARGE DEFINED.—In subparagraph (A), the term “limiting charge” means, with respect to a service furnished—

(i) in 1989, 125 percent of the amount specified for the service in the appropriate fee schedule established under paragraph (1),

(ii) in 1990, 120 percent of the amount specified for the service in the appropriate fee schedule established under paragraph (1), and

(iii) after 1990, 115 percent of the amount specified for the service in the appropriate fee schedule established under paragraph (1).

(C) ENFORCEMENT.—If a physician or supplier knowingly and willfully bills in violation of subparagraph (A), the Secretary may apply sanctions against such physician or supplier in accordance with section 1842(j)(2) in the same manner as such sanctions may apply to a physician.

(6) RADIOLOGIST SERVICES DEFINED.—For the purposes of this subsection and section 1833(a)(1)(J), the term “radiologist services” only includes radiology services performed by, or under the direction or supervision of, a physician—

(A) who is certified, or eligible to be certified, by the American Board of Radiology, or

(B) for whom radiology services account for at least 50 percent of the total amount of charges made under this part.

(c) PAYMENT AND STANDARDS FOR SCREENING MAMMOGRAPHY.—

(1) IN GENERAL.—With respect to expenses incurred for screening mammography (as defined in section 1861(jj)), payment may be made only—

(A) for screening mammography conducted consistent with the frequency permitted under paragraph (2); and

(B) if the screening mammography is conducted by a facility that has a certificate (or provisional certificate) issued under section 354 of the Public Health Service Act.

(2) FREQUENCY COVERED.—

(A) IN GENERAL.—Subject to revision by the Secretary under subparagraph (B)—

(i) no payment may be made under this part for screening mammography performed on a woman under 35 years of age;

(ii) payment may be made under this part for only one screening mammography performed on a woman over 34 years of age, but under 40 years of age; and

(iii) in the case of a woman over 39 years of age, payment may not be made under this part for screening mammography performed within 11 months following the month in which a previous screening mammography was performed.

(B) REVISION OF FREQUENCY.—

(i) REVIEW.—The Secretary, in consultation with the Director of the National Cancer Institute, shall review periodically the appropriate frequency for performing screening mammography, based on age and such other factors as the Secretary believes to be pertinent.

(ii) REVISION OF FREQUENCY.—The Secretary, taking into consideration the review made under clause (i), may revise from time to time the frequency with which screening mammography may be paid for under this subsection.

(d) FREQUENCY LIMITS AND PAYMENT FOR COLORECTAL CANCER SCREENING TESTS.—

(1) SCREENING FECAL-OCCULT BLOOD TESTS.—

(A) PAYMENT AMOUNT.—The payment amount for colorectal cancer screening tests consisting of screening fecal-occult blood tests is equal to the payment amount established for diagnostic fecal-occult blood tests under section 1833(h).

(B) FREQUENCY LIMIT.—No payment may be made under this part for a colorectal cancer screening test consisting of a screening fecal-occult blood test—

(i) if the individual is under 50 years of age; or

(ii) if the test is performed within the 11 months after a previous screening fecal-occult blood test.

(2) SCREENING FLEXIBLE SIGMOIDOSCOPIES.—

(A) FEE SCHEDULE.—With respect to colorectal cancer screening tests consisting of screening flexible sigmoidoscopies, payment under section 1848 shall be consistent with payment under such section for similar or related services.

(B) PAYMENT LIMIT.—In the case of screening flexible sigmoidoscopy services, payment under this part shall not exceed such amount as the Secretary specifies, based upon the rates recognized for diagnostic flexible sigmoidoscopy services.

(C) FACILITY PAYMENT LIMIT.—

(i) IN GENERAL.—Notwithstanding subsections (i)(2)(A) and (t) of section 1833, in the case of screening flexible sigmoidoscopy services furnished on or after January 1, 1999, that—

(I) in accordance with regulations, may be performed in an ambulatory surgical center and for which the Secretary permits ambulatory surgical center payments under this part, and

(II) are performed in an ambulatory surgical center or hospital outpatient department, payment under this part shall be based on the lesser of the amount under the fee schedule that would apply to such services if they were performed in a hospital outpatient department in an area or the amount under the fee schedule that would apply to such services if they were performed in an ambulatory surgical center in the same area.

(ii) LIMITATION ON COINSURANCE.—Notwithstanding any other provision of this title, in the case of a beneficiary who receives the services described in clause (i)—

(I) in computing the amount of any applicable copayment, the computation of such coinsurance shall be based upon the fee schedule under which payment is made for the services, and

(II) the amount of such coinsurance is equal to 25 percent of the payment amount under the fee schedule described in subclause (I).

(D) SPECIAL RULE FOR DETECTED LESIONS.—If during the course of such screening flexible sigmoidoscopy, a lesion or growth is detected which results in a biopsy or removal of the lesion or growth, payment under this part shall not be made for the screening flexible sigmoidoscopy but shall be made for the procedure classified as a flexible sigmoidoscopy with such biopsy or removal.

(E) FREQUENCY LIMIT.—No payment may be made under this part for a colorectal cancer screening test consisting of a screening flexible sigmoidoscopy—

(i) if the individual is under 50 years of age; or

(ii) if the procedure is performed within the 47 months after a previous screening flexible

sigmoidoscopy or, in the case of an individual who is not at high risk for colorectal cancer, if the procedure is performed within the 119 months after a previous screening colonoscopy.

(3) SCREENING COLONOSCOPY.—

(A) FEE SCHEDULE.—With respect to colorectal cancer screening test consisting of a screening colonoscopy, payment under section 1848 shall be consistent with payment amounts under such section for similar or related services.

(B) PAYMENT LIMIT.—In the case of screening colonoscopy services, payment under this part shall not exceed such amount as the Secretary specifies, based upon the rates recognized for diagnostic colonoscopy services.

(C) FACILITY PAYMENT LIMIT.—

(i) IN GENERAL.—Notwithstanding subsections (i)(2)(A) and (t) of section 1833, in the case of screening colonoscopy services furnished on or after January 1, 1999, that are performed in an ambulatory surgical center or a hospital outpatient department, payment under this part shall be based on the lesser of the amount under the fee schedule that would apply to such services if they were performed in a hospital outpatient department in an area or the amount under the fee schedule that would apply to such services if they were performed in an ambulatory surgical center in the same area.

(ii) LIMITATION ON COINSURANCE.—Notwithstanding any other provision of this title, in the case of a beneficiary who receives the services described in clause (i)—

(I) in computing the amount of any applicable coinsurance, the computation of such coinsurance shall be based upon the fee schedule under which payment is made for the services, and

(II) the amount of such coinsurance is equal to 25 percent of the payment amount under the fee schedule described in subclause (I).

(D) SPECIAL RULE FOR DETECTED LESIONS.—If during the course of such screening colonoscopy, a lesion or growth is detected which results in a biopsy or removal of the lesion or growth, payment under this part shall not be made for the screening colonoscopy but shall be made for the procedure classified as a colonoscopy with such biopsy or removal.

(E) FREQUENCY LIMIT.—No payment may be made under this part for a colorectal cancer screening test consisting of a screening colonoscopy for individuals at high risk for colorectal cancer if the procedure is performed within the 23 months after a previous screening colonoscopy or for other individuals if the procedure is performed within the 119 months after a previous screening colonoscopy or within 47 months after a previous screening flexible sigmoidoscopy.

(e) ACCREDITATION REQUIREMENT FOR ADVANCED DIAGNOSTIC IMAGING SERVICES.—

(1) IN GENERAL.—

(A) IN GENERAL.—Beginning with January 1, 2012, with respect to the technical component of advanced diagnostic imaging services for which payment is made under the fee schedule established under section 1848(b) and that are furnished by a supplier, payment may only be made if such supplier is accredited by an accreditation organization designated by the Secretary under paragraph (2)(B)(i).

(B) ADVANCED DIAGNOSTIC IMAGING SERVICES DEFINED.—In this subsection, the term “advanced diagnostic imaging services” includes—

(i) diagnostic magnetic resonance imaging, computed tomography, and nuclear medicine (including positron emission tomography); and

(ii) such other diagnostic imaging services, including services described in section 1848(b)(4)(B) (excluding X-ray, ultrasound, and fluoroscopy), as specified by the Secretary in consultation with physician specialty organizations and other stakeholders.

(C) SUPPLIER DEFINED.—In this subsection, the term “supplier” has the meaning given such term in section 1861(d).

(2) ACCREDITATION ORGANIZATIONS.—

(A) FACTORS FOR DESIGNATION OF ACCREDITATION ORGANIZATIONS.—The Secretary shall consider the following factors in designating accreditation organizations under subparagraph (B)(i) and in reviewing and modifying the list of accreditation organizations designated pursuant to subparagraph (C):

(i) The ability of the organization to conduct timely reviews of accreditation applications.

(ii) Whether the organization has established a process for the timely integration of new advanced diagnostic imaging services into the organization’s accreditation program.

(iii) Whether the organization uses random site visits, site audits, or other strategies for ensuring accredited suppliers maintain adherence to the criteria described in paragraph (3).

(iv) The ability of the organization to take into account the capacities of suppliers located in a rural area (as defined in section 1886(d)(2)(D)).

(v) Whether the organization has established reasonable fees to be charged to suppliers applying for accreditation.

(vi) Such other factors as the Secretary determines appropriate.

(B) DESIGNATION.—Not later than January 1, 2010, the Secretary shall designate organizations to accredit suppliers furnishing the technical component of advanced diagnostic imaging services. The list of accreditation organizations so designated may be modified pursuant to subparagraph (C).

(C) REVIEW AND MODIFICATION OF LIST OF ACCREDITATION ORGANIZATIONS.—

(i) IN GENERAL.—The Secretary shall review the list of accreditation organizations designated under subparagraph (B) taking into account the factors under subparagraph (A). Taking into account the results of such review, the Secretary may, by regulation, modify the list of accreditation organizations designated under subparagraph (B).

(ii) SPECIAL RULE FOR ACCREDITATIONS DONE PRIOR TO REMOVAL FROM LIST OF DESIGNATED ACCREDITATION ORGANIZATIONS.—In the case where the Secretary removes an organization from the list of accreditation organizations designated under subparagraph (B), any supplier that is accredited by the organization during the period beginning on the date on which the organization is designated as an accreditation organization under subparagraph (B) and ending on the date on which the organization is removed from such list shall be considered to have been accredited by an organization designated by the Secretary under subparagraph (B) for the remaining period such accreditation is in effect.

(3) CRITERIA FOR ACCREDITATION.—The Secretary shall establish procedures to ensure that the criteria used by an accreditation organization designated under paragraph (2)(B) to evaluate a supplier that furnishes the technical component of advanced diagnostic imaging services for the purpose of accreditation of such supplier is specific to each imaging modality. Such criteria shall include—

(A) standards for qualifications of medical personnel who are not physicians and who furnish the technical component of advanced diagnostic imaging services;

(B) standards for qualifications and responsibilities of medical directors and supervising physicians, including standards that recognize the considerations described in paragraph (4);

(C) procedures to ensure that equipment used in furnishing the technical component of advanced diagnostic imaging services meets performance specifications;

(D) standards that require the supplier have procedures in place to ensure the safety of persons who furnish the technical component of advanced diagnostic imaging services and individuals to whom such services are furnished;

(E) standards that require the establishment and maintenance of a quality assurance and quality control program by the supplier that is adequate and appropriate to ensure the reliability, clarity, and accuracy of the technical quality of diagnostic images produced by such supplier; and

(F) any other standards or procedures the Secretary determines appropriate.

(4) RECOGNITION IN STANDARDS FOR THE EVALUATION OF MEDICAL DIRECTORS AND SUPERVISING PHYSICIANS.—The standards described in paragraph (3)(B) shall recognize whether a medical director or supervising physician—

(A) in a particular specialty receives training in advanced diagnostic imaging services in a residency program;

(B) has attained, through experience, the necessary expertise to be a medical director or a supervising physician;
 (C) has completed any continuing medical education courses relating to such services; or
 (D) has met such other standards as the Secretary determines appropriate.

(5) RULE FOR ACCREDITATIONS MADE PRIOR TO DESIGNATION.—In the case of a supplier that is accredited before January 1, 2010, by an accreditation organization designated by the Secretary under paragraph (2)(B) as of January 1, 2010, such supplier shall be considered to have been accredited by an organization designated by the Secretary under such paragraph as of January 1, 2012, for the remaining period such accreditation is in effect.

(f) REDUCTION IN PAYMENTS FOR PHYSICIAN PATHOLOGY SERVICES DURING 1991.—

(1) IN GENERAL.—For physician pathology services furnished under this part during 1991, the prevailing charges used in a locality under this part shall be 7 percent below the prevailing charges used in the locality under this part in 1990 after March 31.

(2) LIMITATION.—The prevailing charge for the technical and professional components of an physician pathology service furnished by a physician through an independent laboratory shall not be reduced pursuant to paragraph (1) to the extent that such reduction would reduce such prevailing charge below 115 percent of the prevailing charge for the professional component of such service when furnished by a hospital-based physician in the same locality. For purposes of the preceding sentence, an independent laboratory is a laboratory that is independent of a hospital and separate from the attending or consulting physicians' office.

(g) PAYMENT FOR OUTPATIENT CRITICAL ACCESS HOSPITAL SERVICES.—

(1) IN GENERAL.—The amount of payment for outpatient critical access hospital services of a critical access hospital is equal to 101 percent of the reasonable costs of the hospital in providing such services, unless the hospital makes the election under paragraph (2).

(2) ELECTION OF COST-BASED HOSPITAL OUTPATIENT SERVICE PAYMENT PLUS FEE SCHEDULE FOR PROFESSIONAL SERVICES.—A critical access hospital may elect to be paid for outpatient critical access hospital services amounts equal to the sum of the following, less the amount that such hospital may charge as described in section 1866(a)(2)(A):

(A) FACILITY FEE.—With respect to facility services, not including any services for which payment may be made under subparagraph (B), 101 percent of the reasonable costs of the critical access hospital in providing such services.

(B) FEE SCHEDULE FOR PROFESSIONAL SERVICES.—With respect to professional services otherwise included within outpatient critical access hospital services, 115 percent of such amounts as would otherwise be paid under this part if such services were not included in outpatient critical ac-

cess hospital services. Subsections (x) and (y) of section 1833 shall not be taken into account in determining the amounts that would otherwise be paid pursuant to the preceding sentence.

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.

(3) DISREGARDING CHARGES.—The payment amounts under this subsection shall be determined without regard to the amount of the customary or other charge.

(4) TREATMENT OF CLINICAL DIAGNOSTIC LABORATORY SERVICES.—No coinsurance, deductible, copayment, or other cost-sharing otherwise applicable under this part shall apply with respect to clinical diagnostic laboratory services furnished as an outpatient critical access hospital service. Nothing in this title shall be construed as providing for payment for clinical diagnostic laboratory services furnished as part of outpatient critical access hospital services, other than on the basis described in this subsection. For purposes of the preceding sentence and section 1861(mm)(3), clinical diagnostic laboratory services furnished by a critical access hospital shall be treated as being furnished as part of outpatient critical access services without regard to whether the individual with respect to whom such services are furnished is physically present in the critical access hospital, or in a skilled nursing facility or a clinic (including a rural health clinic) that is operated by a critical access hospital, at the time the specimen is collected.

(5) COVERAGE OF COSTS FOR CERTAIN EMERGENCY ROOM ON-CALL PROVIDERS.—In determining the reasonable costs of outpatient critical access hospital services under paragraphs (1) and (2)(A), the Secretary shall recognize as allowable costs, amounts (as defined by the Secretary) for reasonable compensation and related costs for physicians, physician assistants, nurse practitioners, and clinical nurse specialists who are on-call (as defined by the Secretary) to provide emergency services but who are not present on the premises of the critical access hospital involved, and are not otherwise furnishing services covered under this title and are not on-call at any other provider or facility.

(h) PAYMENT FOR PROSTHETIC DEVICES AND ORTHOTICS AND PROSTHETICS.—

(1) GENERAL RULE FOR PAYMENT.—

(A) IN GENERAL.—Payment under this subsection for prosthetic devices and orthotics and prosthetics shall be made in a lump-sum amount for the purchase of the item in an amount equal to 80 percent of the payment basis described in subparagraph (B).

(B) PAYMENT BASIS.—Except as provided in subparagraphs (C), (E), and (H)(i), the payment basis described in this subparagraph is the lesser of—

(i) the actual charge for the item; or

(ii) the amount recognized under paragraph (2) as the purchase price for the item.

(C) EXCEPTION FOR CERTAIN PUBLIC HOME HEALTH AGENCIES.—Subparagraph (B)(i) shall not apply to an item furnished by a public home health agency (or by another home health agency which demonstrates to the satisfaction of the Secretary that a significant portion of its patients are low income) free of charge or at nominal charges to the public.

(D) EXCLUSIVE PAYMENT RULE.—Subject to subparagraph (H)(ii), this subsection shall constitute the exclusive provision of this title for payment for prosthetic devices, orthotics, and prosthetics under this part or under part A to a home health agency.

(E) EXCEPTION FOR CERTAIN ITEMS.—Payment for ostomy supplies, tracheostomy supplies, and urologicals shall be made in accordance with subparagraphs (B) and (C) of section 1834(a)(2).

(F) SPECIAL PAYMENT RULES FOR CERTAIN PROSTHETICS AND CUSTOM-FABRICATED ORTHOTICS.—

(i) IN GENERAL.—No payment shall be made under this subsection for an item of custom-fabricated orthotics described in clause (ii) or for an item of prosthetics unless such item is—

(I) furnished by a qualified practitioner; and

(II) fabricated by a qualified practitioner or a qualified supplier at a facility that meets such criteria as the Secretary determines appropriate.

(ii) DESCRIPTION OF CUSTOM-FABRICATED ITEM.—

(I) IN GENERAL.—An item described in this clause is an item of custom-fabricated orthotics that requires education, training, and experience to custom-fabricate and that is included in a list established by the Secretary in subclause (II). Such an item does not include shoes and shoe inserts.

(II) LIST OF ITEMS.—The Secretary, in consultation with appropriate experts in orthotics (including national organizations representing manufacturers of orthotics), shall establish and update as appropriate a list of items to which this subparagraph applies. No item may be included in such list unless the item is individually fabricated for the patient over a positive model of the patient.

(iii) QUALIFIED PRACTITIONER DEFINED.—In this subparagraph, the term “qualified practitioner” means a physician or other individual who—

(I) is a qualified physical therapist or a qualified occupational therapist;

(II) in the case of a State that provides for the licensing of orthotics and prosthetics, is licensed in orthotics or prosthetics by the State in which the item is supplied; or

(III) in the case of a State that does not provide for the licensing of orthotics and prosthetics, is

specifically trained and educated to provide or manage the provision of prosthetics and custom-designed or -fabricated orthotics, and is certified by the American Board for Certification in Orthotics and Prosthetics, Inc. or by the Board for Orthotist/Prosthetist Certification, or is credentialed and approved by a program that the Secretary determines, in consultation with appropriate experts in orthotics and prosthetics, has training and education standards that are necessary to provide such prosthetics and orthotics.

(iv) QUALIFIED SUPPLIER DEFINED.—In this subparagraph, the term “qualified supplier” means any entity that is accredited by the American Board for Certification in Orthotics and Prosthetics, Inc. or by the Board for Orthotist/Prosthetist Certification, or accredited and approved by a program that the Secretary determines has accreditation and approval standards that are essentially equivalent to those of such Board.

(G) REPLACEMENT OF PROSTHETIC DEVICES AND PARTS.—

(i) IN GENERAL.—Payment shall be made for the replacement of prosthetic devices which are artificial limbs, or for the replacement of any part of such devices, without regard to continuous use or useful lifetime restrictions if an ordering physician determines that the provision of a replacement device, or a replacement part of such a device, is necessary because of any of the following:

(I) A change in the physiological condition of the patient.

(II) An irreparable change in the condition of the device, or in a part of the device.

(III) The condition of the device, or the part of the device, requires repairs and the cost of such repairs would be more than 60 percent of the cost of a replacement device, or, as the case may be, of the part being replaced.

(ii) CONFIRMATION MAY BE REQUIRED IF DEVICE OR PART BEING REPLACED IS LESS THAN 3 YEARS OLD.—If a physician determines that a replacement device, or a replacement part, is necessary pursuant to clause (i)—

(I) such determination shall be controlling; and

(II) such replacement device or part shall be deemed to be reasonable and necessary for purposes of section 1862(a)(1)(A);

except that if the device, or part, being replaced is less than 3 years old (calculated from the date on which the beneficiary began to use the device or part), the Secretary may also require confirmation of necessity of the replacement device or replacement part, as the case may be.

(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, subject to subsection (a)(1)(G), 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) subject to subsection (a)(1)(G), 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.

(2) PURCHASE PRICE RECOGNIZED.—For purposes of paragraph (1), the amount that is recognized under this paragraph as the purchase price for prosthetic devices, orthotics, and prosthetics is the amount described in subparagraph (C) of this paragraph, determined as follows:

(A) COMPUTATION OF LOCAL PURCHASE PRICE.—Each carrier under section 1842 shall compute a base local purchase price for the item as follows:

(i) The carrier shall compute a base local purchase price for each item equal to the average reasonable charge in the locality for the purchase of the item for the 12-month period ending with June 1987.

(ii) The carrier shall compute a local purchase price, with respect to the furnishing of each particular item—

(I) in 1989 and 1990, equal to the base local purchase price computed under clause (i) increased by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 6-month period ending with December 1987, or

(II) in 1991, 1992 or 1993, equal to the local purchase price computed under this clause for the previous year increased by the applicable percentage increase for the year.

(B) COMPUTATION OF REGIONAL PURCHASE PRICE.—With respect to the furnishing of a particular item in each region (as defined by the Secretary), the Secretary shall compute a regional purchase price—

(i) for 1992, equal to the average (weighted by relative volume of all claims among carriers) of the local purchase prices for the carriers in the region computed under subparagraph (A)(ii)(II) for the year, and

(ii) for each subsequent year, equal to the regional purchase price computed under this subparagraph for the previous year increased by the applicable percentage increase for the year.

(C) PURCHASE PRICE RECOGNIZED.—For purposes of paragraph (1) and subject to subparagraph (D), the amount

that is recognized under this paragraph as the purchase price for each item furnished—

(i) in 1989, 1990, or 1991, is 100 percent of the local purchase price computed under subparagraph (A)(ii);

(ii) in 1992, is the sum of (I) 75 percent of the local purchase price computed under subparagraph (A)(ii)(II) for 1992, and (II) 25 percent of the regional purchase price computed under subparagraph (B) for 1992;

(iii) in 1993, is the sum of (I) 50 percent of the local purchase price computed under subparagraph (A)(ii)(II) for 1993, and (II) 50 percent of the regional purchase price computed under subparagraph (B) for 1993; and

(iv) in 1994 or a subsequent year, is the regional purchase price computed under subparagraph (B) for that year.

(D) RANGE ON AMOUNT RECOGNIZED.—The amount that is recognized under subparagraph (C) as the purchase price for an item furnished—

(i) in 1992, may not exceed 125 percent, and may not be lower than 85 percent, of the average of the purchase prices recognized under such subparagraph for all the carrier service areas in the United States in that year; and

(ii) in a subsequent year, may not exceed 120 percent, and may not be lower than 90 percent, of the average of the purchase prices recognized under such subparagraph for all the carrier service areas in the United States in that year.

(3) APPLICABILITY OF CERTAIN PROVISIONS RELATING TO DURABLE MEDICAL EQUIPMENT.—Paragraphs (12) and (17) and subparagraphs (A) and (B) of paragraph (10) and paragraph (11) of subsection (a) shall apply to prosthetic devices, orthotics, and prosthetics in the same manner as such provisions apply to covered items under such subsection.

(4) DEFINITIONS.—In this subsection—

(A) the term “applicable percentage increase” means—

(i) for 1991, 0 percent;

(ii) for 1992 and 1993, 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;

(iii) for 1994 and 1995, 0 percent;

(iv) for 1996 and 1997, 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;

(v) for each of the years 1998 through 2000, 1 percent;

(vi) for 2001, the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June 2000;

(vii) for 2002, 1 percent;

(viii) for 2003, 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;

(ix) for 2004, 2005, and 2006, 0 percent;

(x) for for each of 2007 through 2010, 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; and

(xi) for 2011 and each subsequent year—

(I) 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, reduced by—

(II) the productivity adjustment described in section 1886(b)(3)(B)(xi)(II).

(B) the term “prosthetic devices” has the meaning given such term in section 1861(s)(8), except that such term does not include parenteral and enteral nutrition nutrients, supplies, and equipment and does not include an implantable item for which payment may be made under section 1833(t); and

(C) the term “orthotics and prosthetics” has the meaning given such term in section 1861(s)(9) (and includes shoes described in section 1861(s)(12)), but does not include intraocular lenses or medical supplies (including catheters, catheter supplies, ostomy bags, and supplies related to ostomy care) furnished by a home health agency under section 1861(m)(5).

The application of subparagraph (A)(xi)(II) may result in the applicable percentage increase under subparagraph (A) being less than 0.0 for a year, and may result in payment rates under this subsection for a year being less than such payment rates for the preceding year.

(5) DOCUMENTATION CREATED BY ORTHOTISTS AND PROSTHETISTS.—For purposes of determining the reasonableness and medical necessity of orthotics and prosthetics, documentation created by an orthotist or prosthetist shall be considered part of the individual’s medical record to support documentation created by eligible professionals described in section 1848(k)(3)(B).

(i) PAYMENT FOR SURGICAL DRESSINGS.—

(1) IN GENERAL.—Payment under this subsection for surgical dressings (described in section 1861(s)(5)) shall be made in a lump sum amount for the purchase of the item in an amount equal to 80 percent of the lesser of—

(A) the actual charge for the item; or

(B) a payment amount determined in accordance with the methodology described in subparagraphs (B) and (C) of subsection (a)(2) (except that in applying such methodology, the national limited payment amount referred to in such subparagraphs shall be initially computed based on local payment amounts using average reasonable charges for the 12-month period ending December 31, 1992, in-

created by the covered item updates described in such subsection for 1993 and 1994).

(2) EXCEPTIONS.—Paragraph (1) shall not apply to surgical dressings that are—

(A) furnished as an incident to a physician's professional service; or

(B) furnished by a home health agency.

(j) REQUIREMENTS FOR SUPPLIERS OF MEDICAL EQUIPMENT AND SUPPLIES.—

(1) ISSUANCE AND RENEWAL OF SUPPLIER NUMBER.—

(A) PAYMENT.—Except as provided in subparagraph (C), no payment may be made under this part after the date of the enactment of the Social Security Act Amendments of 1994 for items furnished by a supplier of medical equipment and supplies unless such supplier obtains (and renews at such intervals as the Secretary may require) a supplier number.

(B) STANDARDS FOR POSSESSING A SUPPLIER NUMBER.—A supplier may not obtain a supplier number unless—

(i) for medical equipment and supplies furnished on or after the date of the enactment of the Social Security Act Amendments of 1994 and before January 1, 1996, the supplier meets standards prescribed by the Secretary in regulations issued on June 18, 1992; and

(ii) for medical equipment and supplies furnished on or after January 1, 1996, the supplier meets revised standards prescribed by the Secretary (in consultation with representatives of suppliers of medical equipment and supplies, carriers, and consumers) that shall include requirements that the supplier—

(I) comply with all applicable State and Federal licensure and regulatory requirements;

(II) maintain a physical facility on an appropriate site;

(III) have proof of appropriate liability insurance; and

(IV) meet such other requirements as the Secretary may specify.

(C) EXCEPTION FOR ITEMS FURNISHED AS INCIDENT TO A PHYSICIAN'S SERVICE.—Subparagraph (A) shall not apply with respect to medical equipment and supplies furnished incident to a physician's service.

(D) PROHIBITION AGAINST MULTIPLE SUPPLIER NUMBERS.—The Secretary may not issue more than one supplier number to any supplier of medical equipment and supplies unless the issuance of more than one number is appropriate to identify subsidiary or regional entities under the supplier's ownership or control.

(E) PROHIBITION AGAINST DELEGATION OF SUPPLIER DETERMINATIONS.—The Secretary may not delegate (other than by contract under section 1842) the responsibility to determine whether suppliers meet the standards necessary to obtain a supplier number.

(2) CERTIFICATES OF MEDICAL NECESSITY.—

(A) LIMITATION ON INFORMATION PROVIDED BY SUPPLIERS ON CERTIFICATES OF MEDICAL NECESSITY.—

(i) IN GENERAL.—Effective 60 days after the date of the enactment of the Social Security Act Amendments of 1994, a supplier of medical equipment and supplies may distribute to physicians, or to individuals entitled to benefits under this part, a certificate of medical necessity for commercial purposes which contains no more than the following information completed by the supplier:

(I) An identification of the supplier and the beneficiary to whom such medical equipment and supplies are furnished.

(II) A description of such medical equipment and supplies.

(III) Any product code identifying such medical equipment and supplies.

(IV) Any other administrative information (other than information relating to the beneficiary's medical condition) identified by the Secretary.

(ii) INFORMATION ON PAYMENT AMOUNT AND CHARGES.—If a supplier distributes a certificate of medical necessity containing any of the information permitted to be supplied under clause (i), the supplier shall also list on the certificate of medical necessity the fee schedule amount and the supplier's charge for the medical equipment or supplies being furnished prior to distribution of such certificate to the physician.

(iii) PENALTY.—Any supplier of medical equipment and supplies who knowingly and willfully distributes a certificate of medical necessity in violation of clause (i) or fails to provide the information required under clause (ii) is subject to a civil money penalty in an amount not to exceed \$1,000 for each such certificate of medical necessity so distributed. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to civil money penalties under this subparagraph in the same manner as they apply to a penalty or proceeding under section 1128A(a).

(B) DEFINITION.—For purposes of this paragraph, the term "certificate of medical necessity" means a form or other document containing information required by the carrier to be submitted to show that an item is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

(3) COVERAGE AND REVIEW CRITERIA.—The Secretary shall annually review the coverage and utilization of items of medical equipment and supplies to determine whether such items should be made subject to coverage and utilization review criteria, and if appropriate, shall develop and apply such criteria to such items.

(4) LIMITATION ON PATIENT LIABILITY.—If a supplier of medical equipment and supplies (as defined in paragraph (5))—

(A) furnishes an item or service to a beneficiary for which no payment may be made by reason of paragraph (1);

(B) furnishes an item or service to a beneficiary for which payment is denied in advance under subsection (a)(15); or

(C) furnishes an item or service to a beneficiary for which payment is denied under section 1862(a)(1); any expenses incurred for items and services furnished to an individual by such a supplier not on an assigned basis shall be the responsibility of such supplier. The individual shall have no financial responsibility for such expenses and the supplier shall refund on a timely basis to the individual (and shall be liable to the individual for) any amounts collected from the individual for such items or services. The provisions of subsection (a)(18) shall apply to refunds required under the previous sentence in the same manner as such provisions apply to refunds under such subsection.

(5) DEFINITION.—The term “medical equipment and supplies” means—

(A) durable medical equipment (as defined in section 1861(n));

(B) prosthetic devices (as described in section 1861(s)(8));

(C) orthotics and prosthetics (as described in section 1861(s)(9));

(D) surgical dressings (as described in section 1861(s)(5));

(E) such other items as the Secretary may determine; and

(F) for purposes of paragraphs (1) and (3)—

(i) home dialysis supplies and equipment (as described in section 1861(s)(2)(F)),

(ii) immunosuppressive drugs (as described in section 1861(s)(2)(J)),

(iii) therapeutic shoes for diabetics (as described in section 1861(s)(12)),

(iv) oral drugs prescribed for use as an anticancer therapeutic agent (as described in section 1861(s)(2)(Q)), and

(v) self-administered erythropoetin (as described in section 1861(s)(2)(P)).

(k) PAYMENT FOR OUTPATIENT THERAPY SERVICES AND COMPREHENSIVE OUTPATIENT REHABILITATION SERVICES.—

(1) IN GENERAL.—With respect to services described in section 1833(a)(8) or 1833(a)(9) for which payment is determined under this subsection, the payment basis shall be—

(A) for services furnished during 1998, the amount determined under paragraph (2); or

(B) for services furnished during a subsequent year, 80 percent of the lesser of—

(i) the actual charge for the services, or

(ii) the applicable fee schedule amount (as defined in paragraph (3)) for the services.

(2) PAYMENT IN 1998 BASED UPON ADJUSTED REASONABLE COSTS.—The amount under this paragraph for services is the lesser of—

(A) the charges imposed for the services, or

(B) the adjusted reasonable costs (as defined in paragraph (4)) for the services, less 20 percent of the amount of the charges imposed for such services.

(3) APPLICABLE FEE SCHEDULE AMOUNT.—In this subsection, the term “applicable fee schedule amount” means, with respect to services furnished in a year, the amount determined under the fee schedule established under section 1848 for such services furnished during the year or, if there is no such fee schedule established for such services, the amount determined under the fee schedule established for such comparable services as the Secretary specifies.

(4) ADJUSTED REASONABLE COSTS.—In paragraph (2), the term “adjusted reasonable costs” means, with respect to any services, reasonable costs determined for such services, reduced by 10 percent. The 10-percent reduction shall not apply to services described in section 1833(a)(8)(B) (relating to services provided by hospitals).

(5) UNIFORM CODING.—For claims for services submitted on or after April 1, 1998, for which the amount of payment is determined under this subsection, the claim shall include a code (or codes) under a uniform coding system specified by the Secretary that identifies the services furnished.

(6) RESTRAINT ON BILLING.—The provisions of subparagraphs (A) and (B) of section 1842(b)(18) shall apply to therapy services for which payment is made under this subsection in the same manner as they apply to services provided by a practitioner described in section 1842(b)(18)(C).

(7) ADJUSTMENT IN DISCOUNT FOR CERTAIN MULTIPLE THERAPY SERVICES.—In the case of therapy services furnished on or after April 1, 2013, and for which payment is made under this subsection pursuant to the applicable fee schedule amount (as defined in paragraph (3)), instead of the 25 percent multiple procedure payment reduction specified in the final rule published by the Secretary in the Federal Register on November 29, 2010, the reduction percentage shall be 50 percent.

(1) ESTABLISHMENT OF FEE SCHEDULE FOR AMBULANCE SERVICES.—

(1) IN GENERAL.—The Secretary shall establish a fee schedule for payment for ambulance services whether provided directly by a supplier or provider or under arrangement with a provider under this part through a negotiated rulemaking process described in title 5, United States Code, and in accordance with the requirements of this subsection.

(2) CONSIDERATIONS.—In establishing such fee schedule, the Secretary shall—

(A) establish mechanisms to control increases in expenditures for ambulance services under this part;

(B) establish definitions for ambulance services which link payments to the type of services provided;

(C) consider appropriate regional and operational differences;

(D) consider adjustments to payment rates to account for inflation and other relevant factors; and

(E) phase in the application of the payment rates under the fee schedule in an efficient and fair manner consistent with paragraph (11), except that such phase-in shall provide for full payment of any national mileage rate for ambulance services provided by suppliers that are paid by carriers in any of the 50 States where payment by a carrier for such services for all such suppliers in such State did not, prior to the implementation of the fee schedule, include a separate amount for all mileage within the county from which the beneficiary is transported.

(3) SAVINGS.—In establishing such fee schedule, the Secretary shall—

(A) ensure that the aggregate amount of payments made for ambulance services under this part during 2000 does not exceed the aggregate amount of payments which would have been made for such services under this part during such year if the amendments made by section 4531(a) of the Balanced Budget Act of 1997 continued in effect, except that in making such determination the Secretary shall assume an update in such payments for 2002 equal to percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June of the previous year reduced in the case of 2002 by 1.0 percentage points;

(B) set the payment amounts provided under the fee schedule for services furnished in 2001 and each subsequent year at amounts equal to the payment amounts under the fee schedule for services furnished during the previous year, increased, subject to subparagraph (C) and the succeeding sentence of this paragraph, by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June of the previous year reduced in the case of 2002 by 1.0 percentage points; and

(C) for 2011 and each subsequent year, after determining the percentage increase under subparagraph (B) for the year, reduce such percentage increase by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II).

The application of subparagraph (C) may result in the percentage increase under subparagraph (B) being less than 0.0 for a year, and may result in payment rates under the fee schedule under this subsection for a year being less than such payment rates for the preceding year.

(4) CONSULTATION.—In establishing the fee schedule for ambulance services under this subsection, the Secretary shall consult with various national organizations representing individuals and entities who furnish and regulate ambulance services and share with such organizations relevant data in establishing such schedule.

(5) LIMITATION ON REVIEW.—There shall be no administrative or judicial review under section 1869 or otherwise of the amounts established under the fee schedule for ambulance services under this subsection, including matters described in paragraph (2).

(6) RESTRAINT ON BILLING.—The provisions of subparagraphs (A) and (B) of section 1842(b)(18) shall apply to ambulance services for which payment is made under this subsection in the same manner as they apply to services provided by a practitioner described in section 1842(b)(18)(C).

(7) CODING SYSTEM.—The Secretary may require the claim for any services for which the amount of payment is determined under this subsection to include a code (or codes) under a uniform coding system specified by the Secretary that identifies the services furnished.

(8) SERVICES FURNISHED BY CRITICAL ACCESS HOSPITALS.—Notwithstanding any other provision of this subsection, the Secretary shall pay 101 percent of the reasonable costs incurred in furnishing ambulance services if such services are furnished—

(A) by a critical access hospital (as defined in section 1861(mm)(1)), or

(B) by an entity that is owned and operated by a critical access hospital,

but only if the critical access hospital or entity is the only provider or supplier of ambulance services that is located within a 35-mile drive of such critical access hospital.

(9) TRANSITIONAL ASSISTANCE FOR RURAL PROVIDERS.—In the case of ground ambulance services furnished on or after July 1, 2001, and before January 1, 2004, for which the transportation originates 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)), the fee schedule established under this subsection shall provide that, with respect to the payment rate for mileage for a trip above 17 miles, and up to 50 miles, the rate otherwise established shall be increased by not less than $\frac{1}{2}$ of the additional payment per mile established for the first 17 miles of such a trip originating in a rural area.

(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.

(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 $\frac{1}{4}$ of the payment per mile otherwise applicable to miles in excess of 50 miles in such trip.

(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, 2018, 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.

(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, and for such services furnished on or after July 1, 2008, and before January 1, 2018, 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 (or 3 percent if such service is furnished on or after July 1, 2008, and before January 1, 2018); 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 (or 2 percent if such service is furnished on or after July 1, 2008, and before January 1, 2018).

(B) APPLICATION OF INCREASED PAYMENTS AFTER APPLICABLE PERIOD.—The increased payments under subparagraph (A) shall not be taken into account in calculating payments for services furnished after the applicable period specified in such subparagraph.

(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 certifies or reasonably determines 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.

(15) PAYMENT ADJUSTMENT FOR NON-EMERGENCY AMBULANCE TRANSPORTS FOR ESRD BENEFICIARIES.—The fee schedule amount otherwise applicable under the preceding provisions of

this subsection shall be reduced by 10 percent for ambulance services furnished on or after October 1, 2013, consisting of non-emergency basic life support services involving transport of an individual with end-stage renal disease for renal dialysis services (as described in section 1881(b)(14)(B)) furnished other than on an emergency basis by a provider of services or a renal dialysis facility.

(16) PRIOR AUTHORIZATION FOR REPETITIVE SCHEDULED NON-EMERGENCY AMBULANCE TRANSPORTS.—

(A) IN GENERAL.—Beginning January 1, 2017, if the expansion to all States of the model of prior authorization described in paragraph (2) of section 515(a) of the Medicare Access and CHIP Reauthorization Act of 2015 meets the requirements described in paragraphs (1) through (3) of section 1115A(c), then the Secretary shall expand such model to all States.

(B) FUNDING.—The Secretary shall use funds made available under section 1893(h)(10) to carry out this paragraph.

(C) CLARIFICATION REGARDING BUDGET NEUTRALITY.—Nothing in this paragraph may be construed to limit or modify the application of section 1115A(b)(3)(B) to models described in such section, including with respect to the model described in subparagraph (A) and expanded beginning on January 1, 2017, under such subparagraph.

(m) PAYMENT FOR TELEHEALTH SERVICES.—

(1) IN GENERAL.—The Secretary shall pay for telehealth services that are furnished via a telecommunications system by a physician (as defined in section 1861(r)) or a practitioner (described in section 1842(b)(18)(C)) to an eligible telehealth individual enrolled under this part notwithstanding that the individual physician or practitioner providing the telehealth service is not at the same location as the beneficiary. For purposes of the preceding sentence, in the case of any Federal telemedicine demonstration program conducted in Alaska or Hawaii, the term “telecommunications system” includes store-and-forward technologies that provide for the asynchronous transmission of health care information in single or multimedia formats.

(2) PAYMENT AMOUNT.—

(A) DISTANT SITE.—The Secretary shall pay to a physician or practitioner located at a distant site that furnishes a telehealth service to an eligible telehealth individual an amount equal to the amount that such physician or practitioner would have been paid under this title had such service been furnished without the use of a telecommunications system.

(B) FACILITY FEE FOR ORIGINATING [SITE.—] [With respect to] SITE.—

(i) IN GENERAL.—Subject to clause (ii), with respect to a telehealth service, subject to section 1833(a)(1)(U), there shall be paid to the originating site a facility fee equal to—

[(i)] (I) for the period beginning on October 1, 2001, and ending on December 31, 2001, and for 2002, \$20; and

[(ii)] (II) for a subsequent year, the facility fee specified in [clause (i) or this clause] *subclause (I) or this subclause* for the preceding year increased by the percentage increase in the MEI (as defined in section 1842(i)(3)) for such subsequent year.

(ii) *NO FACILITY FEE IF ORIGINATING SITE FOR HOME DIALYSIS THERAPY IS THE HOME.*—No facility fee shall be paid under this subparagraph to an originating site described in subclause (X) of paragraph (4)(C)(ii).

(C) TELEPRESENTER NOT REQUIRED.—Nothing in this subsection shall be construed as requiring an eligible telehealth individual to be presented by a physician or practitioner at the originating site for the furnishing of a service via a telecommunications system, unless it is medically necessary (as determined by the physician or practitioner at the distant site).

(3) LIMITATION ON BENEFICIARY CHARGES.—

(A) PHYSICIAN AND PRACTITIONER.—The provisions of section 1848(g) and subparagraphs (A) and (B) of section 1842(b)(18) shall apply to a physician or practitioner receiving payment under this subsection in the same manner as they apply to physicians or practitioners under such sections.

(B) ORIGINATING SITE.—The provisions of section 1842(b)(18) shall apply to originating sites receiving a facility fee in the same manner as they apply to practitioners under such section.

(4) DEFINITIONS.—For purposes of this subsection:

(A) DISTANT SITE.—The term “distant site” means the site at which the physician or practitioner is located at the time the service is provided via a telecommunications system.

(B) ELIGIBLE TELEHEALTH INDIVIDUAL.—The term “eligible telehealth individual” means an individual enrolled under this part who receives a telehealth service furnished at an originating site.

(C) ORIGINATING SITE.—

(i) IN GENERAL.—The term “originating site” means only those sites described in clause (ii) at which the eligible telehealth individual is located at the time the service is furnished via a telecommunications system and only if such site is located—

(I) in an area that is designated as a rural health professional shortage area under section 332(a)(1)(A) of the Public Health Service Act (42 U.S.C. 254e(a)(1)(A));

(II) in a county that is not included in a Metropolitan Statistical Area; or

(III) from an entity that participates in a Federal telemedicine demonstration project that has been approved by (or receives funding from) the

Secretary of Health and Human Services as of December 31, 2000.

(ii) SITES DESCRIBED.—The sites referred to in clause (i) are the following sites:

(I) The office of a physician or practitioner.

(II) A critical access hospital (as defined in section 1861(mm)(1)).

(III) A rural health clinic (as defined in section 1861(aa)(2)).

(IV) A Federally qualified health center (as defined in section 1861(aa)(4)).

(V) A hospital (as defined in section 1861(e)).

(VI) A hospital-based or critical access hospital-based renal dialysis center (including satellites).

(VII) A skilled nursing facility (as defined in section 1819(a)).

(VIII) A community mental health center (as defined in section 1861(ff)(3)(B)).

(IX) A renal dialysis facility, but only for purposes of section 1881(b)(3)(B).

(X) The home of an individual, but only for purposes of section 1881(b)(3)(B).

(D) PHYSICIAN.—The term “physician” has the meaning given that term in section 1861(r).

(E) PRACTITIONER.—The term “practitioner” has the meaning given that term in section 1842(b)(18)(C).

(F) TELEHEALTH SERVICE.—

(i) IN GENERAL.—The term “telehealth service” means professional consultations, office visits, and office psychiatry services (identified as of July 1, 2000, by HCPCS codes 99241 99275, 99201 99215, 90804 90809, and 90862 (and as subsequently modified by the Secretary)), and any additional service specified by the Secretary.

(ii) YEARLY UPDATE.—The Secretary shall establish a process that provides, on an annual basis, for the addition or deletion of services (and HCPCS codes), as appropriate, to those specified in clause (i) for authorized payment under paragraph (1).

(5) TREATMENT OF HOME DIALYSIS MONTHLY ESRD-RELATED VISIT.—*The geographic requirements described in paragraph (4)(C)(i) shall not apply with respect to telehealth services furnished on or after January 1, 2019, for purposes of section 1881(b)(3)(B), at an originating site described in subclause (VI), (IX), or (X) of paragraph (4)(C)(ii), subject to applicable State law requirements, including State licensure requirements.*

(n) AUTHORITY TO MODIFY OR ELIMINATE COVERAGE OF CERTAIN PREVENTIVE SERVICES.—Notwithstanding any other provision of this title, effective beginning on January 1, 2010, if the Secretary determines appropriate, the Secretary may—

(1) modify—

(A) the coverage of any preventive service described in subparagraph (A) of section 1861(ddd)(3) to the extent that such modification is consistent with the recommendations of the United States Preventive Services Task Force; and

- (B) the services included in the initial preventive physical examination described in subparagraph (B) of such section; and
- (2) provide that no payment shall be made under this title for a preventive service described in subparagraph (A) of such section that has not received a grade of A, B, C, or I by such Task Force.
- (o) DEVELOPMENT AND IMPLEMENTATION OF PROSPECTIVE PAYMENT SYSTEM.—
- (1) DEVELOPMENT.—
- (A) IN GENERAL.—The Secretary shall develop a prospective payment system for payment for Federally qualified health center services furnished by Federally qualified health centers under this title. Such system shall include a process for appropriately describing the services furnished by Federally qualified health centers and shall establish payment rates for specific payment codes based on such appropriate descriptions of services. Such system shall be established to take into account the type, intensity, and duration of services furnished by Federally qualified health centers. Such system may include adjustments, including geographic adjustments, determined appropriate by the Secretary.
- (B) COLLECTION OF DATA AND EVALUATION.—By not later than January 1, 2011, the Secretary shall require Federally qualified health centers to submit to the Secretary such information as the Secretary may require in order to develop and implement the prospective payment system under this subsection, including the reporting of services using HCPCS codes.
- (2) IMPLEMENTATION.—
- (A) IN GENERAL.—Notwithstanding section 1833(a)(3)(A), the Secretary shall provide, for cost reporting periods beginning on or after October 1, 2014, for payments of prospective payment rates for Federally qualified health center services furnished by Federally qualified health centers under this title in accordance with the prospective payment system developed by the Secretary under paragraph (1).
- (B) PAYMENTS.—
- (i) INITIAL PAYMENTS.—The Secretary shall implement such prospective payment system so that the estimated aggregate amount of prospective payment rates (determined prior to the application of section 1833(a)(1)(Z)) under this title for Federally qualified health center services in the first year that such system is implemented is equal to 100 percent of the estimated amount of reasonable costs (determined without the application of a per visit payment limit or productivity screen and prior to the application of section 1866(a)(2)(A)(ii)) that would have occurred for such services under this title in such year if the system had not been implemented.
- (ii) PAYMENTS IN SUBSEQUENT YEARS.—Payment rates in years after the year of implementation of such

system shall be the payment rates in the previous year increased—

(I) in the first year after implementation of such system, by the percentage increase in the MEI (as defined in section 1842(i)(3)) for the year involved; and

(II) in subsequent years, by the percentage increase in a market basket of Federally qualified health center goods and services as promulgated through regulations, or if such an index is not available, by the percentage increase in the MEI (as defined in section 1842(i)(3)) for the year involved.

(C) PREPARATION FOR PPS IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary may establish and implement by program instruction or otherwise the payment codes to be used under the prospective payment system under this section.

(p) QUALITY INCENTIVES TO PROMOTE PATIENT SAFETY AND PUBLIC HEALTH IN COMPUTED TOMOGRAPHY.—

(1) QUALITY INCENTIVES.—In the case of an applicable computed tomography service (as defined in paragraph (2)) for which payment is made under an applicable payment system (as defined in paragraph (3)) and that is furnished on or after January 1, 2016, using equipment that is not consistent with the CT equipment standard (described in paragraph (4)), the payment amount for such service shall be reduced by the applicable percentage (as defined in paragraph (5)).

(2) APPLICABLE COMPUTED TOMOGRAPHY SERVICES DEFINED.—In this subsection, the term “applicable computed tomography service” means a service billed using diagnostic radiological imaging codes for computed tomography (identified as of January 1, 2014, by HCPCS codes 70450 70498, 71250 71275, 72125 72133, 72191 72194, 73200 73206, 73700 73706, 74150 74178, 74261 74263, and 75571 75574 (and any succeeding codes)).

(3) APPLICABLE PAYMENT SYSTEM DEFINED.—In this subsection, the term “applicable payment system” means the following:

(A) The technical component and the technical component of the global fee under the fee schedule established under section 1848(b).

(B) The prospective payment system for hospital outpatient department services under section 1833(t).

(4) CONSISTENCY WITH CT EQUIPMENT STANDARD.—In this subsection, the term “not consistent with the CT equipment standard” means, with respect to an applicable computed tomography service, that the service was furnished using equipment that does not meet each of the attributes of the National Electrical Manufacturers Association (NEMA) Standard XR 29 2013, entitled “Standard Attributes on CT Equipment Related to Dose Optimization and Management”. Through rulemaking, the Secretary may apply successor standards.

(5) APPLICABLE PERCENTAGE DEFINED.—In this subsection, the term “applicable percentage” means—

(A) for 2016, 5 percent; and

(B) for 2017 and subsequent years, 15 percent.

(6) IMPLEMENTATION.—

(A) INFORMATION.—The Secretary shall require that information be provided and attested to by a supplier and a hospital outpatient department that indicates whether an applicable computed tomography service was furnished that was not consistent with the CT equipment standard (described in paragraph (4)). Such information may be included on a claim and may be a modifier. Such information shall be verified, as appropriate, as part of the periodic accreditation of suppliers under section 1834(e) and hospitals under section 1865(a).

(B) ADMINISTRATION.—Chapter 35 of title 44, United States Code, shall not apply to information described in subparagraph (A).

(q) RECOGNIZING APPROPRIATE USE CRITERIA FOR CERTAIN IMAGING SERVICES.—

(1) PROGRAM ESTABLISHED.—

(A) IN GENERAL.—The Secretary shall establish a program to promote the use of appropriate use criteria (as defined in subparagraph (B)) for applicable imaging services (as defined in subparagraph (C)) furnished in an applicable setting (as defined in subparagraph (D)) by ordering professionals and furnishing professionals (as defined in subparagraphs (E) and (F), respectively).

(B) APPROPRIATE USE CRITERIA DEFINED.—In this subsection, the term “appropriate use criteria” means criteria, only developed or endorsed by national professional medical specialty societies or other provider-led entities, to assist ordering professionals and furnishing professionals in making the most appropriate treatment decision for a specific clinical condition for an individual. To the extent feasible, such criteria shall be evidence-based.

(C) APPLICABLE IMAGING SERVICE DEFINED.—In this subsection, the term “applicable imaging service” means an advanced diagnostic imaging service (as defined in subsection (e)(1)(B)) for which the Secretary determines—

- (i) one or more applicable appropriate use criteria specified under paragraph (2) apply;
- (ii) there are one or more qualified clinical decision support mechanisms listed under paragraph (3)(C); and
- (iii) one or more of such mechanisms is available free of charge.

(D) APPLICABLE SETTING DEFINED.—In this subsection, the term “applicable setting” means a physician’s office, a hospital outpatient department (including an emergency department), an ambulatory surgical center, and any other provider-led outpatient setting determined appropriate by the Secretary.

(E) ORDERING PROFESSIONAL DEFINED.—In this subsection, the term “ordering professional” means a physician (as defined in section 1861(r)) or a practitioner described in section 1842(b)(18)(C) who orders an applicable imaging service.

(F) FURNISHING PROFESSIONAL DEFINED.—In this subsection, the term “furnishing professional” means a physician (as defined in section 1861(r)) or a practitioner described in section 1842(b)(18)(C) who furnishes an applicable imaging service.

(2) ESTABLISHMENT OF APPLICABLE APPROPRIATE USE CRITERIA.—

(A) IN GENERAL.—Not later than November 15, 2015, the Secretary shall through rulemaking, and in consultation with physicians, practitioners, and other stakeholders, specify applicable appropriate use criteria for applicable imaging services only from among appropriate use criteria developed or endorsed by national professional medical specialty societies or other provider-led entities.

(B) CONSIDERATIONS.—In specifying applicable appropriate use criteria under subparagraph (A), the Secretary shall take into account whether the criteria—

- (i) have stakeholder consensus;
- (ii) are scientifically valid and evidence based; and
- (iii) are based on studies that are published and reviewable by stakeholders.

(C) REVISIONS.—The Secretary shall review, on an annual basis, the specified applicable appropriate use criteria to determine if there is a need to update or revise (as appropriate) such specification of applicable appropriate use criteria and make such updates or revisions through rulemaking.

(D) TREATMENT OF MULTIPLE APPLICABLE APPROPRIATE USE CRITERIA.—In the case where the Secretary determines that more than one appropriate use criterion applies with respect to an applicable imaging service, the Secretary shall apply one or more applicable appropriate use criteria under this paragraph for the service.

(3) MECHANISMS FOR CONSULTATION WITH APPLICABLE APPROPRIATE USE CRITERIA.—

(A) IDENTIFICATION OF MECHANISMS TO CONSULT WITH APPLICABLE APPROPRIATE USE CRITERIA.—

(i) IN GENERAL.—The Secretary shall specify qualified clinical decision support mechanisms that could be used by ordering professionals to consult with applicable appropriate use criteria for applicable imaging services.

(ii) CONSULTATION.—The Secretary shall consult with physicians, practitioners, health care technology experts, and other stakeholders in specifying mechanisms under this paragraph.

(iii) INCLUSION OF CERTAIN MECHANISMS.—Mechanisms specified under this paragraph may include any or all of the following that meet the requirements described in subparagraph (B)(ii):

(I) Use of clinical decision support modules in certified EHR technology (as defined in section 1848(o)(4)).

(II) Use of private sector clinical decision support mechanisms that are independent from cer-

tified EHR technology, which may include use of clinical decision support mechanisms available from medical specialty organizations.

(III) Use of a clinical decision support mechanism established by the Secretary.

(B) QUALIFIED CLINICAL DECISION SUPPORT MECHANISMS.—

(i) IN GENERAL.—For purposes of this subsection, a qualified clinical decision support mechanism is a mechanism that the Secretary determines meets the requirements described in clause (ii).

(ii) REQUIREMENTS.—The requirements described in this clause are the following:

(I) The mechanism makes available to the ordering professional applicable appropriate use criteria specified under paragraph (2) and the supporting documentation for the applicable imaging service ordered.

(II) In the case where there is more than one applicable appropriate use criterion specified under such paragraph for an applicable imaging service, the mechanism indicates the criteria that it uses for the service.

(III) The mechanism determines the extent to which an applicable imaging service ordered is consistent with the applicable appropriate use criteria so specified.

(IV) The mechanism generates and provides to the ordering professional a certification or documentation that documents that the qualified clinical decision support mechanism was consulted by the ordering professional.

(V) The mechanism is updated on a timely basis to reflect revisions to the specification of applicable appropriate use criteria under such paragraph.

(VI) The mechanism meets privacy and security standards under applicable provisions of law.

(VII) The mechanism performs such other functions as specified by the Secretary, which may include a requirement to provide aggregate feedback to the ordering professional.

(C) LIST OF MECHANISMS FOR CONSULTATION WITH APPLICABLE APPROPRIATE USE CRITERIA.—

(i) INITIAL LIST.—Not later than April 1, 2016, the Secretary shall publish a list of mechanisms specified under this paragraph.

(ii) PERIODIC UPDATING OF LIST.—The Secretary shall identify on an annual basis the list of qualified clinical decision support mechanisms specified under this paragraph.

(4) CONSULTATION WITH APPLICABLE APPROPRIATE USE CRITERIA.—

(A) CONSULTATION BY ORDERING PROFESSIONAL.—Beginning with January 1, 2017, subject to subparagraph (C), with respect to an applicable imaging service ordered by

an ordering professional that would be furnished in an applicable setting and paid for under an applicable payment system (as defined in subparagraph (D)), an ordering professional shall—

(i) consult with a qualified decision support mechanism listed under paragraph (3)(C); and

(ii) provide to the furnishing professional the information described in clauses (i) through (iii) of subparagraph (B).

(B) REPORTING BY FURNISHING PROFESSIONAL.—Beginning with January 1, 2017, subject to subparagraph (C), with respect to an applicable imaging service furnished in an applicable setting and paid for under an applicable payment system (as defined in subparagraph (D)), payment for such service may only be made if the claim for the service includes the following:

(i) Information about which qualified clinical decision support mechanism was consulted by the ordering professional for the service.

(ii) Information regarding—

(I) whether the service ordered would adhere to the applicable appropriate use criteria specified under paragraph (2);

(II) whether the service ordered would not adhere to such criteria; or

(III) whether such criteria was not applicable to the service ordered.

(iii) The national provider identifier of the ordering professional (if different from the furnishing professional).

(C) EXCEPTIONS.—The provisions of subparagraphs (A) and (B) and paragraph (6)(A) shall not apply to the following:

(i) EMERGENCY SERVICES.—An applicable imaging service ordered for an individual with an emergency medical condition (as defined in section 1867(e)(1)).

(ii) INPATIENT SERVICES.—An applicable imaging service ordered for an inpatient and for which payment is made under part A.

(iii) SIGNIFICANT HARDSHIP.—An applicable imaging service ordered by an ordering professional who the Secretary may, on a case-by-case basis, exempt from the application of such provisions if the Secretary determines, subject to annual renewal, that consultation with applicable appropriate use criteria would result in a significant hardship, such as in the case of a professional who practices in a rural area without sufficient Internet access.

(D) APPLICABLE PAYMENT SYSTEM DEFINED.—In this subsection, the term “applicable payment system” means the following:

(i) The physician fee schedule established under section 1848(b).

(ii) The prospective payment system for hospital outpatient department services under section 1833(t).

(iii) The ambulatory surgical center payment systems under section 1833(i).

(5) IDENTIFICATION OF OUTLIER ORDERING PROFESSIONALS.—

(A) IN GENERAL.—With respect to applicable imaging services furnished beginning with 2017, the Secretary shall determine, on an annual basis, no more than five percent of the total number of ordering professionals who are outlier ordering professionals.

(B) OUTLIER ORDERING PROFESSIONALS.—The determination of an outlier ordering professional shall—

(i) be based on low adherence to applicable appropriate use criteria specified under paragraph (2), which may be based on comparison to other ordering professionals; and

(ii) include data for ordering professionals for whom prior authorization under paragraph (6)(A) applies.

(C) USE OF TWO YEARS OF DATA.—The Secretary shall use two years of data to identify outlier ordering professionals under this paragraph.

(D) PROCESS.—The Secretary shall establish a process for determining when an outlier ordering professional is no longer an outlier ordering professional.

(E) CONSULTATION WITH STAKEHOLDERS.—The Secretary shall consult with physicians, practitioners and other stakeholders in developing methods to identify outlier ordering professionals under this paragraph.

(6) PRIOR AUTHORIZATION FOR ORDERING PROFESSIONALS WHO ARE OUTLIERS.—

(A) IN GENERAL.—Beginning January 1, 2020, subject to paragraph (4)(C), with respect to services furnished during a year, the Secretary shall, for a period determined appropriate by the Secretary, apply prior authorization for applicable imaging services that are ordered by an outlier ordering professional identified under paragraph (5).

(B) APPROPRIATE USE CRITERIA IN PRIOR AUTHORIZATION.—In applying prior authorization under subparagraph (A), the Secretary shall utilize only the applicable appropriate use criteria specified under this subsection.

(C) FUNDING.—For purposes of carrying out this paragraph, the Secretary shall provide for the transfer, from the Federal Supplementary Medical Insurance Trust Fund under section 1841, of \$5,000,000 to the Centers for Medicare & Medicaid Services Program Management Account for each of fiscal years 2019 through 2021. Amounts transferred under the preceding sentence shall remain available until expended.

(7) CONSTRUCTION.—Nothing in this subsection shall be construed as granting the Secretary the authority to develop or initiate the development of clinical practice guidelines or appropriate use criteria.

(r) PAYMENT FOR RENAL DIALYSIS SERVICES FOR INDIVIDUALS WITH ACUTE KIDNEY INJURY.—

(1) PAYMENT RATE.—In the case of renal dialysis services (as defined in subparagraph (B) of section 1881(b)(14)) furnished under this part by a renal dialysis facility or provider of serv-

ices paid under such section during a year (beginning with 2017) to an individual with acute kidney injury (as defined in paragraph (2)), the amount of payment under this part for such services shall be the base rate for renal dialysis services determined for such year under such section, as adjusted by any applicable geographic adjustment factor applied under subparagraph (D)(iv)(II) of such section and may be adjusted by the Secretary (on a budget neutral basis for payments under this paragraph) by any other adjustment factor under subparagraph (D) of such section.

(2) INDIVIDUAL WITH ACUTE KIDNEY INJURY DEFINED.—In this subsection, the term “individual with acute kidney injury” means an individual who has acute loss of renal function and does not receive renal dialysis services for which payment is made under section 1881(b)(14).

(s) PAYMENT FOR APPLICABLE DISPOSABLE DEVICES.—

(1) SEPARATE PAYMENT.—The Secretary shall make a payment (separate from the payments otherwise made under section 1895) in the amount established under paragraph (3) to a home health agency for an applicable disposable device (as defined in paragraph (2)) when furnished on or after January 1, 2017, to an individual who receives home health services for which payment is made under section 1895(b).

(2) APPLICABLE DISPOSABLE DEVICE.—In this subsection, the term applicable disposable device means a disposable device that, as determined by the Secretary, is—

(A) a disposable negative pressure wound therapy device that is an integrated system comprised of a non-manual vacuum pump, a receptacle for collecting exudate, and dressings for the purposes of wound therapy; and

(B) a substitute for, and used in lieu of, a negative pressure wound therapy durable medical equipment item that is an integrated system of a negative pressure vacuum pump, a separate exudate collection canister, and dressings that would otherwise be covered for individuals for such wound therapy.

(3) PAYMENT AMOUNT.—The separate payment amount established under this paragraph for an applicable disposable device for a year shall be equal to the amount of the payment that would be made under section 1833(t) (relating to payment for covered OPD services) for the year for the Level I Healthcare Common Procedure Coding System (HCPCS) code for which the description for a professional service includes the furnishing of such device.

(t) SITE-OF-SERVICE PRICE TRANSPARENCY.—

(1) IN GENERAL.—In order to facilitate price transparency with respect to items and services for which payment may be made either to a hospital outpatient department or to an ambulatory surgical center under this title, the Secretary shall, for 2018 and each year thereafter, make available to the public via a searchable Internet website, with respect to an appropriate number of such items and services—

(A) the estimated payment amount for the item or service under the outpatient department fee schedule under subsection (t) of section 1833 and the ambulatory surgical

center payment system under subsection (i) of such section; and

(B) the estimated amount of beneficiary liability applicable to the item or service.

(2) CALCULATION OF ESTIMATED BENEFICIARY LIABILITY.—For purposes of paragraph (1)(B), the estimated amount of beneficiary liability, with respect to an item or service, is the amount for such item or service for which an individual who does not have coverage under a Medicare supplemental policy certified under section 1882 or any other supplemental insurance coverage is responsible.

(3) IMPLEMENTATION.—In carrying out this subsection, the Secretary—

(A) shall include in the notice described in section 1804(a) a notification of the availability of the estimated amounts made available under paragraph (1); and

(B) may utilize mechanisms in existence on the date of enactment of this subsection, such as the portion of the Internet website of the Centers for Medicare & Medicaid Services on which information comparing physician performance is posted (commonly referred to as the Physician Compare Internet website), to make available such estimated amounts under such paragraph.

(4) FUNDING.—For purposes of implementing this subsection, the Secretary shall provide for the transfer, from the Federal Supplementary Medical Insurance Trust Fund under section 1841 to the Centers for Medicare & Medicaid Services Program Management Account, of \$6,000,000 for fiscal year 2017, to remain available until expended.

(u) PAYMENT AND RELATED REQUIREMENTS FOR HOME INFUSION THERAPY.—

(1) PAYMENT.—

(A) SINGLE PAYMENT.—

(i) IN GENERAL.—Subject to clause (iii) and subparagraphs (B) and (C), the Secretary shall implement a payment system under which a single payment is made under this title to a qualified home infusion therapy supplier for items and services described in subparagraphs (A) and (B) of section 1861(iii)(2) furnished by a qualified home infusion therapy supplier (as defined in section 1861(iii)(3)(D)) in coordination with the furnishing of home infusion drugs (as defined in section 1861(iii)(3)(C)) under this part.

(ii) UNIT OF SINGLE PAYMENT.—A unit of single payment under the payment system implemented under this subparagraph is for each infusion drug administration calendar day in the individual's home. The Secretary shall, as appropriate, establish single payment amounts for types of infusion therapy, including to take into account variation in utilization of nursing services by therapy type.

(iii) LIMITATION.—The single payment amount determined under this subparagraph after application of subparagraph (B) and paragraph (3) shall not exceed the amount determined under the fee schedule under

section 1848 for infusion therapy services furnished in a calendar day if furnished in a physician office setting, except such single payment shall not reflect more than 5 hours of infusion for a particular therapy in a calendar day.

(B) REQUIRED ADJUSTMENTS.—The Secretary shall adjust the single payment amount determined under subparagraph (A) for home infusion therapy services under section 1861(iii)(1) to reflect other factors such as—

- (i) a geographic wage index and other costs that may vary by region; and
- (ii) patient acuity and complexity of drug administration.

(C) DISCRETIONARY ADJUSTMENTS.—

(i) IN GENERAL.—Subject to clause (ii), the Secretary may adjust the single payment amount determined under subparagraph (A) (after application of subparagraph (B)) to reflect outlier situations and other factors as the Secretary determines appropriate.

(ii) REQUIREMENT OF BUDGET NEUTRALITY.—Any adjustment under this subparagraph shall be made in a budget neutral manner.

(2) CONSIDERATIONS.—In developing the payment system under this subsection, the Secretary may consider the costs of furnishing infusion therapy in the home, consult with home infusion therapy suppliers, consider payment amounts for similar items and services under this part and part A, and consider payment amounts established by Medicare Advantage plans under part C and in the private insurance market for home infusion therapy (including average per treatment day payment amounts by type of home infusion therapy).

(3) ANNUAL UPDATES.—

(A) IN GENERAL.—Subject to subparagraph (B), the Secretary shall update the single payment amount under this subsection from year to year beginning in 2022 by increasing the single payment amount from the prior year by 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 preceding year.

(B) ADJUSTMENT.—For each year, the Secretary shall reduce the percentage increase described in subparagraph (A) by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II). The application of the preceding sentence may result in a percentage being less than 0.0 for a year, and may result in payment being less than such payment rates for the preceding year.

(4) AUTHORITY TO APPLY PRIOR AUTHORIZATION.—The Secretary may, as determined appropriate by the Secretary, apply prior authorization for home infusion therapy services under section 1861(iii)(1).

(5) ACCREDITATION OF QUALIFIED HOME INFUSION THERAPY SUPPLIERS.—

(A) FACTORS FOR DESIGNATION OF ACCREDITATION ORGANIZATIONS.—The Secretary shall consider the following factors in designating accreditation organizations under sub-

paragraph (B) and in reviewing and modifying the list of accreditation organizations designated pursuant to subparagraph (C):

(i) The ability of the organization to conduct timely reviews of accreditation applications.

(ii) The ability of the organization to take into account the capacities of suppliers located in a rural area (as defined in section 1886(d)(2)(D)).

(iii) Whether the organization has established reasonable fees to be charged to suppliers applying for accreditation.

(iv) Such other factors as the Secretary determines appropriate.

(B) DESIGNATION.—Not later than January 1, 2021, the Secretary shall designate organizations to accredit suppliers furnishing home infusion therapy. The list of accreditation organizations so designated may be modified pursuant to subparagraph (C).

(C) REVIEW AND MODIFICATION OF LIST OF ACCREDITATION ORGANIZATIONS.—

(i) IN GENERAL.—The Secretary shall review the list of accreditation organizations designated under subparagraph (B) taking into account the factors under subparagraph (A). Taking into account the results of such review, the Secretary may, by regulation, modify the list of accreditation organizations designated under subparagraph (B).

(ii) SPECIAL RULE FOR ACCREDITATIONS DONE PRIOR TO REMOVAL FROM LIST OF DESIGNATED ACCREDITATION ORGANIZATIONS.—In the case where the Secretary removes an organization from the list of accreditation organizations designated under subparagraph (B), any supplier that is accredited by the organization during the period beginning on the date on which the organization is designated as an accreditation organization under subparagraph (B) and ending on the date on which the organization is removed from such list shall be considered to have been accredited by an organization designated by the Secretary under subparagraph (B) for the remaining period such accreditation is in effect.

(D) RULE FOR ACCREDITATIONS MADE PRIOR TO DESIGNATION.—In the case of a supplier that is accredited before January 1, 2021, by an accreditation organization designated by the Secretary under subparagraph (B) as of January 1, 2019, such supplier shall be considered to have been accredited by an organization designated by the Secretary under such paragraph as of January 1, 2023, for the remaining period such accreditation is in effect.

(6) NOTIFICATION OF INFUSION THERAPY OPTIONS AVAILABLE PRIOR TO FURNISHING HOME INFUSION THERAPY.—Prior to the furnishing of home infusion therapy to an individual, the physician who establishes the plan described in section 1861(iii)(1) for the individual shall provide notification (in a form, manner, and frequency determined appropriate by the Secretary) of the

options available (such as home, physician's office, hospital outpatient department) for the furnishing of infusion therapy under this part.

(7) *HOME INFUSION THERAPY SERVICES TEMPORARY TRANSITIONAL PAYMENT.*—

(A) *TEMPORARY TRANSITIONAL PAYMENT.*—

(i) *IN GENERAL.*—*The Secretary shall, in accordance with the payment methodology described in subparagraph (B) and subject to the provisions of this paragraph, provide a home infusion therapy services temporary transitional payment under this part to an eligible home infusion supplier (as defined in subparagraph (F)) for items and services described in subparagraphs (A) and (B) of section 1861(ii)(2) furnished during the period specified in clause (ii) by such supplier in coordination with the furnishing of transitional home infusion drugs (as defined in clause (iii)).*

(ii) *PERIOD SPECIFIED.*—*For purposes of clause (i), the period specified in this clause is the period beginning on January 1, 2019, and ending on the day before the date of the implementation of the payment system under paragraph (1)(A).*

(iii) *TRANSITIONAL HOME INFUSION DRUG DEFINED.*—*For purposes of this paragraph, the term “transitional home infusion drug” has the meaning given to the term “home infusion drug” under section 1861(ii)(3)(C), except that clause (ii) of such section shall not apply if a drug described in such clause is identified in clauses (i), (ii), (iii) or (iv) of subparagraph (C) as of the date of the enactment of this paragraph.*

(B) *PAYMENT METHODOLOGY.*—*For purposes of this paragraph, the Secretary shall establish a payment methodology, with respect to items and services described in subparagraph (A)(i). Under such payment methodology the Secretary shall—*

(i) *create the three payment categories described in clauses (i), (ii), and (iii) of subparagraph (C);*

(ii) *assign drugs to such categories, in accordance with such clauses;*

(iii) *assign appropriate Healthcare Common Procedure Coding System (HCPCS) codes to each payment category; and*

(iv) *establish a single payment amount for each such payment category, in accordance with subparagraph (D), for each infusion drug administration calendar day in the individual's home for drugs assigned to such category.*

(C) *PAYMENT CATEGORIES.*—

(i) *PAYMENT CATEGORY 1.*—*The Secretary shall create a payment category 1 and assign to such category drugs which are covered under the Local Coverage Determination on External Infusion Pumps (LCD number L33794) and billed with the following HCPCS codes (as identified as of July 1, 2017, and as subsequently modified by the Secretary): J0133, J0285, J0287,*

J0288, J0289, J0895, J1170, J1250, J1265, J1325, J1455, J1457, J1570, J2175, J2260, J2270, J2274, J2278, J3010, or J3285.

(ii) PAYMENT CATEGORY 2.—The Secretary shall create a payment category 2 and assign to such category drugs which are covered under such local coverage determination and billed with the following HCPCS codes (as identified as of July 1, 2017, and as subsequently modified by the Secretary): J1559 JB, J1561 JB, J1562 JB, J1569 JB, or J1575 JB.

(iii) PAYMENT CATEGORY 3.—The Secretary shall create a payment category 3 and assign to such category drugs which are covered under such local coverage determination and billed with the following HCPCS codes (as identified as of July 1, 2017, and as subsequently modified by the Secretary): J9000, J9039, J9040, J9065, J9100, J9190, J9200, J9360, or J9370.

(iv) INFUSION DRUGS NOT OTHERWISE INCLUDED.—With respect to drugs that are not included in payment category 1, 2, or 3 under clause (i), (ii), or (iii), respectively, the Secretary shall assign to the most appropriate of such categories, as determined by the Secretary, drugs which are—

(I) covered under such local coverage determination and billed under HCPCS codes J7799 or J7999 (as identified as of July 1, 2017, and as subsequently modified by the Secretary); or

(II) billed under any code that is implemented after the date of the enactment of this paragraph and included in such local coverage determination or included in subregulatory guidance as a home infusion drug described in subparagraph (A)(i).

(D) PAYMENT AMOUNTS.—

(i) IN GENERAL.—Under the payment methodology, the Secretary shall pay eligible home infusion suppliers, with respect to items and services described in subparagraph (A)(i) furnished during the period described in subparagraph (A)(ii) by such supplier to an individual, at amounts equal to the amounts determined under the physician fee schedule established under section 1848 for services furnished during the year for codes and units of such codes described in clauses (ii), (iii), and (iv) with respect to drugs included in the payment category under subparagraph (C) specified in the respective clause, determined without application of any adjustment under such section.

(ii) PAYMENT AMOUNT FOR CATEGORY 1.—For purposes of clause (i), the codes and units described in this clause, with respect to drugs included in payment category 1 described in subparagraph (C)(i), are one unit of HCPCS code 96365 plus four units of HCPCS code 96366 (as identified as of July 1, 2017, and as subsequently modified by the Secretary).

(iii) PAYMENT AMOUNT FOR CATEGORY 2.—For purposes of clause (i), the codes and units described in this

clause, with respect to drugs included in payment category 2 described in subparagraph (C)(i), are one unit of HCPCS code 96369 plus four units of HCPCS code 96370 (as identified as of July 1, 2017, and as subsequently modified by the Secretary).

(iv) PAYMENT AMOUNT FOR CATEGORY 3.—For purposes of clause (i), the codes and units described in this clause, with respect to drugs included in payment category 3 described in subparagraph (C)(i), are one unit of HCPCS code 96413 plus four units of HCPCS code 96415 (as identified as of July 1, 2017, and as subsequently modified by the Secretary).

(E) CLARIFICATIONS.—

(i) INFUSION DRUG ADMINISTRATION DAY.—For purposes of this subsection, a reference, with respect to the furnishing of transitional home infusion drugs or home infusion drugs to an individual by an eligible home infusion supplier, to payment to such supplier for an infusion drug administration calendar day in the individual's home shall refer to payment only for the date on which professional services (as described in section 1861(iii)(2)(A)) were furnished to administer such drugs to such individual. For purposes of the previous sentence, an infusion drug administration calendar day shall include all such drugs administered to such individual on such day.

(ii) TREATMENT OF MULTIPLE DRUGS ADMINISTERED ON SAME INFUSION DRUG ADMINISTRATION DAY.—In the case that an eligible home infusion supplier, with respect to an infusion drug administration calendar day in an individual's home, furnishes to such individual transitional home infusion drugs which are not all assigned to the same payment category under subparagraph (C), payment to such supplier for such infusion drug administration calendar day in the individual's home shall be a single payment equal to the amount of payment under this paragraph for the drug, among all such drugs so furnished to such individual during such calendar day, for which the highest payment would be made under this paragraph.

(F) ELIGIBLE HOME INFUSION SUPPLIERS.—In this paragraph, the term "eligible home infusion supplier" means a supplier that is enrolled under this part as a pharmacy that provides external infusion pumps and external infusion pump supplies and that maintains all pharmacy licensure requirements in the State in which the applicable infusion drugs are administered.

(G) IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary may implement this paragraph by program instruction or otherwise.

* * * * *

PROVISIONS RELATING TO THE ADMINISTRATION OF PART B

SEC. 1842. (a) The administration of this part shall be conducted through contracts with medicare administrative contractors under section 1874A.

(b)

(2)

(C) In the case of residents of nursing facilities who receive services described in clause (i) or (ii) of section 1861(s)(2)(K) performed by a member of a team, the Secretary shall instruct medicare administrative contractors to develop mechanisms which permit routine payment under this part for up to 1.5 visits per month per resident. In the previous sentence, the term "team" refers to a physician and includes a physician assistant acting under the supervision of the physician or a nurse practitioner working in collaboration with that physician, or both.

(3) The Secretary—

(A) shall take such action as may be necessary to assure that, where payment under this part for a service is on a cost basis, the cost is reasonable cost (as determined under section 1861(v));

(B) shall take such action as may be necessary to assure that, where payment under this part for a service is on a charge basis, such charge will be reasonable and not higher than the charge applicable, for a comparable service and under comparable circumstances, to the policyholders and subscribers of the medicare administrative contractor, and such payment will (except as otherwise provided in section 1870(f)) be made—

(i) on the basis of an itemized bill; or

(ii) on the basis of an assignment under the terms of which (I) the reasonable charge is the full charge for the service, (II) the physician or other person furnishing such service agrees not to charge (and to refund amounts already collected) for services for which payment under this title is denied under section 1154(a)(2) by reason of a determination under section 1154(a)(1)(B), and (III) the physician or other person furnishing such service agrees not to charge (and to refund amounts already collected) for such service if payment may not be made therefor by reason of the provisions of paragraph (1) of section 1862(a), and if the individual to whom such service was furnished was without fault in incurring the expenses of such service, and if the Secretary's determination that payment (pursuant to such assignment) was incorrect and was made subsequent to the third year following the year in which notice of such payment was sent to such individual; except that the Secretary may reduce such three-year period to not less than one year if he finds such reduction is consistent with the objectives of this title (except in the case of physicians' services and ambulance service furnished as described in section 1862(a)(4), other than for purposes of section 1870(f));

but (in the case of bills submitted, or requests for payment made, after March 1968) only if the bill is submitted, or a written request for payment is made in such other form as may be

permitted under regulations, no later than the period ending 1 calendar year after the date of service;

(F) shall take such action as may be necessary to assure that where payment under this part for a service rendered is on a charge basis, such payment shall be determined on the basis of the charge that is determined in accordance with this section on the basis of customary and prevailing charge levels in effect at the time the service was rendered or, in the case of services rendered more than 12 months before the year in which the bill is submitted or request for payment is made, on the basis of such levels in effect for the 12-month period preceding such year;

(G) shall, for a service that is furnished with respect to an individual enrolled under this part, that is not paid on an assignment-related basis, and that is subject to a limiting charge under section 1848(g)—

(i) determine, prior to making payment, whether the amount billed for such service exceeds the limiting charge applicable under section 1848(g)(2);

(ii) notify the physician, supplier, or other person periodically (but not less often than once every 30 days) of determinations that amounts billed exceeded such applicable limiting charges; and

(iii) provide for prompt response to inquiries of physicians, suppliers, and other persons concerning the accuracy of such limiting charges for their services;

(H) shall implement—

(i) programs to recruit and retain physicians as participating physicians in the area served by the medicare administrative contractor, including educational and outreach activities and the use of professional relations personnel to handle billing and other problems relating to payment of claims of participating physicians; and

(ii) programs to familiarize beneficiaries with the participating physician program and to assist such beneficiaries in locating participating physicians;

(L) shall monitor and profile physicians' billing patterns within each area or locality and provide comparative data to physicians whose utilization patterns vary significantly from other physicians in the same payment area or locality.

In determining the reasonable charge for services for purposes of this paragraph, there shall be taken into consideration the customary charges for similar services generally made by the physician or other person furnishing such services, as well as the prevailing charges in the locality for similar services. No charge may be determined to be reasonable in the case of bills submitted or requests for payment made under this part after December 31, 1970, if it exceeds the higher of (i) the prevailing charge recognized by the carrier and found acceptable by the Secretary for similar services in the same locality in administering this part on December 31, 1970, or (ii) the prevailing charge level that, on the basis of statistical data and methodology acceptable to the Secretary, would cover 75 percent of the customary charges made for similar services in the same locality during the 12-month period ending on the June 30 last preceding the start of the calendar year in which the

service is rendered. In the case of physicians' services the prevailing charge level determined for purposes of clause (ii) of the preceding sentence for any twelve-month period (beginning after June 30, 1973) specified in clause (ii) of such sentence may not exceed (in the aggregate) the level determined under such clause for the fiscal year ending June 30, 1973, or (with respect to physicians' services furnished in a year after 1987) the level determined under this sentence (or under any other provision of law affecting the prevailing charge level) for the previous year except to the extent that the Secretary finds, on the basis of appropriate economic index data, that such higher level is justified by year-to-year economic changes. With respect to power-operated wheelchairs for which payment may be made in accordance with section 1861(s)(6), charges determined to be reasonable may not exceed the lowest charge at which power-operated wheelchairs are available in the locality. In the case of medical services, supplies, and equipment (including equipment servicing) that, in the judgment of the Secretary, do not generally vary significantly in quality from one supplier to another, the charges incurred after December 31, 1972, determined to be reasonable may not exceed the lowest charge levels at which such services, supplies, and equipment are widely and consistently available in a locality except to the extent and under the circumstances specified by the Secretary. The requirement in subparagraph (B) that a bill be submitted or request for payment be made by the close of the following calendar year shall not apply if (I) failure to submit the bill or request the payment by the close of such year is due to the error or misrepresentation of an officer, employee, fiscal intermediary, carrier, medicare administrative contractor, or agent of the Department of Health and Human Services performing functions under this title and acting within the scope of his or its authority, and (II) the bill is submitted or the payment is requested promptly after such error or misrepresentation is eliminated or corrected. Notwithstanding the provisions of the third and fourth sentences preceding this sentence, the prevailing charge level in the case of a physician service in a particular locality determined pursuant to such third and fourth sentences for any calendar year after 1974 shall, if lower than the prevailing charge level for the fiscal year ending June 30, 1975, in the case of a similar physician service in the same locality by reason of the application of economic index data, be raised to such prevailing charge level for the fiscal year ending June 30, 1975, and shall remain at such prevailing charge level until the prevailing charge for a year (as adjusted by economic index data) equals or exceeds such prevailing charge level. The amount of any charges for outpatient services which shall be considered reasonable shall be subject to the limitations established by regulations issued by the Secretary pursuant to section 1861(v)(1)(K), and in determining the reasonable charge for such services, the Secretary may limit such reasonable charge to a percentage of the amount of the prevailing charge for similar services furnished in a physician's office, taking into account the extent to which overhead costs associated with such outpatient services have been included in the reasonable cost or charge of the facility. In applying subparagraph (B), the Secretary may specify exceptions to the 1 calendar year period specified in such subparagraph.

(4)(A)(i) In determining the prevailing charge levels under the third and fourth sentences of paragraph (3) for physicians' services furnished during the 15-month period beginning July 1, 1984, the Secretary shall not set any level higher than the same level as was set for the 12-month period beginning July 1, 1983.

(ii)(I) In determining the prevailing charge levels under the third and fourth sentences of paragraph (3) for physicians' services furnished during the 8-month period beginning May 1, 1986, by a physician who is not a participating physician (as defined in subsection (h)(1)) at the time of furnishing the services, the Secretary shall not set any level higher than the same level as was set for the 12-month period beginning July 1, 1983.

(II) In determining the prevailing charge levels under the fourth sentence of paragraph (3) for physicians' services furnished during the 8-month period beginning May 1, 1986, by a physician who is a participating physician (as defined in subsection (h)(1)) at the time of furnishing the services, the Secretary shall permit an additional one percentage point increase in the increase otherwise permitted under that sentence.

(iii) In determining the maximum allowable prevailing charges which may be recognized consistent with the index described in the fourth sentence of paragraph (3) for physicians' services furnished on or after January 1, 1987, by participating physicians, the Secretary shall treat the maximum allowable prevailing charges recognized as of December 31, 1986, under such sentence with respect to participating physicians as having been justified by economic changes.

(iv) The reasonable charge for physicians' services furnished on or after January 1, 1987, and before January 1, 1992, by a non-participating physician shall be no greater than the applicable percent of the prevailing charge levels established under the third and fourth sentences of paragraph (3) (or under any other applicable provision of law affecting the prevailing charge level). In the previous sentence, the term "applicable percent" means for services furnished (I) on or after January 1, 1987, and before April 1, 1988, 96 percent, (II) on or after April 1, 1988, and before January 1, 1989, 95.5 percent, and (III) on or after January 1, 1989, 95 percent.

(v) In determining the prevailing charge levels under the third and fourth sentences of paragraph (3) for physicians' services furnished during the 3-month period beginning January 1, 1988, the Secretary shall not set any level higher than the same level as was set for the 12-month period beginning January 1, 1987.

(vi) Before each year (beginning with 1989), the Secretary shall establish a prevailing charge floor for primary care services (as defined in subsection (i)(4)) equal to 60 percent of the estimated average prevailing charge levels based on the best available data (determined, under the third and fourth sentences of paragraph (3) and under paragraph (4), without regard to this clause and without regard to physician specialty) for such service for all localities in the United States (weighted by the relative frequency of the service in each locality) for the year.

(vii) Beginning with 1987, the percentage increase in the MEI (as defined in subsection (i)(3)) for each year shall be the same for non-participating physicians as for participating physicians.

(B)(i) In determining the reasonable charge under paragraph (3) for physicians' services furnished during the 15-month period beginning July 1, 1984, the customary charges shall be the same customary charges as were recognized under this section for the 12-month period beginning July 1, 1983.

(ii) In determining the reasonable charge under paragraph (3) for physicians' services furnished during the 8-month period beginning May 1, 1986, by a physician who is not a participating physician (as defined in subsection (h)(1)) at the time of furnishing the services—

(I) if the physician was not a participating physician at any time during the 12-month period beginning on October 1, 1984, the customary charges shall be the same customary charges as were recognized under this section for the 12-month period beginning July 1, 1983, and

(II) if the physician was a participating physician at any time during the 12-month period beginning on October 1, 1984, the physician's customary charges shall be determined based upon the physician's actual charges billed during the 12-month period ending on March 31, 1985.

(iii) In determining the reasonable charge under paragraph (3) for physicians' services furnished during the 3-month period beginning January 1, 1988, the customary charges shall be the same customary charges as were recognized under this section for the 12-month period beginning January 1, 1987.

(iv) In determining the reasonable charge under paragraph (3) for physicians' services (other than primary care services, as defined in subsection (i)(4)) furnished during 1991, the customary charges shall be the same customary charges as were recognized under this section for the 9-month period beginning April 1, 1990. In a case in which subparagraph (F) applies (relating to new physicians) so as to limit the customary charges of a physician during 1990 to a percent of prevailing charges, the previous sentence shall not prevent such limit on customary charges under such subparagraph from increasing in 1991 to a higher percent of such prevailing charges.

(C) In determining the prevailing charge levels under the third and fourth sentences of paragraph (3) for physicians' services furnished during periods beginning after September 30, 1985, the Secretary shall treat the level as set under subparagraph (A)(i) as having fully provided for the economic changes which would have been taken into account but for the limitations contained in subparagraph (A)(i).

(D)(i) In determining the customary charges for physicians' services furnished during the 8-month period beginning May 1, 1986, or the 12-month period beginning January 1, 1987, by a physician who was not a participating physician (as defined in subsection (h)(1)) on September 30, 1985, the Secretary shall not recognize increases in actual charges for services furnished during the 15-month period beginning on July 1, 1984, above the level of the physician's actual charges billed in the 3-month period ending on June 30, 1984.

(ii) In determining the customary charges for physicians' services furnished during the 12-month period beginning January 1, 1987, by a physician who is not a participating physician (as defined in

subsection (h)(1) on April 30, 1986, the Secretary shall not recognize increases in actual charges for services furnished during the 7-month period beginning on October 1, 1985, above the level of the physician's actual charges billed during the 3-month period ending on June 30, 1984.

(iii) In determining the customary charges for physicians' services furnished during the 12-month period beginning January 1, 1987, or January 1, 1988, by a physician who is not a participating physician (as defined in subsection (h)(1)) on December 31, 1986, the Secretary shall not recognize increases in actual charges for services furnished during the 8-month period beginning on May 1, 1986, above the level of the physician's actual charges billed during the 3-month period ending on June 30, 1984.

(iv) In determining the customary charges for a physicians' service furnished on or after January 1, 1988, if a physician was a non-participating physician in a previous year (beginning with 1987), the Secretary shall not recognize any amount of such actual charges (for that service furnished during such previous year) that exceeds the maximum allowable actual charge for such service established under subsection (j)(1)(C).

(E)(i) For purposes of this part for physicians' services furnished in 1987, the percentage increase in the MEI is 3.2 percent.

(ii) For purposes of this part for physicians' services furnished in 1988, on or after April 1, the percentage increase in the MEI is—

(I) 3.6 percent for primary care services (as defined in subsection (i)(4)), and

(II) 1 percent for other physicians' services.

(iii) For purposes of this part for physicians' services furnished in 1989, the percentage increase in the MEI is—

(I) 3.0 percent for primary care services, and

(II) 1 percent for other physicians' services.

(iv) For purposes of this part for items and services furnished in 1990, after March 31, 1990, the percentage increase in the MEI is—

(I) 0 percent for radiology services, for anesthesia services, and for other services specified in the list referred to in paragraph (14)(C)(i),

(II) 2 percent for other services (other than primary care services), and

(III) such percentage increase in the MEI (as defined in subsection (i)(3)) as would be otherwise determined for primary care services (as defined in subsection (i)(4)).

(v) For purposes of this part for items and services furnished in 1991, the percentage increase in the MEI is—

(I) 0 percent for services (other than primary care services), and

(II) 2 percent for primary care services (as defined in subsection (i)(4)).

(6) No payment under this part for a service provided to any individual shall (except as provided in section 1870) be made to any other than such individual or (pursuant to an assignment described in subparagraph (B)(ii) of paragraph (3)) the physician or other person who provided the service, except that (A) payment may be made (i) to the employer of such physician or other person if such physician or other person is required as a condition of his

employment to turn over his fee for such service to his employer, 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) payment may be made to an entity (i) which provides coverage of the services under a health benefits plan, but only to the extent that payment is not made under this part, (ii) which has paid the person who provided the service an amount (including the amount payable under this part) which that person has accepted as payment in full for the service, and (iii) to which the individual has agreed in writing that payment may be made under this part, (C) in the case of services described in clause (i) of section 1861(s)(2)(K), payment shall be made to either (i) the employer of the physician assistant involved, or (ii) with respect to a physician assistant who was the owner of a rural health clinic (as described in section 1861(aa)(2)) for a continuous period beginning prior to the date of the enactment of the Balanced Budget Act of 1997 and ending on the date that the Secretary determines such rural health clinic no longer meets the requirements of section 1861(aa)(2), payment may be made directly to the physician assistant, (D) payment may be made to a physician for physicians' services (and services furnished incident to such services) furnished by a second physician to patients of the first physician if (i) the first physician is unavailable to provide the services; (ii) the services are furnished pursuant to an arrangement between the two physicians that (I) is informal and reciprocal, or (II) involves per diem or other fee-for-time compensation for such services; (iii) the services are not provided by the second physician over a continuous period of more than 60 days or are provided over a longer continuous period during all of which the first physician has been called or ordered to active duty as a member of a reserve component of the Armed Forces; and (iv) the claim form submitted to the medicare administrative contractor for such services includes the second physician's unique identifier (provided under the system established under subsection (r)) and indicates that the claim meets the requirements of this subparagraph for payment to the first physician, (E) in the case of an item or service (other than services described in section 1888(e)(2)(A)(ii)) furnished by, or under arrangements made by, a skilled nursing facility to an individual who (at the time the item or service is furnished) is a resident of a skilled nursing facility, payment shall be made to the facility, (F) in the case of home health services (including medical supplies described in section 1861(m)(5), but excluding durable medical equipment to the extent provided for in such section) furnished to an individual who (at the time the item or service is furnished) is under a plan of care of a home health agency, payment shall be made to the agency (without regard to whether or not the item or service was furnished by the agency, by others under arrangement with them made by the agency, or when any other contracting or consulting arrangement, or otherwise), (G) in the case of services in a hospital or clinic to which section 1880(e) applies, payment shall be made to such hospital or clinic, (H) in the case of services described in section 1861(aa)(3) that are furnished by a health care professional under

contract with a Federally qualified health center, payment shall be made to the center, (I) in the case of home infusion therapy, payment shall be made to the qualified home infusion therapy supplier or, *in the case of items and services described in clause (i) of section 1834(u)(7)(A) furnished to an individual during the period described in clause (ii) of such section, payment shall be made to the eligible home infusion therapy supplier*, and (J) in the case of outpatient physical therapy services furnished by physical therapists in a health professional shortage area (as defined in section 332(a)(1)(A) of the Public Health Service Act), a medically underserved area (as designated pursuant to section 330(b)(3)(A) of such Act), or a rural area (as defined in section 1886(d)(2)(D)), subparagraph (D) of this sentence shall apply to such services and therapists in the same manner as such subparagraph applies to physicians' services furnished by physicians. No payment which under the preceding sentence may be made directly to the physician or other person providing the service involved (pursuant to an assignment described in subparagraph (B)(ii) of paragraph (3)) shall be made to anyone else under a reassignment or power of attorney (except to an employer or entity as described in subparagraph (A) of such sentence); but nothing in this subsection shall be construed (i) to prevent the making of such a payment in accordance with an assignment from the individual to whom the service was provided or a reassignment from the physician or other person providing such service if such assignment or reassignment is made to a governmental agency or entity or is established by or pursuant to the order of a court of competent jurisdiction, or (ii) to preclude an agent of the physician or other person providing the service from receiving any such payment if (but only if) such agent does so pursuant to an agency agreement under which the compensation to be paid to the agent for his services for or in connection with the billing or collection of payments due such physician or other person under this title is unrelated (directly or indirectly) to the amount of such payments or the billings therefor, and is not dependent upon the actual collection of any such payment. For purposes of subparagraph (C) of the first sentence of this paragraph, an employment relationship may include any independent contractor arrangement, and employer status shall be determined in accordance with the law of the State in which the services described in such clause are performed.

(7)(A) In the case of physicians' services furnished to a patient in a hospital with a teaching program approved as specified in section 1861(b)(6) but which does not meet the conditions described in section 1861(b)(7), the Secretary shall not provide (except on the basis described in subparagraph (C)) for payment for such services under this part—

(i) unless—

(I) the physician renders sufficient personal and identifiable physicians' services to the patient to exercise full, personal control over the management of the portion of the case for which the payment is sought,

(II) the services are of the same character as the services the physician furnishes to patients not entitled to benefits under this title, and

- (III) at least 25 percent of the hospital's patients (during a representative past period, as determined by the Secretary) who were not entitled to benefits under this title and who were furnished services described in subclauses (I) and (II) paid all or a substantial part of charges (other than nominal charges) imposed for such services; and
- (ii) to the extent that the payment is based upon a reasonable charge for the services in excess of the customary charge as determined in accordance with subparagraph (B).
- (B) The customary charge for such services in a hospital shall be determined in accordance with regulations issued by the Secretary and taking into account the following factors:
- (i) In the case of a physician who is not a teaching physician (as defined by the Secretary), the Secretary shall take into account the amounts the physician charges for similar services in the physician's practice outside the teaching setting.
- (ii) In the case of a teaching physician, if the hospital, its physicians, or other appropriate billing entity has established one or more schedules of charges which are collected for medical and surgical services, the Secretary shall base payment under this title on the greatest of—
- (I) the charges (other than nominal charges) which are most frequently collected in full or substantial part with respect to patients who were not entitled to benefits under this title and who were furnished services described in subclauses (I) and (II) of subparagraph (A)(i),
- (II) the mean of the charges (other than nominal charges) which were collected in full or substantial part with respect to such patients, or
- (III) 85 percent of the prevailing charges paid for similar services in the same locality.
- (iii) If all the teaching physicians in a hospital agree to have payment made for all of their physicians' services under this part furnished to patients in such hospital on an assignment-related basis, the customary charge for such services shall be equal to 90 percent of the prevailing charges paid for similar services in the same locality.
- (C) In the case of physicians' services furnished to a patient in a hospital with a teaching program approved as specified in section 1861(b)(6) but which does not meet the conditions described in section 1861(b)(7), if the conditions described in subclauses (I) and (II) of subparagraph (A)(i) are met and if the physician elects payment to be determined under this subparagraph, the Secretary shall provide for payment for such services under this part on the basis of regulations of the Secretary governing reimbursement for the services of hospital-based physicians (and not on any other basis).
- (D)(i) In the case of physicians' services furnished to a patient in a hospital with a teaching program approved as specified in section 1861(b)(6) but which does not meet the conditions described in section 1861(b)(7), no payment shall be made under this part for services of assistants at surgery with respect to a surgical procedure if such hospital has a training program relating to the medical specialty required for such surgical procedure and a qualified individual on the staff of the hospital is available to provide such services; except that payment may be made under this part for such

services, to the extent that such payment is otherwise allowed under this paragraph, if such services, as determined under regulations of the Secretary—

(I) are required due to exceptional medical circumstances,

(II) are performed by team physicians needed to perform complex medical procedures, or

(III) constitute concurrent medical care relating to a medical condition which requires the presence of, and active care by, a physician of another specialty during surgery,

and under such other circumstances as the Secretary determines by regulation to be appropriate.

(ii) For purposes of this subparagraph, the term “assistant at surgery” means a physician who actively assists the physician in charge of a case in performing a surgical procedure.

(iii) The Secretary shall determine appropriate methods of reimbursement of assistants at surgery where such services are reimbursable under this part.

(8)(A)(i) The Secretary shall by regulation—

(I) describe the factors to be used in determining the cases (of particular items or services) in which the application of this title to payment under this part (other than to physicians’ services paid under section 1848) results in the determination of an amount that, because of its being grossly excessive or grossly deficient, is not inherently reasonable, and

(II) provide in those cases for the factors to be considered in determining an amount that is realistic and equitable.

(ii) Notwithstanding the determination made in clause (i), the Secretary may not apply factors that would increase or decrease the payment under this part during any year for any particular item or service by more than 15 percent from such payment during the preceding year except as provided in subparagraph (B).

(B) The Secretary may make a determination under this subparagraph that would result in an increase or decrease under subparagraph (A) of more than 15 percent of the payment amount for a year, but only if—

(i) the Secretary’s determination takes into account the factors described in subparagraph (C) and any additional factors the Secretary determines appropriate,

(ii) the Secretary’s determination takes into account the potential impacts described in subparagraph (D), and

(iii) the Secretary complies with the procedural requirements of paragraph (9).

(C) The factors described in this subparagraph are as follows:

(i) The programs established under this title and title XIX are the sole or primary sources of payment for an item or service.

(ii) The payment amount does not reflect changing technology, increased facility with that technology, or reductions in acquisition or production costs.

(iii) The payment amount for an item or service under this part is substantially higher or lower than the payment made for the item or service by other purchasers.

(D) The potential impacts of a determination under subparagraph (B) on quality, access, and beneficiary liability, including the likely effects on assignment rates and participation rates.

(9)(A) The Secretary shall consult with representatives of suppliers or other individuals who furnish an item or service before making a determination under paragraph (8)(B) with regard to that item or service.

(B) The Secretary shall publish notice of a proposed determination under paragraph (8)(B) in the Federal Register—

(i) specifying the payment amount proposed to be established with respect to an item or service,

(ii) explaining the factors and data that the Secretary took into account in determining the payment amount so specified, and

(iii) explaining the potential impacts described in paragraph (8)(D).

(C) After publication of the notice required by subparagraph (B), the Secretary shall allow not less than 60 days for public comment on the proposed determination.

(D)(i) Taking into consideration the comments made by the public, the Secretary shall publish in the Federal Register a final determination under paragraph (8)(B) with respect to the payment amount to be established with respect to the item or service.

(ii) A final determination published pursuant to clause (i) shall explain the factors and data that the Secretary took into consideration in making the final determination.

(10)(A)(i) In determining the reasonable charge for procedures described in subparagraph (B) and performed during the 9-month period beginning on April 1, 1988, the prevailing charge for such procedure shall be the prevailing charge otherwise recognized for such procedure for 1987—

(I) subject to clause (iii), reduced by 2.0 percent, and

(II) further reduced by the applicable percentage specified in clause (ii).

(ii) For purposes of clause (i), the applicable percentage specified in this clause is—

(I) 15 percent, in the case of a prevailing charge otherwise recognized (without regard to this paragraph and determined without regard to physician specialty) that is at least 150 percent of the weighted national average (as determined by the Secretary) of such prevailing charges for such procedure for all localities in the United States for 1987;

(II) 0 percent, in the case of a prevailing charge that does not exceed 85 percent of such weighted national average; and

(III) in the case of any other prevailing charge, a percent determined on the basis of a straight line sliding scale, equal to $3\frac{1}{3}$ of a percentage point for each percent by which the prevailing charge exceeds 85 percent of such weighted national average.

(iii) In no case shall the reduction under clause (i) for a procedure result in a prevailing charge in a locality for 1988 which is less than 85 percent of the Secretary's estimate of the weighted national average of such prevailing charges for such procedure for all localities in the United States for 1987 (based upon the best available data and determined without regard to physician specialty) after making the reduction described in clause (i)(I).

(B) The procedures described in this subparagraph are as follows: bronchoscopy, carpal tunnel repair, cataract surgery (including sub-

sequent insertion of an intraocular lens), coronary artery bypass surgery, diagnostic and/or therapeutic dilation and curettage, knee arthroscopy, knee arthroplasty, pacemaker implantation surgery, total hip replacement, suprapubic prostatectomy, transurethral resection of the prostate, and upper gastrointestinal endoscopy.

(C) In the case of a reduction in the reasonable charge for a physician's service under subparagraph (A), if a nonparticipating physician furnishes the service to an individual entitled to benefits under this part, after the effective date of such reduction, the physician's actual charge is subject to a limit under subsection (j)(1)(D).

(D) There shall be no administrative or judicial review under section 1869 or otherwise of any determination under subparagraph (A) or under paragraph (11)(B)(ii).

(11)(A) In providing payment for cataract eyeglasses and cataract contact lenses, and professional services relating to them, under this part, each carrier shall—

(i) provide for separate determinations of the payment amount for the eyeglasses and lenses and of the payment amount for the professional services of a physician (as defined in section 1861(r)), and

(ii) not recognize as reasonable for such eyeglasses and lenses more than such amount as the Secretary establishes in guidelines relating to the inherent reasonableness of charges for such eyeglasses and lenses.

(B)(i) In determining the reasonable charge under paragraph (3) for a cataract surgical procedure, subject to clause (ii), the prevailing charge for such procedure otherwise recognized for participating and nonparticipating physicians shall be reduced by 10 percent with respect to procedures performed in 1987.

(ii) In no case shall the reduction under clause (i) for a surgical procedure result in a prevailing charge in a locality for a year which is less than 75 percent of the weighted national average of such prevailing charges for such procedure for all the localities in the United States for 1986.

(C)(i) The prevailing charge level determined with respect to A-mode ophthalmic ultrasound procedures may not exceed 5 percent of the prevailing charge level established with respect to extracapsular cataract removal with lens insertion.

(ii) The reasonable charge for an intraocular lens inserted during or subsequent to cataract surgery in a physician's office may not exceed the actual acquisition cost for the lens (taking into account any discount) plus a handling fee (not to exceed 5 percent of such actual acquisition cost).

(D) In the case of a reduction in the reasonable charge for a physician's service or item under subparagraph (B) or (C), if a nonparticipating physician furnishes the service or item to an individual entitled to benefits under this part after the effective date of such reduction, the physician's actual charge is subject to a limit under subsection (j)(1)(D).

(13)(A) In determining payments under section 1833(l) and section 1848 for anesthesia services furnished on or after January 1, 1994, the methodology for determining the base and time units used shall be the same for services furnished by physicians, for medical direction by physicians of two, three, or four certified reg-

istered nurse anesthetists, or for services furnished by a certified registered nurse anesthetist (whether or not medically directed) and shall be based on the methodology in effect, for anesthesia services furnished by physicians, as of the date of the enactment of the Omnibus Budget Reconciliation Act of 1993.

(B) The Secretary shall require claims for physicians' services for medical direction of nurse anesthetists during the periods in which the provisions of subparagraph (A) apply to indicate the number of such anesthetists being medically directed concurrently at any time during the procedure, the name of each nurse anesthetist being directed, and the type of procedure for which the services are provided.

(14)(A)(i) In determining the reasonable charge for a physicians' service specified in subparagraph (C)(i) and furnished during the 9-month period beginning on April 1, 1990, the prevailing charge for such service shall be the prevailing charge otherwise recognized for such service for 1989 reduced by 15 percent or, if less, $\frac{1}{3}$ of the percent (if any) by which the prevailing charge otherwise applied in the locality in 1989 exceeds the locally-adjusted reduced prevailing amount (as determined under subparagraph (B)(i)) for the service.

(ii) In determining the reasonable charge for a physicians' service specified in subparagraph (C)(i) and furnished during 1991, the prevailing charge for such service shall be the prevailing charge otherwise recognized for such service for the period during 1990 beginning on April 1, reduced by the same amount as the amount of the reduction effected under this paragraph (as amended by the Omnibus Budget Reconciliation Act of 1990) for such service during such period.

(B) For purposes of this paragraph:

(i) The "locally-adjusted reduced prevailing amount" for a locality for a physicians' service is equal to the product of—

(I) the reduced national weighted average prevailing charge for the service (specified under clause (ii)), and

(II) the adjustment factor (specified under clause (iii)) for the locality.

(ii) The "reduced national weighted average prevailing charge" for a physicians' service is equal to the national weighted average prevailing charge for the service (specified in subparagraph (C)(ii)) reduced by the percentage change (specified in subparagraph (C)(iii)) for the service.

(iii) The "adjustment factor", for a physicians' service for a locality, is the sum of—

(I) the practice expense component (percent), divided by 100, specified in appendix A (pages 187 through 194) of the Report of the Medicare and Medicaid Health Budget Reconciliation Amendments of 1989, prepared by the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, House of Representatives, (Committee Print 101 M, 101st Congress, 1st Session) for the service, multiplied by the geographic practice cost index value (specified in subparagraph (C)(iv)) for the locality, and

(II) 1 minus the practice expense component (percent), divided by 100.

(C) For purposes of this paragraph:

(i) The physicians' services specified in this clause are the procedures specified (by code and description) in the Overvalued Procedures List for Finance Committee, Revised September 20, 1989, prepared by the Physician Payment Review Commission which specification is of physicians' services that have been identified as overvalued by at least 10 percent based on a comparison of payments for such services under a resource-based relative value scale and of the national average prevailing charges under this part.

(ii) The "national weighted average prevailing charge" specified in this clause, for a physicians' service specified in clause (i), is the national weighted average prevailing charge for the service in 1989 as determined by the Secretary using the best data available.

(iii) The "percentage change" specified in this clause, for a physicians' service specified in clause (i), is the percent difference (but expressed as a positive number) specified for the service in the list referred to in clause (i).

(iv) The geographic practice cost index value specified in this clause for a locality is the Geographic Overhead Costs Index specified for the locality in table 1 of the September 1989 Supplement to the Geographic Medicare Economic Index: Alternative Approaches (prepared by the Urban Institute and the Center for Health Economics Research).

(D) In the case of a reduction in the prevailing charge for a physicians' service under subparagraph (A), if a nonparticipating physician furnishes the service to an individual entitled to benefits under this part, after the effective date of such reduction, the physician's actual charge is subject to a limit under subsection (j)(1)(D).

(15)(A) In determining the reasonable charge for surgery, radiology, and diagnostic physicians' services which the Secretary shall designate (based on their high volume of expenditures under this part) and for which the prevailing charge (but for this paragraph) differs by physician specialty, the prevailing charge for such a service may not exceed the prevailing charge or fee schedule amount for that specialty of physicians that furnish the service most frequently nationally.

(B) In the case of a reduction in the prevailing charge for a physician's service under subparagraph (A), if a nonparticipating physician furnishes the service to an individual entitled to benefits under this part, after the effective date of the reduction, the physician's actual charge is subject to a limit under subsection (j)(1)(D).

(16)(A) In determining the reasonable charge for all physicians' services other than physicians' services specified in subparagraph (B) furnished during 1991, the prevailing charge for a locality shall be 6.5 percent below the prevailing charges used in the locality under this part in 1990 after March 31.

(B) For purposes of subparagraph (A), the physicians' services specified in this subparagraph are as follows:

(i) Radiology, anesthesia and physician pathology services, the technical components of diagnostic tests specified in para-

graph (17) and physicians' services specified in paragraph (14)(C)(i).

(ii) Primary care services specified in subsection (i)(4), hospital inpatient medical services, consultations, other visits, preventive medicine visits, psychiatric services, emergency care facility services, and critical care services.

(iii) Partial mastectomy; tendon sheath injections and small joint arthrocentesis; femoral fracture and trochanteric fracture treatments; endotracheal intubation; thoracentesis; thoracostomy; aneurysm repair; cystourethroscopy; transurethral fulguration and resection; tympanoplasty with mastoidectomy; and ophthalmoscopy.

(17) With respect to payment under this part for the technical (as distinct from professional) component of diagnostic tests (other than clinical diagnostic laboratory tests, tests specified in paragraph (14)(C)(i), and radiology services, including portable X-ray services) which the Secretary shall designate (based on their high volume of expenditures under this part), the reasonable charge for such technical component (including the applicable portion of a global service) may not exceed the national median of such charges for all localities, as estimated by the Secretary using the best available data.

(18)(A) Payment for any service furnished by a practitioner described in subparagraph (C) and for which payment may be made under this part on a reasonable charge or fee schedule basis may only be made under this part on an assignment-related basis.

(B) A practitioner described in subparagraph (C) or other person may not bill (or collect any amount from) the individual or another person for any service described in subparagraph (A), except for deductible and coinsurance amounts applicable under this part. No person is liable for payment of any amounts billed for such a service in violation of the previous sentence. If a practitioner or other person knowingly and willfully bills (or collects an amount) for such a service in violation of such sentence, the Secretary may apply sanctions against the practitioner or other person in the same manner as the Secretary may apply sanctions against a physician in accordance with subsection (j)(2) in the same manner as such section applies with respect to a physician. Paragraph (4) of subsection (j) shall apply in this subparagraph in the same manner as such paragraph applies to such section.

(C) A practitioner described in this subparagraph is any of the following:

(i) A physician assistant, nurse practitioner, or clinical nurse specialist (as defined in section 1861(aa)(5)).

(ii) A certified registered nurse anesthetist (as defined in section 1861(bb)(2)).

(iii) A certified nurse-midwife (as defined in section 1861(gg)(2)).

(iv) A clinical social worker (as defined in section 1861(hh)(1)).

(v) A clinical psychologist (as defined by the Secretary for purposes of section 1861(ii)).

(vi) A registered dietitian or nutrition professional.

(D) For purposes of this paragraph, a service furnished by a practitioner described in subparagraph (C) includes any services and

supplies furnished as incident to the service as would otherwise be covered under this part if furnished by a physician or as incident to a physician's service.

(19) For purposes of section 1833(a)(1), the reasonable charge for ambulance services (as described in section 1861(s)(7)) provided during calendar year 1998 and calendar year 1999 may not exceed the reasonable charge for such services provided during the previous calendar year (after application of this paragraph), 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 reduced by 1.0 percentage point.

(c)

(2)(A) Each contract under section 1874A that provides for making payments under this part shall provide that payment shall be issued, mailed, or otherwise transmitted with respect to not less than 95 percent of all claims submitted under this part—

(i) which are clean claims, and

(ii) for which payment is not made on a periodic interim payment basis,

within the applicable number of calendar days after the date on which the claim is received.

(B) In this paragraph:

(i) The term "clean claim" means a claim that has no defect or impropriety (including any lack of any required substantiating documentation) or particular circumstance requiring special treatment that prevents timely payment from being made on the claim under this part.

(ii) The term "applicable number of calendar days" means—

(I) with respect to claims received in the 12-month period beginning October 1, 1986, 30 calendar days,

(II) with respect to claims received in the 12-month period beginning October 1, 1987, 26 calendar days (or 19 calendar days with respect to claims submitted by participating physicians),

(III) with respect to claims received in the 12-month period beginning October 1, 1988, 25 calendar days (or 18 calendar days with respect to claims submitted by participating physicians),

(IV) with respect to claims received in the 12-month period beginning October 1, 1989, and claims received in any succeeding 12-month period ending on or before September 30, 1993, 24 calendar days (or 17 calendar days with respect to claims submitted by participating physicians), and

(V) with respect to claims received in the 12-month period beginning October 1, 1993, and claims received in any succeeding 12-month period, 30 calendar days.

(C) If payment is not issued, mailed, or otherwise transmitted within the applicable number of calendar days (as defined in clause (ii) of subparagraph (B)) after a clean claim (as defined in clause (i) of such subparagraph) is received, interest shall be paid at the rate used for purposes of section 3902(a) of title 31, United States Code (relating to interest penalties for failure to make prompt payments) for the period beginning on the day after the required payment date and ending on the date on which payment is made.

(3)(A) Each contract under this section which provides for the disbursement of funds, as described in section 1874A(a)(3)(B), shall provide that no payment shall be issued, mailed, or otherwise transmitted with respect to any claim submitted under this title within the applicable number of calendar days after the date on which the claim is received.

(B) In this paragraph, the term “applicable number of calendar days” means—

(i) with respect to claims submitted electronically as prescribed by the Secretary, 13 days, and

(ii) with respect to claims submitted otherwise, 28 days.

(4) Neither a medicare administrative contractor nor the Secretary may impose a fee under this title—

(A) for the filing of claims related to physicians’ services,

(B) for an error in filing a claim relating to physicians’ services or for such a claim which is denied,

(C) for any appeal under this title with respect to physicians’ services,

(D) for applying for (or obtaining) a unique identifier under subsection (r), or

(E) for responding to inquiries respecting physicians’ services or for providing information with respect to medical review of such services.

(g) The Railroad Retirement Board shall, in accordance with such regulations as the Secretary may prescribe, contract with a medicare administrative contractor or contractors to perform the functions set out in this section with respect to individuals entitled to benefits as qualified railroad retirement beneficiaries pursuant to section 226(a) of this Act and section 7(d) of the Railroad Retirement Act of 1974.

(h)(1) Any physician or supplier may voluntarily enter into an agreement with the Secretary to become a participating physician or supplier. For purposes of this section, the term “participating physician or supplier” means a physician or supplier (excluding any provider of services) who, before the beginning of any year beginning with 1984, enters into an agreement with the Secretary which provides that such physician or supplier will accept payment under this part on an assignment-related basis for all items and services furnished to individuals enrolled under this part during such year. In the case of a newly licensed physician or a physician who begins a practice in a new area, or in the case of a new supplier who begins a new business, or in such similar cases as the Secretary may specify, such physician or supplier may enter into such an agreement after the beginning of a year, for items and services furnished during the remainder of the year.

(2) The Secretary shall maintain a toll-free telephone number or numbers at which individuals enrolled under this part may obtain the names, addresses, specialty, and telephone numbers of participating physicians and suppliers and may request a copy of an appropriate directory published under paragraph (4). The Secretary shall, without charge, mail a copy of such directory upon such a request.

(3)(A) In any case in which medicare administrative contractor having a contract under section 1874A that provides for making payments under this part is able to develop a system for the elec-

tronic transmission to such contractor of bills for services, such carrier shall establish direct lines for the electronic receipt of claims from participating physicians and suppliers.

(B) The Secretary shall establish a procedure whereby an individual enrolled under this part may assign, in an appropriate manner on the form claiming a benefit under this part for an item or service furnished by a participating physician or supplier, the individual's rights of payment under a medicare supplemental policy (described in section 1882(g)(1)) in which the individual is enrolled. In the case such an assignment is properly executed and a payment determination is made by a medicare administrative contractor with a contract under this section, the contractor shall transmit to the private entity issuing the medicare supplemental policy notice of such fact and shall include an explanation of benefits and any additional information that the Secretary may determine to be appropriate in order to enable the entity to decide whether (and the amount of) any payment is due under the policy. The Secretary may enter into agreements for the transmittal of such information to entities electronically. The Secretary shall impose user fees for the transmittal of information under this subparagraph by a medicare administrative contractor, whether electronically or otherwise, and such user fees shall be collected and retained by the contractor.

(4) At the beginning of each year the Secretary shall publish directories (for appropriate local geographic areas) containing the name, address, and specialty of all participating physicians and suppliers (as defined in paragraph (1)) for that area for that year. Each directory shall be organized to make the most useful presentation of the information (as determined by the Secretary) for individuals enrolled under this part. Each participating physician directory for an area shall provide an alphabetical listing of all participating physicians practicing in the area and an alphabetical listing by locality and specialty of such physicians.

(5)(A) The Secretary shall promptly notify individuals enrolled under this part through an annual mailing of the participation program under this subsection and the publication and availability of the directories and shall make the appropriate area directory or directories available in each district and branch office of the Social Security Administration, in the offices of medicare administrative contractors, and to senior citizen organizations.

(B) The annual notice provided under subparagraph (A) shall include—

- (i) a description of the participation program,
- (ii) an explanation of the advantages to beneficiaries of obtaining covered services through a participating physician or supplier,
- (iii) an explanation of the assistance offered by medicare administrative contractors in obtaining the names of participating physicians and suppliers, and
- (iv) the toll-free telephone number under paragraph (2)(A) for inquiries concerning the program and for requests for free copies of appropriate directories.

(6) The Secretary shall provide that the directories shall be available for purchase by the public. The Secretary shall provide that each appropriate area directory is sent to each participating physi-

cian located in that area and that an appropriate number of copies of each such directory is sent to hospitals located in the area. Such copies shall be sent free of charge.

(7) The Secretary shall provide that each explanation of benefits provided under this part for services furnished in the United States, in conjunction with the payment of claims under section 1833(a)(1) (made other than on an assignment-related basis), shall include—

(A) a prominent reminder of the participating physician and supplier program established under this subsection (including the limitation on charges that may be imposed by such physicians and suppliers and a clear statement of any amounts charged for the particular items or services on the claim involved above the amount recognized under this part),

(B) the toll-free telephone number or numbers, maintained under paragraph (2), at which an individual enrolled under this part may obtain information on participating physicians and suppliers,

(C)(i) an offer of assistance to such an individual in obtaining the names of participating physicians of appropriate specialty and (ii) an offer to provide a free copy of the appropriate participating physician directory, and

(D) in the case of services for which the billed amount exceeds the limiting charge imposed under section 1848(g), information regarding such applicable limiting charge (including information concerning the right to a refund under section 1848(g)(1)(A)(iv)).

(8) The Secretary may refuse to enter into an agreement with a physician or supplier under this subsection, or may terminate or refuse to renew such agreement, in the event that such physician or supplier has been convicted of a felony under Federal or State law for an offense which the Secretary determines is detrimental to the best interests of the program or program beneficiaries.

(9) The Secretary may revoke enrollment, for a period of not more than one year for each act, for a physician or supplier under section 1866(j) if such physician or supplier fails to maintain and, upon request of the Secretary, provide access to documentation relating to written orders or requests for payment for durable medical equipment, certifications for home health services, or referrals for other items or services written or ordered by such physician or supplier under this title, as specified by the Secretary.

(i) For purposes of this title:

(1) A claim is considered to be paid on an “assignment-related basis” if the claim is paid on the basis of an assignment described in subsection (b)(3)(B)(ii), in accordance with subsection (b)(6)(B), or under the procedure described in section 1870(f)(1).

(2) The term “participating physician” refers, with respect to the furnishing of services, to a physician who at the time of furnishing the services is a participating physician (under subsection (h)(1)); the term “nonparticipating physician” refers, with respect to the furnishing of services, to a physician who at the time of furnishing the services is not a participating physician; and the term “nonparticipating supplier or other person” means a supplier or other person (excluding a provider

of services) that is not a participating physician or supplier (as defined in subsection (h)(1)).

(3) The term “percentage increase in the MEI” means, with respect to physicians’ services furnished in a year, the percentage increase in the medicare economic index (referred to in the fourth sentence of subsection (b)(3)) applicable to such services furnished as of the first day of that year.

(4) The term “primary care services” means physicians’ services which constitute office medical services, emergency department services, home medical services, skilled nursing, intermediate care, and long-term care medical services, or nursing home, boarding home, domiciliary, or custodial care medical services.

(j)(1)(A) In the case of a physician who is not a participating physician for items and services furnished during a portion of the 30-month period beginning July 1, 1984, the Secretary shall monitor the physician’s actual charges to individuals enrolled under this part for physicians’ services during that portion of that period. If such physician knowingly and willfully bills individuals enrolled under this part for actual charges in excess of such physician’s actual charges for the calendar quarter beginning on April 1, 1984, the Secretary may apply sanctions against such physician in accordance with paragraph (2).

(B)(i) During any period (on or after January 1, 1987, and before the date specified in clause (ii)), during which a physician is a non-participating physician, the Secretary shall monitor the actual charges of each such physician for physicians’ services furnished to individuals enrolled under this part. If such physician knowingly and willfully bills on a repeated basis for such a service an actual charge in excess of the maximum allowable actual charge determined under subparagraph (C) for that service, the Secretary may apply sanctions against such physician in accordance with paragraph (2).

(ii) Clause (i) shall not apply to services furnished after December 31, 1990.

(C)(i) For a particular physicians’ service furnished by a non-participating physician to individuals enrolled under this part during a year, for purposes of subparagraph (B), the maximum allowable actual charge is determined as follows: If the physician’s maximum allowable actual charge for that service in the previous year was—

(I) less than 115 percent of the applicable percent (as defined in subsection (b)(4)(A)(iv)) of the prevailing charge for the year and service involved, the maximum allowable actual charge for the year involved is the greater of the maximum allowable actual charge described in subclause (II) or the charge described in clause (ii), or

(II) equal to, or greater than, 115 percent of the applicable percent (as defined in subsection (b)(4)(A)(iv)) of the prevailing charge for the year and service involved, the maximum allowable actual charge is 101 percent of the physician’s maximum allowable actual charge for the service for the previous year.

(ii) For purposes of clause (i)(I), the charge described in this clause for a particular physicians’ service furnished in a year is the maximum allowable actual charge for the service of the physician

for the previous year plus the product of (I) the applicable fraction (as defined in clause (iii)) and (II) the amount by which 115 percent of the prevailing charge for the year involved for such service furnished by nonparticipating physicians, exceeds the physician's maximum allowable actual charge for the service for the previous year.

(iii) In clause (ii), the "applicable fraction" is—

(I) for 1987, $\frac{1}{4}$,

(II) for 1988, $\frac{1}{3}$,

(III) for 1989, $\frac{1}{2}$, and

(IV) for any subsequent year, 1.

(iv) For purposes of determining the maximum allowable actual charge under clauses (i) and (ii) for 1987, in the case of a physicians' service for which the physician has actual charges for the calendar quarter beginning on April 1, 1984, the "maximum allowable actual charge" for 1986 is the physician's actual charge for such service furnished during such quarter.

(v) For purposes of determining the maximum allowable actual charge under clauses (i) and (ii) for a year after 1986, in the case of a physicians' service for which the physician has no actual charges for the calendar quarter beginning on April 1, 1984, and for which a maximum allowable actual charge has not been previously established under this clause, the "maximum allowable actual charge" for the previous year shall be the 50th percentile of the customary charges for the service (weighted by frequency of the service) performed by nonparticipating physicians in the locality during the 12-month period ending June 30 of that previous year.

(vi) For purposes of this subparagraph, a "physician's actual charge" for a physicians' service furnished in a year or other period is the weighted average (or, at the option of the Secretary for a service furnished in the calendar quarter beginning April 1, 1984, the median) of the physician's charges for such service furnished in the year or other period.

(vii) In the case of a nonparticipating physician who was a participating physician during a previous period, for the purpose of computing the physician's maximum allowable actual charge during the physician's period of nonparticipation, the physician shall be deemed to have had a maximum allowable actual charge during the period of participation, and such deemed maximum allowable actual charge shall be determined according to clauses (i) through (vi).

(viii) Notwithstanding any other provision of this subparagraph, the maximum allowable actual charge for a particular physician's service furnished by a nonparticipating physician to individuals enrolled under this part during the 3-month period beginning on January 1, 1988, shall be the amount determined under this subparagraph for 1987. The maximum allowable actual charge for any such service otherwise determined under this subparagraph for 1988 shall take effect on April 1, 1988.

(ix) If there is a reduction under subsection (b)(13) in the reasonable charge for medical direction furnished by a nonparticipating physician, the maximum allowable actual charge otherwise permitted under this subsection for such services shall be reduced in the same manner and in the same percentage as the reduction in such reasonable charge.

(D)(i) If an action described in clause (ii) results in a reduction in a reasonable charge for a physicians' service or item and a non-participating physician furnishes the service or item to an individual entitled to benefits under this part after the effective date of such action, the physician may not charge the individual more than 125 percent of the reduced payment allowance (as defined in clause (iii)) plus (for services or items furnished during the 12-month period (or 9-month period in the case of an action described in clause (ii)(II)) beginning on the effective date of the action) $\frac{1}{2}$ of the amount by which the physician's maximum allowable actual charge for the service or item for the previous 12-month period exceeds such 125 percent level.

(ii) The first sentence of clause (i) shall apply to—

(I) an adjustment under subsection (b)(8)(B) (relating to inherent reasonableness),

(II) a reduction under subsection (b)(10)(A) or (b)(14)(A) (relating to certain overpriced procedures),

(III) a reduction under subsection (b)(11)(B) (relating to certain cataract procedures),

(IV) a prevailing charge limit established under subsection (b)(11)(C)(i) or (b)(15)(A),

(V) a reasonable charge limit established under subsection (b)(11)(C)(ii), and

(VI) an adjustment under section 1833(l)(3)(B) (relating to physician supervision of certified registered nurse anesthetists).

(iii) In clause (i), the term "reduced payment allowance" means, with respect to an action—

(I) under subsection (b)(8)(B), the inherently reasonable charge established under subsection (b)(8);

(II) under subsection (b)(10)(A), (b)(11)(B), (b)(11)(C)(i), (b)(14)(A), or (b)(15)(A) or under section 1833(l)(3)(B), the prevailing charge for the service after the action; or

(III) under subsection (b)(11)(C)(ii), the payment allowance established under such subsection.

(iv) If a physician knowingly and willfully bills in violation of clause (i) (whether or not such charge violates subparagraph (B)), the Secretary may apply sanctions against such physician in accordance with paragraph (2).

(v) Clause (i) shall not apply to items and services furnished after December 31, 1990.

(2) Subject to paragraph (3), the sanctions which the Secretary may apply under this paragraph are—

(A) excluding a physician from participation in the programs under this Act for a period not to exceed 5 years, in accordance with the procedures of subsections (c), (f), and (g) of section 1128, or

(B) civil monetary penalties and assessments, in the same manner as such penalties and assessments are authorized under section 1128A(a),

or both. The provisions of section 1128A (other than the first 2 sentences of subsection (a) and other than subsection (b)) shall apply to a civil money penalty and assessment under subparagraph (B) in the same manner as such provisions apply to a penalty, assessment, or proceeding under section 1128A(a), except to the extent

such provisions are inconsistent with subparagraph (A) or paragraph (3).

(3)(A) The Secretary may not exclude a physician pursuant to paragraph (2)(A) if such physician is a sole community physician or sole source of essential specialized services in a community.

(B) The Secretary shall take into account access of beneficiaries to physicians' services for which payment may be made under this part in determining whether to bar a physician from participation under paragraph (2)(A).

(4) The Secretary may, out of any civil monetary penalty or assessment collected from a physician pursuant to this subsection, make a payment to a beneficiary enrolled under this part in the nature of restitution for amounts paid by such beneficiary to such physician which was determined to be an excess charge under paragraph (1).

(k)(1) If a physician knowingly and willfully presents or causes to be presented a claim or bills an individual enrolled under this part for charges for services as an assistant at surgery for which payment may not be made by reason of section 1862(a)(15), the Secretary may apply sanctions against such physician in accordance with subsection (j)(2) in the case of surgery performed on or after March 1, 1987.

(2) If a physician knowingly and willfully presents or causes to be presented a claim or bills an individual enrolled under this part for charges that includes a charge for an assistant at surgery for which payment may not be made by reason of section 1862(a)(15), the Secretary may apply sanctions against such physician in accordance with subsection (j)(2) in the case of surgery performed on or after March 1, 1987.

(l)(1)(A) Subject to subparagraph (C), if—

(i) a nonparticipating physician furnishes services to an individual enrolled for benefits under this part,

(ii) payment for such services is not accepted on an assignment-related basis,

(iii)(I) a medicare administrative contractor determines under this part or a quality improvement organization determines under part B of title XI that payment may not be made by reason of section 1862(a)(1) because a service otherwise covered under this title is not reasonable and necessary under the standards described in that section or (II) payment under this title for such services is denied under section 1154(a)(2) by reason of a determination under section 1154(a)(1)(B), and

(iv) the physician has collected any amounts for such services,

the physician shall refund on a timely basis to the individual (and shall be liable to the individual for) any amounts so collected.

(B) A refund under subparagraph (A) is considered to be on a timely basis only if—

(i) in the case of a physician who does not request reconsideration or seek appeal on a timely basis, the refund is made within 30 days after the date the physician receives a denial notice under paragraph (2), or

(ii) in the case in which such a reconsideration or appeal is taken, the refund is made within 15 days after the date the

physician receives notice of an adverse determination on reconsideration or appeal.

(C) Subparagraph (A) shall not apply to the furnishing of a service by a physician to an individual in the case described in subparagraph (A)(iii)(I) if—

(i) the physician establishes that the physician did not know and could not reasonably have been expected to know that payment may not be made for the service by reason of section 1862(a)(1), or

(ii) before the service was provided, the individual was informed that payment under this part may not be made for the specific service and the individual has agreed to pay for that service.

(2) Each medicare administrative contractor with a contract in effect under this section with respect to physicians and each quality improvement organization with a contract under part B of title XI shall send any notice of denial of payment for physicians' services based on section 1862(a)(1) and for which payment is not requested on an assignment-related basis to the physician and the individual involved.

(3) If a physician knowingly and willfully fails to make refunds in violation of paragraph (1)(A), the Secretary may apply sanctions against such physician in accordance with subsection (j)(2).

(m)(1) In the case of a nonparticipating physician who—

(A) performs an elective surgical procedure for an individual enrolled for benefits under this part and for which the physician's actual charge is at least \$500, and

(B) does not accept payment for such procedure on an assignment-related basis,

the physician must disclose to the individual, in writing and in a form approved by the Secretary, the physician's estimated actual charge for the procedure, the estimated approved charge under this part for the procedure, the excess of the physician's actual charge over the approved charge, and the coinsurance amount applicable to the procedure. The written estimate may not be used as the basis for, or evidence in, a civil suit.

(2) A physician who fails to make a disclosure required under paragraph (1) with respect to a procedure shall refund on a timely basis to the individual (and shall be liable to the individual for) any amounts collected for the procedure in excess of the charges recognized and approved under this part.

(3) If a physician knowingly and willfully fails to comply with paragraph (2), the Secretary may apply sanctions against such physician in accordance with subsection (j)(2).

(4) The Secretary shall provide for such monitoring of requests for payment for physicians' services to which paragraph (1) applies as is necessary to assure compliance with paragraph (2).

(n)(1) If a physician's bill or a request for payment for services billed by a physician includes a charge for a diagnostic test described in section 1861(s)(3) (other than a clinical diagnostic laboratory test) for which the bill or request for payment does not indicate that the billing physician personally performed or supervised the performance of the test or that another physician with whom the physician who shares a practice personally performed or super-

vised the performance of the test, the amount payable with respect to the test shall be determined as follows:

(A) If the bill or request for payment indicates that the test was performed by a supplier, identifies the supplier, and indicates the amount the supplier charged the billing physician, payment for the test (less the applicable deductible and coinsurance amounts) shall be the actual acquisition costs (net of any discounts) or, if lower, the supplier's reasonable charge (or other applicable limit) for the test.

(B) If the bill or request for payment (i) does not indicate who performed the test, or (ii) indicates that the test was performed by a supplier but does not identify the supplier or include the amount charged by the supplier, no payment shall be made under this part.

(2) A physician may not bill an individual enrolled under this part—

(A) any amount other than the payment amount specified in paragraph (1)(A) and any applicable deductible and coinsurance for a diagnostic test for which payment is made pursuant to paragraph (1)(A), or

(B) any amount for a diagnostic test for which payment may not be made pursuant to paragraph (1)(B).

(3) If a physician knowingly and willfully in repeated cases bills one or more individuals in violation of paragraph (2), the Secretary may apply sanctions against such physician in accordance with section 1842(j)(2).

(o)(1) If a physician's, supplier's, or any other person's bill or request for payment for services includes a charge for a drug or biological for which payment may be made under this part and the drug or biological is not paid on a cost or prospective payment basis as otherwise provided in this part, the amount payable for the drug or biological is 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 (and including a drug or biological described in subparagraph (D)(i) furnished on or after January 1, 2017), 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 or biologicals furnished through an item of durable medical equipment covered under section 1861(n) on or after January 1, 2004, and before January 1, 2017, 95 percent of the average wholesale price in effect on October 1, 2003.

(ii) In the case of such infusion drugs or biologicals furnished in a competitive acquisition area under section 1847 on or after January 1, 2007, and before the date of the enactment of the 21st Century Cures Act., 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) 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.

(2) If payment for a drug or biological is made to a licensed pharmacy approved to dispense drugs or biologicals under this part, the Secretary may pay a dispensing fee (less the applicable deductible and coinsurance amounts) to the pharmacy. This paragraph shall not apply in the case of payment under paragraph (1)(C).

(3)(A) Payment for a charge for any drug or biological for which payment may be made under this part may be made only on an assignment-related basis.

(B) The provisions of subsection (b)(18)(B) shall apply to charges for such drugs or biologicals in the same manner as they apply to services furnished by a practitioner described in subsection (b)(18)(C).

(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.

(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.

(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).

(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).

(p)(1) Each request for payment, or bill submitted, for an item or service furnished by a physician or practitioner specified in subsection (b)(18)(C) for which payment may be made under this part shall include the appropriate diagnosis code (or codes) as established by the Secretary for such item or service.

(2) In the case of a request for payment for an item or service furnished by a physician or practitioner specified in subsection (b)(18)(C) on an assignment-related basis which does not include the code (or codes) required under paragraph (1), payment may be denied under this part.

(3) In the case of a request for payment for an item or service furnished by a physician not submitted on an assignment-related basis and which does not include the code (or codes) required under paragraph (1)—

(A) if the physician knowingly and willfully fails to provide the code (or codes) promptly upon request of the Secretary or a medicare administrative contractor, the physician may be subject to a civil money penalty in an amount not to exceed \$2,000, and

(B) if the physician knowingly, willfully, and in repeated cases fails, after being notified by the Secretary of the obligations and requirements of this subsection, to include the code (or codes) required under paragraph (1), the physician may be subject to the sanction described in section 1842(j)(2)(A).

The provisions of section 1128A (other than subsections (a) and (b)) shall apply to civil money penalties under subparagraph (A) in the same manner as they apply to a penalty or proceeding under section 1128A(a).

(4) In the case of an item or service defined in paragraph (3), (6), (8), or (9) of subsection 1861(s) ordered by a physician or a practitioner specified in subsection (b)(18)(C), but furnished by another entity, if the Secretary (or fiscal agent of the Secretary) requires the entity furnishing the item or service to provide diagnostic or other medical information in order for payment to be made to the entity, the physician or practitioner shall provide that information to the entity at the time that the item or service is ordered by the physician or practitioner.

(q)(1)(A) The Secretary, in consultation with groups representing physicians who furnish anesthesia services, shall establish by regulation a relative value guide for use in all localities in making payment for physician anesthesia services furnished under this part. Such guide shall be designed so as to result in expenditures under this title for such services in an amount that would not exceed the amount of such expenditures which would otherwise occur.

(B) For physician anesthesia services furnished under this part during 1991, the prevailing charge conversion factor used in a locality under this subsection shall, subject to clause (iv), be reduced to the adjusted prevailing charge conversion factor for the locality determined as follows:

(i) The Secretary shall estimate the national weighted average of the prevailing charge conversion factors used under this subsection for services furnished during 1990 after March 31, using the best available data.

(ii) The national weighted average estimated under clause (i) shall be reduced by 7 percent.

(iii) The adjusted prevailing charge conversion factor for a locality is the sum of—

(I) the product of (a) the portion of the reduced national weighted average prevailing charge conversion factor computed under clause (ii) which is attributable to physician

work and (b) the geographic work index value for the locality (specified in Addendum C to the Model Fee Schedule for Physician Services (published on September 4, 1990, 55 Federal Register pp. 36238 36243)); and

(II) the product of (a) the remaining portion of the reduced national weighted average prevailing charge conversion factor computed under clause (ii) and (b) the geographic practice cost index value specified in section 1842(b)(14)(C)(iv) for the locality.

In applying this clause, 70 percent of the prevailing charge conversion factor shall be considered to be attributable to physician work.

(iv) The prevailing charge conversion factor to be applied to a locality under this subparagraph shall not be reduced by more than 15 percent below the prevailing charge conversion factor applied in the locality for the period during 1990 after March 31, but in no case shall the prevailing charge conversion factor be less than 60 percent of the national weighted average of the prevailing charge conversion factors (computed under clause (i)).

(2) For purposes of payment for anesthesia services (whether furnished by physicians or by certified registered nurse anesthetists) under this part, the time units shall be counted based on actual time rather than rounded to full time units.

(r) The Secretary shall establish a system which provides for a unique identifier for each physician who furnishes services for which payment may be made under this title. Under such system, the Secretary may impose appropriate fees on such physicians to cover the costs of investigation and recertification activities with respect to the issuance of the identifiers.

(s)(1)(A) Subject to paragraph (3), the Secretary may implement a statewide or other areawide fee schedule to be used for payment of any item or service described in paragraph (2) which is paid on a reasonable charge basis.

(B) Any fee schedule established under this paragraph for such item or service shall be updated—

(i) for years before 2011—

(I) subject to subclause (II), by 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 preceding year; and

(II) for items and services described in paragraph (2)(D) for 2009, section 1834(a)(14)(J) shall apply under this paragraph instead of the percentage increase otherwise applicable; and

(ii) for 2011 and subsequent years—

(I) 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, reduced by—

(II) the productivity adjustment described in section 1886(b)(3)(B)(xi)(II).

The application of subparagraph (B)(ii)(II) may result in the update under this paragraph being less than 0.0 for a year,

and may result in payment rates under any fee schedule established under this paragraph for a year being less than such payment rates for the preceding year.

(2) The items and services described in this paragraph are as follows:

- (A) Medical supplies.
- (B) Home dialysis supplies and equipment (as defined in section 1881(b)(8)).
- (D) Parenteral and enteral nutrients, equipment, and supplies.
- (E) Electromyogram devices.
- (F) Salivation devices.
- (G) Blood products.
- (H) Transfusion medicine.

(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) subject to section 1834(a)(1)(G), 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.

(t)(1) Each request for payment, or bill submitted, for an item or service furnished to an individual who is a resident of a skilled nursing facility for which payment may be made under this part shall include the facility's medicare provider number.

(2) Each request for payment, or bill submitted, for therapy services described in paragraph (1) or (3) of section 1833(g), including services described in section 1833(a)(8)(B), furnished on or after October 1, 2012, for which payment may be made under this part shall include the national provider identifier of the physician who periodically reviews the plan for such services under section 1861(p)(2).

(u) Each request for payment, or bill submitted, for a drug furnished to an individual for the treatment of anemia in connection with the treatment of cancer shall include (in a form and manner specified by the Secretary) information on the hemoglobin or hematocrit levels for the individual.

PART E—MISCELLANEOUS PROVISIONS

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EFFECT OF ACCREDITATION

SEC. 1865. (a)(1) If the Secretary finds that accreditation of a provider entity (as defined in paragraph (4)) by the American Osteopathic Association or any other national accreditation body demonstrates that all of the applicable conditions or requirements of this title (other than the requirements of section 1834(j) [or the

conditions and requirements under section 1881(b)] are met or exceeded—

(A) in the case of a provider entity not described in paragraph (3)(B), the Secretary shall treat such entity as meeting those conditions or requirements with respect to which the Secretary made such finding; or

(B) in the case of a provider entity described in paragraph (3)(B), the Secretary may treat such entity as meeting those conditions or requirements with respect to which the Secretary made such finding.

(2) In making such a finding, the Secretary shall consider, among other factors with respect to a national accreditation body, its requirements for accreditation, its survey procedures, its ability to provide adequate resources for conducting required surveys and supplying information for use in enforcement activities, its monitoring procedures for provider entities found out of compliance with the conditions or requirements, and its ability to provide the Secretary with necessary data for validation.

(3)(A) Except as provided in subparagraph (B), not later than 60 days after the date of receipt of a written request for a finding under paragraph (1) (with any documentation necessary to make a determination on the request), the Secretary shall publish a notice identifying the national accreditation body making the request, describing the nature of the request, and providing a period of at least 30 days for the public to comment on the request. The Secretary shall approve or deny a request for such a finding, and shall publish notice of such approval or denial, not later than 210 days after the date of receipt of the request (with such documentation). Such an approval shall be effective with respect to accreditation determinations made on or after such effective date (which may not be later than the date of publication of the approval) as the Secretary specifies in the publication notice.

(B) The 210-day and 60-day deadlines specified in subparagraph (A) shall not apply in the case of any request for a finding with respect to accreditation of a provider entity to which the conditions and requirements of sections 1819 and 1861(j) apply.

(4) For purposes of this section, the term “provider entity” means a provider of services, supplier, facility (*including a renal dialysis facility*), clinic, agency, or laboratory.

(b) The Secretary may not disclose any accreditation survey (other than a survey with respect to a home health agency) made and released to the Secretary by the American Osteopathic Association or any other national accreditation body, of an entity accredited by such body, except that the Secretary may disclose such a survey and information related to such a survey to the extent such survey and information relate to an enforcement action taken by the Secretary.

(c) Notwithstanding any other provision of this title, if the Secretary finds that a provider entity has significant deficiencies (as defined in regulations pertaining to health and safety), the entity shall, after the date of notice of such finding to the entity and for such period as may be prescribed in regulations, be deemed not to meet the conditions or requirements the entity has been treated as meeting pursuant to subsection (a)(1).

(d) For provisions relating to validation surveys of entities that are treated as meeting applicable conditions or requirements of this title pursuant to subsection (a)(1), see section 1864(c).

(e) *With respect to an accreditation body that has received approval from the Secretary under subsection (a)(3)(A) for accreditation of provider entities that are required to meet the conditions and requirements under section 1881(b), in addition to review and oversight authorities otherwise applicable under this title, the Secretary shall (as the Secretary determines appropriate) conduct, with respect to such accreditation body and provider entities, any or all of the following more frequently than is otherwise required to be conducted under this title with respect to other accreditation bodies or other provider entities:*

(1) *Validation surveys referred to in subsection (d).*

(2) *Accreditation program reviews (as defined in section 488.8(c) of title 42 of the Code of Federal Regulations, or a successor regulation).*

(3) *Performance reviews (as defined in section 488.8(a) of title 42 of the Code of Federal Regulations, or a successor regulation).*

* * * * *

LIMITATION ON CERTAIN PHYSICIAN REFERRALS

SEC. 1877. (a) PROHIBITION OF CERTAIN REFERRALS.—

(1) **IN GENERAL.**—Except as provided in subsection (b), if a physician (or an immediate family member of such physician) has a financial relationship with an entity specified in paragraph (2), then—

(A) the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made under this title, and

(B) the entity may not present or cause to be presented a claim under this title or bill to any individual, third party payor, or other entity for designated health services furnished pursuant to a referral prohibited under subparagraph (A).

(2) **FINANCIAL RELATIONSHIP SPECIFIED.**—For purposes of this section, a financial relationship of a physician (or an immediate family member of such physician) with an entity specified in this paragraph is—

(A) except as provided in subsections (c) and (d), an ownership or investment interest in the entity, or

(B) except as provided in subsection (e), a compensation arrangement (as defined in subsection (h)(1)) between the physician (or an immediate family member of such physician) and the entity.

An ownership or investment interest described in subparagraph (A) may be through equity, debt, or other means and includes an interest in an entity that holds an ownership or investment interest in any entity providing the designated health service.

(b) **GENERAL EXCEPTIONS TO BOTH OWNERSHIP AND COMPENSATION ARRANGEMENT PROHIBITIONS.**—Subsection (a)(1) shall not apply in the following cases:

(1) PHYSICIANS' SERVICES.—In the case of physicians' services (as defined in section 1861(q)) provided personally by (or under the personal supervision of) another physician in the same group practice (as defined in subsection (h)(4)) as the referring physician.

(2) IN-OFFICE ANCILLARY SERVICES.—In the case of services (other than durable medical equipment (excluding infusion pumps) and parenteral and enteral nutrients, equipment, and supplies)—

(A) that are furnished—

(i) personally by the referring physician, personally by a physician who is a member of the same group practice as the referring physician, or personally by individuals who are directly supervised by the physician or by another physician in the group practice, and

(ii)(I) in a building in which the referring physician (or another physician who is a member of the same group practice) furnishes physicians' services unrelated to the furnishing of designated health services, or

(II) in the case of a referring physician who is a member of a group practice, in another building which is used by the group practice—

(aa) for the provision of some or all of the group's clinical laboratory services, or

(bb) for the centralized provision of the group's designated health services (other than clinical laboratory services),

unless the Secretary determines other terms and conditions under which the provision of such services does not present a risk of program or patient abuse, and

(B) that are billed by the physician performing or supervising the services, by a group practice of which such physician is a member under a billing number assigned to the group practice, or by an entity that is wholly owned by such physician or such group practice,

if the ownership or investment interest in such services meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse. Such requirements shall, with respect to magnetic resonance imaging, computed tomography, positron emission tomography, and any other designated health services specified under subsection (h)(6)(D) that the Secretary determines appropriate, include a requirement that the referring physician inform the individual in writing at the time of the referral that the individual may obtain the services for which the individual is being referred from a person other than a person described in subparagraph (A)(i) and provide such individual with a written list of suppliers (as defined in section 1861(d)) who furnish such services in the area in which such individual resides.

(3) PREPAID PLANS.—In the case of services furnished by an organization—

(A) with a contract under section 1876 to an individual enrolled with the organization,

(B) described in section 1833(a)(1)(A) to an individual enrolled with the organization,

(C) receiving payments on a prepaid basis, under a demonstration project under section 402(a) of the Social Security Amendments of 1967 or under section 222(a) of the Social Security Amendments of 1972, to an individual enrolled with the organization,

(D) that is a qualified health maintenance organization (within the meaning of section 1310(d) of the Public Health Service Act) to an individual enrolled with the organization, or

(E) that is a Medicare+Choice organization under part C that is offering a coordinated care plan described in section 1851(a)(2)(A) to an individual enrolled with the organization.

(4) OTHER PERMISSIBLE EXCEPTIONS.—In the case of any other financial relationship which the Secretary determines, and specifies in regulations, does not pose a risk of program or patient abuse.

(5) ELECTRONIC PRESCRIBING.—An exception established by regulation under section 1860D 3(e)(6).

(c) GENERAL EXCEPTION RELATED ONLY TO OWNERSHIP OR INVESTMENT PROHIBITION FOR OWNERSHIP IN PUBLICLY TRADED SECURITIES AND MUTUAL FUNDS.—Ownership of the following shall not be considered to be an ownership or investment interest described in subsection (a)(2)(A):

(1) Ownership of investment securities (including shares or bonds, debentures, notes, or other debt instruments) which may be purchased on terms generally available to the public and which are—

(A)(i) securities listed on the New York Stock Exchange, the American Stock Exchange, or any regional exchange in which quotations are published on a daily basis, or foreign securities listed on a recognized foreign, national, or regional exchange in which quotations are published on a daily basis, or

(ii) traded under an automated interdealer quotation system operated by the National Association of Securities Dealers, and

(B) in a corporation that had, at the end of the corporation's most recent fiscal year, or on average during the previous 3 fiscal years, stockholder equity exceeding \$75,000,000.

(2) Ownership of shares in a regulated investment company as defined in section 851(a) of the Internal Revenue Code of 1986, if such company had, at the end of the company's most recent fiscal year, or on average during the previous 3 fiscal years, total assets exceeding \$75,000,000.

(d) ADDITIONAL EXCEPTIONS RELATED ONLY TO OWNERSHIP OR INVESTMENT PROHIBITION.—The following, if not otherwise excepted under subsection (b), shall not be considered to be an ownership or investment interest described in subsection (a)(2)(A):

(1) HOSPITALS IN PUERTO RICO.—In the case of designated health services provided by a hospital located in Puerto Rico.

(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;

(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)); and

(C) in the case where the entity is a hospital, the hospital meets the requirements of paragraph (3)(D).

(3) HOSPITAL OWNERSHIP.—In the case of designated health services provided by a hospital (other than a hospital described in paragraph (1)) if—

(A) the referring physician is authorized to perform services at the hospital;

(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));

(C) the ownership or investment interest is in the hospital itself (and not merely in a subdivision of the hospital); and

(D) the hospital meets the requirements described in subsection (i)(1) not later than 18 months after the date of the enactment of this subparagraph.

(e) EXCEPTIONS RELATING TO OTHER COMPENSATION ARRANGEMENTS.—The following shall not be considered to be a compensation arrangement described in subsection (a)(2)(B):

(1) RENTAL OF OFFICE SPACE; RENTAL OF EQUIPMENT.—

(A) OFFICE SPACE.—Payments made by a lessee to a lessor for the use of premises if—

(i) the lease is set out in writing, signed by the parties *before or not later than 90 days after the effective date of the lease*, and specifies the premises covered by the lease,

(ii) the space rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee, except that the lessee may make payments for the use of space consisting of common areas if such payments do not exceed the lessee's pro rata share of expenses for such space based upon the ratio of the space used exclusively by the lessee to the total amount of space (other than common areas) occupied by all persons using such common areas,

(iii) the lease provides for a term of rental or lease for at least 1 year,

(iv) the rental charges over the term of the lease are set in advance, are consistent with fair market value, and are not determined in a manner that takes into

account the volume or value of any referrals or other business generated between the parties,

(v) the lease would be commercially reasonable even if no referrals were made between the parties, and

(vi) the lease meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

(B) EQUIPMENT.—Payments made by a lessee of equipment to the lessor of the equipment for the use of the equipment if—

(i) the lease is set out in writing, signed by the parties *before or not later than 90 days after the effective date of the lease*, and specifies the equipment covered by the lease,

(ii) the equipment rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee,

(iii) the lease provides for a term of rental or lease of at least 1 year,

(iv) the rental charges over the term of the lease are set in advance, are consistent with fair market value, and are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties,

(v) the lease would be commercially reasonable even if no referrals were made between the parties, and

(vi) the lease meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

(C) *HOLDOVER LEASE ARRANGEMENTS.*—*In the case of a holdover lease arrangement for the lease of office space or equipment, which immediately follows a lease arrangement described in subparagraph (A) for the use of such office space or subparagraph (B) for the use of such equipment and that expired after a term of at least one year, payments made by the lessee to the lessor pursuant to such holdover lease arrangement, if—*

(i) the lease arrangement met the conditions of subparagraph (A) for the lease of office space or subparagraph (B) for the use of equipment when the arrangement expired;

(ii) the holdover lease arrangement is on the same terms and conditions as the immediately preceding arrangement; and

(iii) the holdover arrangement continues to satisfy the conditions of subparagraph (A) for the lease of office space or subparagraph (B) for the use of equipment.

(2) BONA FIDE EMPLOYMENT RELATIONSHIPS.—Any amount paid by an employer to a physician (or an immediate family member of such physician) who has a bona fide employment relationship with the employer for the provision of services if—

(A) the employment is for identifiable services,

(B) the amount of the remuneration under the employment—

(i) is consistent with the fair market value of the services, and

(ii) is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician,

(C) the remuneration is provided pursuant to an agreement which would be commercially reasonable even if no referrals were made to the employer, and

(D) the employment meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

Subparagraph (B)(ii) shall not prohibit the payment of remuneration in the form of a productivity bonus based on services performed personally by the physician (or an immediate family member of such physician).

(3) PERSONAL SERVICE ARRANGEMENTS.—

(A) IN GENERAL.—Remuneration from an entity under an arrangement (including remuneration for specific physicians' services furnished to a nonprofit blood center) if—

(i) the arrangement is set out in writing, signed by the parties *before or not later than 90 days after the effective date of the arrangement*, and specifies the services covered by the arrangement,

(ii) the arrangement covers all of the services to be provided by the physician (or an immediate family member of such physician) to the entity,

(iii) the aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement,

(iv) the term of the arrangement is for at least 1 year,

(v) the compensation to be paid over the term of the arrangement is set in advance, does not exceed fair market value, and except in the case of a physician incentive plan described in subparagraph (B), is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties,

(vi) the services to be performed under the arrangement do not involve the counseling or promotion or a business arrangement or other activity that violates any State or Federal law, and

(vii) the arrangement meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

(B) PHYSICIAN INCENTIVE PLAN EXCEPTION.—

(i) IN GENERAL.—In the case of a physician incentive plan (as defined in clause (ii)) between a physician and an entity, the compensation may be determined in a manner (through a withhold, capitation, bonus, or otherwise) that takes into account directly or indirectly the volume or value of any referrals or other business

generated between the parties, if the plan meets the following requirements:

(I) No specific payment is made directly or indirectly under the plan to a physician or a physician group as an inducement to reduce or limit medically necessary services provided with respect to a specific individual enrolled with the entity.

(II) In the case of a plan that places a physician or a physician group at substantial financial risk as determined by the Secretary pursuant to section 1876(i)(8)(A)(ii), the plan complies with any requirements the Secretary may impose pursuant to such section.

(III) Upon request by the Secretary, the entity provides the Secretary with access to descriptive information regarding the plan, in order to permit the Secretary to determine whether the plan is in compliance with the requirements of this clause.

(ii) PHYSICIAN INCENTIVE PLAN DEFINED.—For purposes of this subparagraph, the term “physician incentive plan” means any compensation arrangement between an entity and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services provided with respect to individuals enrolled with the entity.

(C) *HOLDOVER PERSONAL SERVICE ARRANGEMENT.*—*In the case of a holdover personal service arrangement, which immediately follows an arrangement described in subparagraph (A) that expired after a term of at least one year, remuneration from an entity pursuant to such holdover personal service arrangement, if—*

(i) the personal service arrangement met the conditions of subparagraph (A) when the arrangement expired;

(ii) the holdover personal service arrangement is on the same terms and conditions as the immediately preceding arrangement; and

(iii) the holdover arrangement continues to satisfy the conditions of subparagraph (A).

(4) REMUNERATION UNRELATED TO THE PROVISION OF DESIGNATED HEALTH SERVICES.—In the case of remuneration which is provided by a hospital to a physician if such remuneration does not relate to the provision of designated health services.

(5) PHYSICIAN RECRUITMENT.—In the case of remuneration which is provided by a hospital to a physician to induce the physician to relocate to the geographic area served by the hospital in order to be a member of the medical staff of the hospital, if—

(A) the physician is not required to refer patients to the hospital,

(B) the amount of the remuneration under the arrangement is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician, and

- (C) the arrangement meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.
- (6) ISOLATED TRANSACTIONS.—In the case of an isolated financial transaction, such as a one-time sale of property or practice, if—
- (A) the requirements described in subparagraphs (B) and (C) of paragraph (2) are met with respect to the entity in the same manner as they apply to an employer, and
- (B) the transaction meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.
- (7) CERTAIN GROUP PRACTICE ARRANGEMENTS WITH A HOSPITAL.—
- (A) In general.—An arrangement between a hospital and a group under which designated health services are provided by the group but are billed by the hospital if—
- (i) with respect to services provided to an inpatient of the hospital, the arrangement is pursuant to the provision of inpatient hospital services under section 1861(b)(3),
- (ii) the arrangement began before December 19, 1989, and has continued in effect without interruption since such date,
- (iii) with respect to the designated health services covered under the arrangement, substantially all of such services furnished to patients of the hospital are furnished by the group under the arrangement,
- (iv) the arrangement is pursuant to an agreement that is set out in writing and that specifies the services to be provided by the parties and the compensation for services provided under the agreement,
- (v) the compensation paid over the term of the agreement is consistent with fair market value and the compensation per unit of services is fixed in advance and is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties,
- (vi) the compensation is provided pursuant to an agreement which would be commercially reasonable even if no referrals were made to the entity, and
- (vii) the arrangement between the parties meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.
- (8) PAYMENTS BY A PHYSICIAN FOR ITEMS AND SERVICES.—
- Payments made by a physician—
- (A) to a laboratory in exchange for the provision of clinical laboratory services, or
- (B) to an entity as compensation for other items or services if the items or services are furnished at a price that is consistent with fair market value.
- (f) REPORTING REQUIREMENTS.—Each entity providing covered items or services for which payment may be made under this title shall provide the Secretary with the information concerning the en-

tity's ownership, investment, and compensation arrangements, including—

(1) the covered items and services provided by the entity, and

(2) the names and unique physician identification numbers of all physicians with an ownership or investment interest (as described in subsection (a)(2)(A)), or with a compensation arrangement (as described in subsection (a)(2)(B)), in the entity, or whose immediate relatives have such an ownership or investment interest or who have such a compensation relationship with the entity.

Such information shall be provided in such form, manner, and at such times as the Secretary shall specify. The requirement of this subsection shall not apply to designated health services provided outside the United States or to entities which the Secretary determines provides services for which payment may be made under this title very infrequently.

(g) SANCTIONS.—

(1) DENIAL OF PAYMENT.—No payment may be made under this title for a designated health service which is provided in violation of subsection (a)(1).

(2) REQUIRING REFUNDS FOR CERTAIN CLAIMS.—If a person collects any amounts that were billed in violation of subsection (a)(1), the person shall be liable to the individual for, and shall refund on a timely basis to the individual, any amounts so collected.

(3) CIVIL MONEY PENALTY AND EXCLUSION FOR IMPROPER CLAIMS.—Any person that presents or causes to be presented a bill or a claim for a service that such person knows or should know is for a service for which payment may not be made under paragraph (1) or for which a refund has not been made under paragraph (2) shall be subject to a civil money penalty of not more than \$15,000 for each such service. The provisions of section 1128A (other than the first sentence of subsection (a) and other than subsection (b)) 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).

(4) CIVIL MONEY PENALTY AND EXCLUSION FOR CIRCUMVENTION SCHEMES.—Any physician or other entity that enters into an arrangement or scheme (such as a cross-referral arrangement) which the physician or entity knows or should know has a principal purpose of assuring referrals by the physician to a particular entity which, if the physician directly made referrals to such entity, would be in violation of this section, shall be subject to a civil money penalty of not more than \$100,000 for each such arrangement or scheme. The provisions of section 1128A (other than the first sentence of subsection (a) and other than subsection (b)) 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).

(5) FAILURE TO REPORT INFORMATION.—Any person who is required, but fails, to meet a reporting requirement of subsection (f) is subject to a civil money penalty of not more than \$10,000 for each day for which reporting is required to have been

made. The provisions of section 1128A (other than the first sentence of subsection (a) and other than subsection (b)) 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).

(6) ADVISORY OPINIONS.—

(A) IN GENERAL.—The Secretary shall issue written advisory opinions concerning whether a referral relating to designated health services (other than clinical laboratory services) is prohibited under this section. Each advisory opinion issued by the Secretary shall be binding as to the Secretary and the party or parties requesting the opinion.

(B) APPLICATION OF CERTAIN RULES.—The Secretary shall, to the extent practicable, apply the rules under subsections (b)(3) and (b)(4) and take into account the regulations promulgated under subsection (b)(5) of section 1128D in the issuance of advisory opinions under this paragraph.

(C) REGULATIONS.—In order to implement this paragraph in a timely manner, the Secretary may promulgate regulations that take effect on an interim basis, after notice and pending opportunity for public comment.

(D) APPLICABILITY.—This paragraph shall apply to requests for advisory opinions made after the date which is 90 days after the date of the enactment of this paragraph and before the close of the period described in section 1128D(b)(6).

(h) DEFINITIONS AND SPECIAL RULES.—For purposes of this section:

(1) COMPENSATION ARRANGEMENT; REMUNERATION; *HOLDOVER ARRANGEMENT*.—(A) The term “compensation arrangement” means any arrangement involving any remuneration between a physician (or an immediate family member of such physician) and an entity other than an arrangement involving only remuneration described in subparagraph (C).

(B) The term “remuneration” includes any remuneration, directly or indirectly, overtly or covertly, in cash or in kind.

(C) Remuneration described in this subparagraph is any remuneration consisting of any of the following:

(i) The forgiveness of amounts owed for inaccurate tests or procedures, mistakenly performed tests or procedures, or the correction of minor billing errors.

(ii) The provision of items, devices, or supplies that are used solely to—

(I) collect, transport, process, or store specimens for the entity providing the item, device, or supply, or

(II) order or communicate the results of tests or procedures for such entity.

(iii) A payment made by an insurer or a self-insured plan to a physician to satisfy a claim, submitted on a fee for service basis, for the furnishing of health services by that physician to an individual who is covered by a policy with the insurer or by the self-insured plan, if—

(I) the health services are not furnished, and the payment is not made, pursuant to a contract or other

arrangement between the insurer or the plan and the physician,

(II) the payment is made to the physician on behalf of the covered individual and would otherwise be made directly to such individual,

(III) the amount of the payment is set in advance, does not exceed fair market value, and is not determined in a manner that takes into account directly or indirectly the volume or value of any referrals, and

(IV) the payment meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

(D) WRITTEN REQUIREMENT CLARIFIED.—In the case of any requirement pursuant to this section for a compensation arrangement to be in writing, such requirement shall be satisfied by such means as determined by the Secretary, including by a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties involved.

(E) HOLDOVER ARRANGEMENT.—The term “holdover arrangement” means an arrangement, with respect to an agreement (including a lease or other arrangement) that has expired but as of the date of such expiration had been in compliance with the applicable requirements of this section, under which the parties to such expired agreement have, since such date of expiration, continued to perform under the terms and conditions of such expired agreement.

(2) EMPLOYEE.—An individual is considered to be “employed by” or an “employee” of an entity if the individual would be considered to be an employee of the entity under the usual common law rules applicable in determining the employer-employee relationship (as applied for purposes of section 3121(d)(2) of the Internal Revenue Code of 1986).

(3) FAIR MARKET VALUE.—The term “fair market value” means the value in arms length transactions, consistent with the general market value, and, with respect to rentals or leases, the value of rental property for general commercial purposes (not taking into account its intended use) and, in the case of a lease of space, not adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee.

(4) GROUP PRACTICE.—

(A) DEFINITION OF GROUP PRACTICE.—The term “group practice” means a group of 2 or more physicians legally organized as a partnership, professional corporation, foundation, not-for-profit corporation, faculty practice plan, or similar association—

(i) in which each physician who is a member of the group provides substantially the full range of services which the physician routinely provides, including medical care, consultation, diagnosis, or treatment, through the joint use of shared office space, facilities, equipment and personnel,

(ii) for which substantially all of the services of the physicians who are members of the group are provided

through the group and are billed under a billing number assigned to the group and amounts so received are treated as receipts of the group,

(iii) in which the overhead expenses of and the income from the practice are distributed in accordance with methods previously determined,

(iv) except as provided in subparagraph (B)(i), in which no physician who is a member of the group directly or indirectly receives compensation based on the volume or value of referrals by the physician,

(v) in which members of the group personally conduct no less than 75 percent of the physician-patient encounters of the group practice, and

(vi) which meets such other standards as the Secretary may impose by regulation.

(B) SPECIAL RULES.—

(i) PROFITS AND PRODUCTIVITY BONUSES.—A physician in a group practice may be paid a share of overall profits of the group, or a productivity bonus based on services personally performed or services incident to such personally performed services, so long as the share or bonus is not determined in any manner which is directly related to the volume or value of referrals by such physician.

(ii) FACULTY PRACTICE PLANS.—In the case of a faculty practice plan associated with a hospital, institution of higher education, or medical school with an approved medical residency training program in which physician members may provide a variety of different specialty services and provide professional services both within and outside the group, as well as perform other tasks such as research, subparagraph (A) shall be applied only with respect to the services provided within the faculty practice plan.

(5) REFERRAL; REFERRING PHYSICIAN.—

(A) PHYSICIANS' SERVICES.—Except as provided in subparagraph (C), in the case of an item or service for which payment may be made under part B, the request by a physician for the item or service, including the request by a physician for a consultation with another physician (and any test or procedure ordered by, or to be performed by (or under the supervision of) that other physician), constitutes a "referral" by a "referring physician".

(B) OTHER ITEMS.—Except as provided in subparagraph (C), the request or establishment of a plan of care by a physician which includes the provision of the designated health service constitutes a "referral" by a "referring physician".

(C) CLARIFICATION RESPECTING CERTAIN SERVICES INTEGRAL TO A CONSULTATION BY CERTAIN SPECIALISTS.—A request by a pathologist for clinical diagnostic laboratory tests and pathological examination services, a request by a radiologist for diagnostic radiology services, and a request by a radiation oncologist for radiation therapy, if such services are furnished by (or under the supervision

- of) such pathologist, radiologist, or radiation oncologist pursuant to a consultation requested by another physician does not constitute a “referral” by a “referring physician”.
- (6) DESIGNATED HEALTH SERVICES.—The term “designated health services” means any of the following items or services:
- (A) Clinical laboratory services.
 - (B) Physical therapy services.
 - (C) Occupational therapy services.
 - (D) Radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services.
 - (E) Radiation therapy services and supplies.
 - (F) Durable medical equipment and supplies.
 - (G) Parenteral and enteral nutrients, equipment, and supplies.
 - (H) Prosthetics, orthotics, and prosthetic devices and supplies.
 - (I) Home health services.
 - (J) Outpatient prescription drugs.
 - (K) Inpatient and outpatient hospital services.
 - (L) Outpatient speech-language pathology services.
- (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.

(i) REQUIREMENTS FOR HOSPITALS TO QUALIFY FOR RURAL PROVIDER AND HOSPITAL EXCEPTION TO OWNERSHIP OR INVESTMENT PROHIBITION.—

(1) REQUIREMENTS DESCRIBED.—For purposes of subsection (d)(3)(D), the requirements described in this paragraph for a hospital are as follows:

(A) PROVIDER AGREEMENT.—The hospital had—

- (i) physician ownership or investment on December 31, 2010; and
- (ii) a provider agreement under section 1866 in effect on such date.

(B) LIMITATION ON EXPANSION OF FACILITY CAPACITY.—

Except as provided in paragraph (3), the number of operating rooms, procedure rooms, and beds for which the hospital is licensed at any time on or after the date of the enactment of this subsection is no greater than the number of operating rooms, procedure rooms, and beds for which the hospital is licensed as of such date.

(C) PREVENTING CONFLICTS OF INTEREST.—

(i) The hospital submits to the Secretary an annual report containing a detailed description of—

(I) the identity of each physician owner or investor and any other owners or investors of the hospital; and

(II) the nature and extent of all ownership and investment interests in the hospital.

(ii) The hospital has procedures in place to require that any referring physician owner or investor discloses to the patient being referred, by a time that permits the patient to make a meaningful decision regarding the receipt of care, as determined by the Secretary—

(I) the ownership or investment interest, as applicable, of such referring physician in the hospital; and

(II) if applicable, any such ownership or investment interest of the treating physician.

(iii) The hospital does not condition any physician ownership or investment interests either directly or indirectly on the physician owner or investor making or influencing referrals to the hospital or otherwise generating business for the hospital.

(iv) The hospital discloses the fact that the hospital is partially owned or invested in by physicians—

(I) on any public website for the hospital; and

(II) in any public advertising for the hospital.

(D) ENSURING BONA FIDE INVESTMENT.—

(i) The percentage of the total value of the ownership or investment interests held in the hospital, or in an entity whose assets include the hospital, by physician owners or investors in the aggregate does not exceed such percentage as of the date of enactment of this subsection.

(ii) Any ownership or investment interests that the hospital offers to a physician owner or investor are not

offered on more favorable terms than the terms offered to a person who is not a physician owner or investor.

(iii) The hospital (or any owner or investor in the hospital) does not directly or indirectly provide loans or financing for any investment in the hospital by a physician owner or investor.

(iv) The hospital (or any owner or investor in the hospital) does not directly or indirectly guarantee a loan, make a payment toward a loan, or otherwise subsidize a loan, for any individual physician owner or investor or group of physician owners or investors that is related to acquiring any ownership or investment interest in the hospital.

(v) Ownership or investment returns are distributed to each owner or investor in the hospital in an amount that is directly proportional to the ownership or investment interest of such owner or investor in the hospital.

(vi) Physician owners and investors do not receive, directly or indirectly, any guaranteed receipt of or right to purchase other business interests related to the hospital, including the purchase or lease of any property under the control of other owners or investors in the hospital or located near the premises of the hospital.

(vii) The hospital does not offer a physician owner or investor the opportunity to purchase or lease any property under the control of the hospital or any other owner or investor in the hospital on more favorable terms than the terms offered to an individual who is not a physician owner or investor.

(E) PATIENT SAFETY.—

(i) Insofar as the hospital admits a patient and does not have any physician available on the premises to provide services during all hours in which the hospital is providing services to such patient, before admitting the patient—

(I) the hospital discloses such fact to a patient; and

(II) following such disclosure, the hospital receives from the patient a signed acknowledgment that the patient understands such fact.

(ii) The hospital has the capacity to—

(I) provide assessment and initial treatment for patients; and

(II) refer and transfer patients to hospitals with the capability to treat the needs of the patient involved.

(F) LIMITATION ON APPLICATION TO CERTAIN CONVERTED FACILITIES.—The hospital was not converted from an ambulatory surgical center to a hospital on or after the date of enactment of this subsection.

(2) PUBLICATION OF INFORMATION REPORTED.—The Secretary shall publish, and update on an annual basis, the information submitted by hospitals under paragraph (1)(C)(i) on the public

Internet website of the Centers for Medicare & Medicaid Services.

(3) EXCEPTION TO PROHIBITION ON EXPANSION OF FACILITY CAPACITY.—

(A) PROCESS.—

(i) ESTABLISHMENT.—The Secretary shall establish and implement a process under which a hospital that is an applicable hospital (as defined in subparagraph (E)) or is a high Medicaid facility described in subparagraph (F) may apply for an exception from the requirement under paragraph (1)(B).

(ii) OPPORTUNITY FOR COMMUNITY INPUT.—The process under clause (i) shall provide individuals and entities in the community in which the applicable hospital applying for an exception is located with the opportunity to provide input with respect to the application.

(iii) TIMING FOR IMPLEMENTATION.—The Secretary shall implement the process under clause (i) on February 1, 2012.

(iv) REGULATIONS.—Not later than January 1, 2012, the Secretary shall promulgate regulations to carry out the process under clause (i).

(B) FREQUENCY.—The process described in subparagraph (A) shall permit an applicable hospital to apply for an exception up to once every 2 years.

(C) PERMITTED INCREASE.—

(i) IN GENERAL.—Subject to clause (ii) and subparagraph (D), an applicable hospital granted an exception under the process described in subparagraph (A) may increase the number of operating rooms, procedure rooms, and beds for which the applicable hospital is licensed above the baseline number of operating rooms, procedure rooms, and beds of the applicable hospital (or, if the applicable hospital has been granted a previous exception under this paragraph, above the number of operating rooms, procedure rooms, and beds for which the hospital is licensed after the application of the most recent increase under such an exception).

(ii) 100 PERCENT INCREASE LIMITATION.—The Secretary shall not permit an increase in the number of operating rooms, procedure rooms, and beds for which an applicable hospital is licensed under clause (i) to the extent such increase would result in the number of operating rooms, procedure rooms, and beds for which the applicable hospital is licensed exceeding 200 percent of the baseline number of operating rooms, procedure rooms, and beds of the applicable hospital.

(iii) BASELINE NUMBER OF OPERATING ROOMS, PROCEDURE ROOMS, AND BEDS.—In this paragraph, the term “baseline number of operating rooms, procedure rooms, and beds” means the number of operating rooms, procedure rooms, and beds for which the applicable hospital is licensed as of the date of enactment of this subsection (or, in the case of a hospital that did not have a provider agreement in effect as of such date

but does have such an agreement in effect on December 31, 2010, the effective date of such provider agreement).

(D) INCREASE LIMITED TO FACILITIES ON THE MAIN CAMPUS OF THE HOSPITAL.—Any increase in the number of operating rooms, procedure rooms, and beds for which an applicable hospital is licensed pursuant to this paragraph may only occur in facilities on the main campus of the applicable hospital.

(E) APPLICABLE HOSPITAL.—In this paragraph, the term “applicable hospital” means a hospital—

(i) that is located in a county in which the percentage increase in the population during the most recent 5-year period (as of the date of the application under subparagraph (A)) is at least 150 percent of the percentage increase in the population growth of the State in which the hospital is located during that period, as estimated by Bureau of the Census;

(ii) whose annual percent of total inpatient admissions that represent inpatient admissions under the program under title XIX is equal to or greater than the average percent with respect to such admissions for all hospitals located in the county in which the hospital is located;

(iii) that does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries;

(iv) that is located in a State in which the average bed capacity in the State is less than the national average bed capacity; and

(v) that has an average bed occupancy rate that is greater than the average bed occupancy rate in the State in which the hospital is located.

(F) HIGH MEDICAID FACILITY DESCRIBED.—A high Medicaid facility described in this subparagraph is a hospital that—

(i) is not the sole hospital in a county;

(ii) with respect to each of the 3 most recent years for which data are available, has an annual percent of total inpatient admissions that represent inpatient admissions under title XIX that is estimated to be greater than such percent with respect to such admissions for any other hospital located in the county in which the hospital is located; and

(iii) meets the conditions described in subparagraph (E)(iii).

(G) PROCEDURE ROOMS.—In this subsection, the term “procedure rooms” includes rooms in which catheterizations, angiographies, angiograms, and endoscopies are performed, except such term shall not include emergency rooms or departments (exclusive of rooms in which catheterizations, angiographies, angiograms, and endoscopies are performed).

(H) PUBLICATION OF FINAL DECISIONS.—Not later than 60 days after receiving a complete application under this paragraph, the Secretary shall publish in the Federal Register the final decision with respect to such application.

(I) LIMITATION ON REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise of the process under this paragraph (including the establishment of such process).

(4) COLLECTION OF OWNERSHIP AND INVESTMENT INFORMATION.—For purposes of subparagraphs (A)(i) and (D)(i) of paragraph (1), the Secretary shall collect physician ownership and investment information for each hospital.

(5) PHYSICIAN OWNER OR INVESTOR DEFINED.—For purposes of this subsection, the term “physician owner or investor” means a physician (or an immediate family member of such physician) with a direct or an indirect ownership or investment interest in the hospital.

(6) CLARIFICATION.—Nothing in this subsection shall be construed as preventing the Secretary from revoking a hospital’s provider agreement if not in compliance with regulations implementing section 1866.

* * * * *

MEDICARE COVERAGE FOR END STAGE RENAL DISEASE PATIENTS

SEC. 1881. (a) The benefits provided by parts A and B of this title shall include benefits for individuals who have been determined to have end stage renal disease as provided in section 226A, and benefits for kidney donors as provided in subsection (d) of this section. Notwithstanding any other provision of this title, the type, duration, and scope of the benefit provided by parts A and B with respect to individuals who have been determined to have end stage renal disease and who are entitled to such benefits without regard to section 226A shall in no case be less than the type, duration, and scope of the benefits so provided for individuals entitled to such benefits solely by reason of that section.

(b)(1) Payments under this title with respect to services, in addition to services for which payment would otherwise be made under this title, furnished to individuals who have been determined to have end stage renal disease shall include (A) payments on behalf of such individuals to providers of services and renal dialysis facilities which meet such requirements as the Secretary shall by regulation prescribe for institutional dialysis services and supplies (including self-dialysis services in a self-care dialysis unit maintained by the provider or facility), transplantation services, self-care home dialysis support services which are furnished by the provider or facility, and routine professional services performed by a physician during a maintenance dialysis episode if payments for his other professional services furnished to an individual who has end stage renal disease are made on the basis specified in [paragraph (3)(A)] *paragraph (3)(A)(i)* of this subsection, (B) payments to or on behalf of such individuals for home dialysis supplies and equipment, and (C) payments to a supplier of home dialysis supplies and equipment that is not a provider of services, a renal dialysis facility, or a physician for self-administered erythropoietin as described in sec-

tion 1861(s)(2)(P) if the Secretary finds that the patient receiving such drug from such a supplier can safely and effectively administer the drug (in accordance with the applicable methods and standards established by the Secretary pursuant to such section). The requirements prescribed by the Secretary under subparagraph (A) shall include requirements for a minimum utilization rate for transplantations. *Beginning 180 days after the date of the enactment of this sentence, an initial survey of a provider of services or a renal dialysis facility to determine if the conditions and requirements under this paragraph are met shall be initiated not later than 90 days after such date on which both the provider enrollment form (without regard to whether such form is submitted prior to or after such date of enactment) has been determined by the Secretary to be complete and the provider's enrollment status indicates approval is pending the results of such survey.*

(2)(A) With respect to payments for dialysis services furnished by providers of services and renal dialysis facilities to individuals determined to have end stage renal disease for which payments may be made under part B of this title, such payments (unless otherwise provided in this section) shall be equal to 80 percent of the amounts determined in accordance with subparagraph (B); and with respect to payments for services for which payments may be made under part A of this title, the amounts of such payments (which amounts shall not exceed, in respect to costs in procuring organs attributable to payments made to an organ procurement agency or histocompatibility laboratory, the costs incurred by that agency or laboratory) shall be determined in accordance with section 1861(v) or section 1886 (if applicable). Payments shall be made to a renal dialysis facility only if it agrees to accept such payments as payment in full for covered services, except for payment by the individual of 20 percent of the estimated amounts for such services calculated on the basis established by the Secretary under subparagraph (B) and the deductible amount imposed by section 1833(b).

(B) The Secretary shall prescribe in regulations any methods and procedures to (i) determine the costs incurred by providers of services and renal dialysis facilities in furnishing covered services to individuals determined to have end stage renal disease, and (ii) determine, on a cost-related basis or other economical and equitable basis (including any basis authorized under section 1861(v)) and consistent with any regulations promulgated under paragraph (7), the amounts of payments to be made for part B services furnished by such providers and facilities to such individuals.

(C) Such regulations, in the case of services furnished by proprietary providers and facilities (other than hospital outpatient departments) may include, if the Secretary finds it feasible and appropriate, provision for recognition of a reasonable rate of return on equity capital, providing such rate of return does not exceed the rate of return stipulated in section 1861(v)(1)(B).

(D) For purposes of section 1878, a renal dialysis facility shall be treated as a provider of services.

(3) **[With respect to]** (A) *With respect to* payments for physicians' services furnished to individuals determined to have end stage renal disease, the Secretary shall pay 80 percent of the amounts calculated for such services—

[(A)] (i) on a reasonable charge basis (but may, in such case, make payment on the basis of the prevailing charges of other physicians for comparable services or, for services furnished on or after January 1, 1992, on the basis described in section 1848) except that payment may not be made [under this subparagraph] *under this clause* for routine services furnished during a maintenance dialysis episode, or

[(B)] (ii) *subject to subparagraph (B)*, on a comprehensive monthly fee or other basis (which effectively encourages the efficient delivery of dialysis services and provides incentives for the increased use of home dialysis) for an aggregate of services provided over a period of time (as defined in regulations).

(B)(i) *Subject to clause (ii), an individual who is determined to have end stage renal disease and who is receiving home dialysis may choose to receive monthly end stage renal disease-related visits, furnished on or after January 1, 2019, via telehealth.*

(ii) *Clause (i) shall apply to an individual only if the individual receives a face-to-face visit, without the use of telehealth—*

(I) *in the case of the initial three months of home dialysis of such individual, at least monthly; and*

(II) *after such initial three months, at least once every three consecutive months.*

(4)(A) Pursuant to agreements with approved providers of services and renal dialysis facilities, the Secretary may make payments to such providers and facilities for the cost of home dialysis supplies and equipment and self-care home dialysis support services furnished to patients whose self-care home dialysis is under the direct supervision of such provider or facility, on the basis of a target reimbursement rate (as defined in paragraph (6)) or on the basis of a method established under paragraph (7).

(B) The Secretary shall make payments to a supplier of home dialysis supplies and equipment furnished to a patient whose self-care home dialysis is not under the direct supervision of an approved provider of services or renal dialysis facility only in accordance with a written agreement under which—

(i) the patient certifies that the supplier is the sole provider of such supplies and equipment to the patient,

(ii) the supplier agrees to receive payment for the cost of such supplies and equipment only on an assignment-related basis, and

(iii) the supplier certifies that it has entered into a written agreement with an approved provider of services or renal dialysis facility under which such provider or facility agrees to furnish to such patient all self-care home dialysis support services and all other necessary dialysis services and supplies, including institutional dialysis services and supplies and emergency services.

(5) An agreement under paragraph (4) shall require, in accordance with regulations prescribed by the Secretary, that the provider or facility will—

(A) assume full responsibility for directly obtaining or arranging for the provision of—

- (i) such medically necessary dialysis equipment as is prescribed by the attending physician;
- (ii) dialysis equipment maintenance and repair services;
- (iii) the purchase and delivery of all necessary medical supplies; and
- (iv) where necessary, the services of trained home dialysis aides;

(B) perform all such administrative functions and maintain such information and records as the Secretary may require to verify the transactions and arrangements described in subparagraph (A);

(C) submit such cost reports, data, and information as the Secretary may require with respect to the costs incurred for equipment, supplies, and services furnished to the facility's home dialysis patient population; and

(D) provide for full access for the Secretary to all such records, data, and information as he may require to perform his functions under this section.

(6) The Secretary shall establish, for each calendar year, commencing with January 1, 1979, a target reimbursement rate for home dialysis which shall be adjusted for regional variations in the cost of providing home dialysis. In establishing such a rate, the Secretary shall include—

(A) the Secretary's estimate of the cost of providing medically necessary home dialysis supplies and equipment;

(B) an allowance, in an amount determined by the Secretary, to cover the cost of providing personnel to aid in home dialysis; and

(C) an allowance, in an amount determined by the Secretary, to cover administrative costs and to provide an incentive for the efficient delivery of home dialysis;

but in no event (except as may be provided in regulations under paragraph (7)) shall such target rate exceed 75 percent of the national average payment, adjusted for regional variations, for maintenance dialysis services furnished in approved providers and facilities during the preceding fiscal year. Any such target rate so established shall be utilized, without renegotiation of the rate, throughout the calendar year for which it is established. During the last quarter of each calendar year, the Secretary shall establish a home dialysis target reimbursement rate for the next calendar year based on the most recent data available to the Secretary at the time. In establishing any rate under this paragraph, the Secretary may utilize a competitive-bid procedure, a prenegotiated rate procedure, or any other procedure (including methods established under paragraph (7)) which the Secretary determines is appropriate and feasible in order to carry out this paragraph in an effective and efficient manner.

(7) Subject to paragraph (12), the Secretary shall provide by regulation for a method (or methods) for determining prospectively the amounts of payments to be made for dialysis services furnished by providers of services and renal dialysis facilities to individuals in a facility and to such individuals at home. Such method (or methods) shall provide for the prospective determination of a rate (or rates) for each mode of care based on a single composite weighted formula (which takes into account the mix of patients who receive

dialysis services at a facility or at home and the relative costs of providing such services in such settings) for hospital-based facilities and such a single composite weighted formula for other renal dialysis facilities, or based on such other method or combination of methods which differentiate between hospital-based facilities and other renal dialysis facilities and which the Secretary determines, after detailed analysis, will more effectively encourage the more efficient delivery of dialysis services and will provide greater incentives for increased use of home dialysis than through the single composite weighted formulas. The amount of a payment made under any method other than a method based on a single composite weighted formula may not exceed the amount (or, in the case of continuous cycling peritoneal dialysis, 130 percent of the amount) of the median payment that would have been made under the formula for hospital-based facilities. Subject to section 422(a)(2) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, the Secretary shall provide for such exceptions to such methods as may be warranted by unusual circumstances (including the special circumstances of sole facilities located in isolated, rural areas and of pediatric facilities). Each application for such an exception shall be deemed to be approved unless the Secretary disapproves it by not later than 60 working days after the date the application is filed. The Secretary may provide that such method will serve in lieu of any target reimbursement rate that would otherwise be established under paragraph (6). The Secretary shall reduce the amount of each composite rate payment under this paragraph for each treatment by 50 cents (subject to such adjustments as may be required to reflect modes of dialysis other than hemodialysis) and provide for payment of such amount to the organizations (designated under subsection (c)(1)(A)) for such organizations' necessary and proper administrative costs incurred in carrying out the responsibilities described in subsection (c)(2). The Secretary shall provide that amounts paid under the previous sentence shall be distributed to the organizations described in subsection (c)(1)(A) to ensure equitable treatment of all such network organizations. The Secretary in distributing any such payments to network organizations shall take into account—

- (A) the geographic size of the network area;
- (B) the number of providers of end stage renal disease services in the network area;
- (C) the number of individuals who are entitled to end stage renal disease services in the network area; and
- (D) the proportion of the aggregate administrative funds collected in the network area.

The Secretary shall increase the amount of each composite rate payment for dialysis services furnished during 2000 by 1.2 percent above such composite rate payment amounts for such services furnished on December 31, 1999, for such services furnished on or after January 1, 2001, and before January 1, 2005, by 2.4 percent above such composite rate payment amounts for such services furnished on December 31, 2000, 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.

(8) For purposes of this title, the term “home dialysis supplies and equipment” means medically necessary supplies and equipment (including supportive equipment) required by an individual suffering from end stage renal disease in connection with renal dialysis carried out in his home (as defined in regulations), including obtaining, installing, and maintaining such equipment.

(9) For purposes of this title, the term “self-care home dialysis support services”, to the extent permitted in regulation, means—

(A) periodic monitoring of the patient’s home adaptation, including visits by qualified provider or facility personnel (as defined in regulations), so long as this is done in accordance with a plan prepared and periodically reviewed by a professional team (as defined in regulations) including the individual’s physician;

(B) installation and maintenance of dialysis equipment;

(C) testing and appropriate treatment of the water; and

(D) such additional supportive services as the Secretary finds appropriate and desirable.

(10) For purposes of this title, the term “self-care dialysis unit” means a renal dialysis facility or a distinct part of such facility or of a provider of services, which has been approved by the Secretary to make self-dialysis services, as defined by the Secretary in regulations, available to individuals who have been trained for self-dialysis. A self-care dialysis unit must, at a minimum, furnish the services, equipment and supplies needed for self-care dialysis, have patient-staff ratios which are appropriate to self-dialysis (allowing for such appropriate lesser degree of ongoing medical supervision and assistance of ancillary personnel than is required for full care maintenance dialysis), and meet such other requirements as the Secretary may prescribe with respect to the quality and cost-effectiveness of services.

(11)(A) Hepatitis B vaccine and its administration, when provided to a patient determined to have end stage renal disease, shall not be included as dialysis services for purposes of payment under any prospective payment amount or comprehensive fee established under this section. Payment for such vaccine and its administration shall be made separately in accordance with section 1833.

(B) Erythropoietin, when provided to a patient determined to have end stage renal disease, shall not be included as a dialysis service for purposes of payment under any prospective payment amount or comprehensive fee established under this section, and subject to paragraphs (12) and (13) payment for such item shall be made separately—

(i) in the case of erythropoietin provided by a physician, in accordance with section 1833; and

(ii) in the case of erythropoietin provided by a provider of services, renal dialysis facility, or other supplier of home dialysis supplies and equipment—

(I) for erythropoietin provided during 1994, in an amount equal to \$10 per thousand units (rounded to the nearest 100 units), and

(II) for erythropoietin provided during a subsequent year, in an amount determined to be appropriate by the Secretary, except that such amount may not exceed the amount determined under this clause for the previous year

increased by the percentage increase (if any) in the implicit price deflator for gross national product (as published by the Department of Commerce) for the second quarter of the preceding year over the implicit price deflator for the second quarter of the second preceding year.

(C) The amount payable to a supplier of home dialysis supplies and equipment that is not a provider of services, a renal dialysis facility, or a physician for erythropoietin shall be determined in the same manner as the amount payable to a renal dialysis facility for such item.

(12)(A) Subject to paragraph (14), 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. Under such system, the payment rate for dialysis services furnished on or after January 1, 2009, by providers of services shall be the same as the payment rate (computed without regard to this sentence) for such services furnished by renal dialysis facilities, and in applying the geographic index under subparagraph (D) to providers of services, the labor share shall be based on the labor share otherwise applied for renal dialysis facilities.

(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).

Except as provided in subparagraph (G), nothing in this paragraph or paragraph (14) shall be construed as providing for an update to the composite rate component of the basic case-mix adjusted system under subparagraph (B) or under the system under paragraph (14).

(G) The Secretary shall increase the amount of the composite rate component of the basic case-mix adjusted system under subparagraph (B) for dialysis services—

(i) furnished on or after January 1, 2006, and before April 1, 2007, by 1.6 percent above the amount of such composite rate component for such services furnished on December 31, 2005;

(ii) furnished on or after April 1, 2007, and before January 1, 2009, by 1.6 percent above the amount of such composite rate component for such services furnished on March 31, 2007;

(iii) furnished on or after January 1, 2009, and before January 1, 2010, by 1.0 percent above the amount of such composite rate component for such services furnished on December 31, 2008; and

(iv) furnished on or after January 1, 2010, by 1.0 percent above the amount of such composite rate component for such services furnished on December 31, 2009.

(H) 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) Subject to paragraph (14), 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) 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, subject to paragraph (14).

(14)(A)(i) Subject to subparagraph (E), for services furnished on or after January 1, 2011, the Secretary shall implement a payment system under which a single payment is made under this title to a provider of services or a renal dialysis facility for renal dialysis services (as defined in subparagraph (B)) in lieu of any other payment (including a payment adjustment under paragraph (12)(B)(ii)) and for such services and items furnished pursuant to paragraph (4).

(ii) In implementing the system under this paragraph the Secretary shall ensure that the estimated total amount of payments under this title for 2011 for renal dialysis services shall equal 98 percent of the estimated total amount of payments for renal dialysis services, including payments under paragraph (12)(B)(ii), that would have been made under this title with respect to services furnished in 2011 if such system had not been implemented. In making the estimation under subclause (I), the Secretary shall use per patient utilization data from 2007, 2008, or 2009, whichever has the lowest per patient utilization.

(B) For purposes of this paragraph, the term “renal dialysis services” includes—

(i) items and services included in the composite rate for renal dialysis services as of December 31, 2010;

(ii) erythropoiesis stimulating agents and any oral form of such agents that are furnished to individuals for the treatment of end stage renal disease;

(iii) other drugs and biologicals that are furnished to individuals for the treatment of end stage renal disease and for which payment was (before the application of this paragraph) made separately under this title, and any oral equivalent form of such drug or biological; and

(iv) diagnostic laboratory tests and other items and services not described in clause (i) that are furnished to individuals for the treatment of end stage renal disease.

Such term does not include vaccines.

(C) The system under this paragraph may provide for payment on the basis of services furnished during a week or month or such other appropriate unit of payment as the Secretary specifies.

(D) Such system—

(i) shall include a payment adjustment based on case mix that may take into account patient weight, body mass index, comorbidities, length of time on dialysis, age, race, ethnicity, and other appropriate factors;

(ii) shall include a payment adjustment for high cost outliers due to unusual variations in the type or amount of medically necessary care, including variations in the amount of erythropoiesis stimulating agents necessary for anemia management;

(iii) shall include a payment adjustment that reflects the extent to which costs incurred by low-volume facilities (as defined by the Secretary) in furnishing renal dialysis services exceed the costs incurred by other facilities in furnishing such services, and for payment for renal dialysis services furnished on or after January 1, 2011, and before January 1, 2014, such payment adjustment shall not be less than 10 percent; and

(iv) may include such other payment adjustments as the Secretary determines appropriate, such as a payment adjustment—

(I) for pediatric providers of services and renal dialysis facilities;

(II) by a geographic index, such as the index referred to in paragraph (12)(D), as the Secretary determines to be appropriate; and

(III) for providers of services or renal dialysis facilities located in rural areas.

The Secretary shall take into consideration the unique treatment needs of children and young adults in establishing such system.

(E)(i) The Secretary shall provide for a four-year phase-in (in equal increments) of the payment amount under the payment system under this paragraph, with such payment amount being fully implemented for renal dialysis services furnished on or after January 1, 2014.

(ii) A provider of services or renal dialysis facility may make a one-time election to be excluded from the phase-in under clause (i) and be paid entirely based on the payment amount under the payment system under this paragraph. Such an election shall be made prior to January 1, 2011, in a form and manner specified by the Secretary, and is final and may not be rescinded.

(iii) The Secretary shall make an adjustment to the payments under this paragraph for years during which the phase-in under clause (i) is applicable so that the estimated total amount of payments under this paragraph, including payments under this subparagraph, shall equal the estimated total amount of payments that would otherwise occur under this paragraph without such phase-in.

(F)(i)(I) Subject to subclauses (II) and (III) and clause (ii), beginning in 2012, the Secretary shall annually increase payment amounts established under this paragraph by an ESRD market basket percentage increase factor for a bundled payment system for renal dialysis services that reflects changes over time in the prices

of an appropriate mix of goods and services included in renal dialysis services.120 (II) For 2012 and each subsequent year, after determining the increase factor described in subclause (I), the Secretary shall reduce such increase factor by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II). The application of the preceding sentence may result in such increase factor being less than 0.0 for a year, and may result in payment rates under the payment system under this paragraph for a year being less than such payment rates for the preceding year. In order to accomplish the purposes of subparagraph (I) with respect to 2016, 2017, and 2018, after determining the increase factor described in the preceding sentence for each of 2016, 2017, and 2018, the Secretary shall reduce such increase factor by 1.25 percentage points for each of 2016 and 2017 and by 1 percentage point for 2018.

(II) Subject to subclause (III), for 2012 and each subsequent year, after determining the increase factor described in subclause (I), the Secretary shall reduce such increase factor by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II). The application of the preceding sentence may result in such increase factor being less than 0.0 for a year, and may result in payment rates under the payment system under this paragraph for a year being less than such payment rates for the preceding year.

(III) Notwithstanding subclauses (I) and (II), in order to accomplish the purposes of subparagraph (I) with respect to 2015, the increase factor described in subclause (I) for 2015 shall be 0.0 percent pursuant to the regulation issued by the Secretary on December 2, 2013, entitled “Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies; Final Rule” (78 Fed. Reg. 72156).

(ii) For years during which a phase-in of the payment system pursuant to subparagraph (E) is applicable, the following rules shall apply to the portion of the payment under the system that is based on the payment of the composite rate that would otherwise apply if the system under this paragraph had not been enacted:

(I) The update under clause (i) shall not apply.

(II) Subject to clause (i)(II), the Secretary shall annually increase such composite rate by the ESRD market basket percentage increase factor described in clause (i)(I).

(G) There shall be no administrative or judicial review under section 1869, section 1878, or otherwise of the determination of payment amounts under subparagraph (A), the establishment of an appropriate unit of payment under subparagraph (C), the identification of renal dialysis services included in the bundled payment, the adjustments under subparagraph (D), the application of the phase-in under subparagraph (E), and the establishment of the market basket percentage increase factors under subparagraph (F).

(H) Erythropoiesis stimulating agents and other drugs and biologicals shall be treated as prescribed and dispensed or administered and available only under part B if they are—

(i) furnished to an individual for the treatment of end stage renal disease; and

(ii) included in subparagraph (B) for purposes of payment under this paragraph.

(I) For services furnished on or after January 1, 2014, and before January 1, 2015, the Secretary shall, by comparing per patient utilization data from 2007 with such data from 2012, make reductions to the single payment that would otherwise apply under this paragraph for renal dialysis services to reflect the Secretary's estimate of the change in the utilization of drugs and biologicals described in clauses (ii), (iii), and (iv) of subparagraph (B) (other than oral-only ESRD-related drugs, as such term is used in the final rule promulgated by the Secretary in the Federal Register on August 12, 2010 (75 Fed. Reg. 49030)). In making reductions under the preceding sentence, the Secretary shall take into account the most recently available data on average sales prices and changes in prices for drugs and biological reflected in the ESRD market basket percentage increase factor under subparagraph (F).

(c)(1)(A)(i) For the purpose of assuring effective and efficient administration of the benefits provided under this section, the Secretary shall, in accordance with such criteria as he finds necessary to assure the performance of the responsibilities and functions specified in paragraph (2)—

(I) establish at least 17 end stage renal disease network areas, and

(II) for each such area, designate a network administrative organization which, in accordance with regulations of the Secretary, shall establish (aa) a network council of renal dialysis and transplant facilities located in the area and (bb) a medical review board, which has a membership including at least one patient representative and physicians, nurses, and social workers engaged in treatment relating to end stage renal disease.

The Secretary shall publish in the Federal Register a description of the geographic area that he determines, after consultation with appropriate professional and patient organizations, constitutes each network area and the criteria on the basis of which such determination is made.

(ii)(I) In order to determine whether the Secretary should enter into, continue, or terminate an agreement with a network administrative organization designated for an area established under clause (i), the Secretary shall develop and publish in the Federal Register standards, criteria, and procedures to evaluate an applicant organization's capabilities to perform (and, in the case of an organization with which such an agreement is in effect, actual performance of) the responsibilities described in paragraph (2). The Secretary shall evaluate each applicant based on quality and scope of services and may not accord more than 20 percent of the weight of the evaluation to the element of price.

(II) An agreement with a network administrative organization may be terminated by the Secretary only if he finds, after applying such standards and criteria, that the organization has failed to perform its prescribed responsibilities effectively and efficiently. If such an agreement is to be terminated, the Secretary shall select a successor to the agreement on the basis of competitive bidding and in a manner that provides an orderly transition.

(B) At least one patient representative shall serve as a member of each network council and each medical review board.

(C) The Secretary shall, in regulations, prescribe requirements with respect to membership in network organizations by individuals (and the relatives of such individuals) (i) who have an ownership or control interest in a facility or provider which furnishes services referred to in section 1861(s)(2)(F), or (ii) who have received remuneration from any such facility or provider in excess of such amounts as constitute reasonable compensation for services (including time and effort relative to the provision of professional medical services) or goods supplied to such facility or provider; and such requirements shall provide for the definition, disclosure, and, to the maximum extent consistent with effective administration, prevention of potential or actual financial or professional conflicts of interest with respect to decisions concerning the appropriateness, nature, or site of patient care.

(2) The network organizations of each network shall be responsible, in addition to such other duties and functions as may be prescribed by the Secretary, for—

(A) encouraging, consistent with sound medical practice, the use of those treatment settings most compatible with the successful rehabilitation of the patient and the participation of patients, providers of services, and renal disease facilities in vocational rehabilitation programs;

(B) developing criteria and standards relating to the quality and appropriateness of patient care and with respect to working with patients, facilities, and providers in encouraging participation in vocational rehabilitation programs; and network goals with respect to the placement of patients in self-care settings and undergoing or preparing for transplantation;

(C) evaluating the procedure by which facilities and providers in the network assess the appropriateness of patients for proposed treatment modalities;

(D) implementing a procedure for evaluating and resolving patient grievances;

(E) conducting on-site reviews of facilities and providers as necessary (as determined by a medical review board or the Secretary), utilizing standards of care established by the network organization to assure proper medical care;

(F) collecting, validating, and analyzing such data as are necessary to prepare the reports required by subparagraph (H) and to assure the maintenance of the registry established under paragraph (7);

(G) identifying facilities and providers that are not cooperating toward meeting network goals and assisting such facilities and providers in developing appropriate plans for correction and reporting to the Secretary on facilities and providers that are not providing appropriate medical care; and

(H) submitting an annual report to the Secretary on July 1 of each year which shall include a full statement of the network's goals, data on the network's performance in meeting its goals (including data on the comparative performance of facilities and providers with respect to the identification and placement of suitable candidates in self-care settings and transplantation and encouraging participation in vocational rehabilitation programs), identification of those facilities that have consistently failed to cooperate with network goals, and rec-

ommendations with respect to the need for additional or alternative services or facilities in the network in order to meet the network goals, including self-dialysis training, transplantation, and organ procurement facilities.

(3) Where the Secretary determines, on the basis of the data contained in the network's annual report and such other relevant data as may be available to him, that a facility or provider has consistently failed to cooperate with network plans and goals or to follow the recommendations of the medical review board, he may terminate or withhold certification of such facility or provider (for purposes of payment for services furnished to individuals with end stage renal disease) until he determines that such provider or facility is making reasonable and appropriate efforts to cooperate with the network's plans and goals. If the Secretary determines that the facility's or provider's failure to cooperate with network plans and goals does not jeopardize patient health or safety or justify termination of certification, he may instead, after reasonable notice to the provider or facility and to the public, impose such other sanctions as he determines to be appropriate, which sanctions may include denial of reimbursement with respect to some or all patients admitted to the facility after the date of notice to the facility or provider, and graduated reduction in reimbursement for all patients.

(4) The Secretary shall, in determining whether to certify additional facilities or expansion of existing facilities within a network, take into account the network's goals and performance as reflected in the network's annual report.

(5) The Secretary, after consultation with appropriate professional and planning organizations, shall provide such guidelines with respect to the planning and delivery of renal disease services as are necessary to assist network organizations in their development of their respective networks' goals to promote the optimum use of self-dialysis and transplantation by suitable candidates for such modalities.

(6) It is the intent of the Congress that the maximum practical number of patients who are medically, socially, and psychologically suitable candidates for home dialysis or transplantation should be so treated and that the maximum practical number of patients who are suitable candidates for vocational rehabilitation services be given access to such services and encouraged to return to gainful employment. The Secretary shall consult with appropriate professional and network organizations and consider available evidence relating to developments in research, treatment methods, and technology for home dialysis and transplantation.

(7) The Secretary shall establish a national end stage renal disease registry the purpose of which shall be to assemble and analyze the data reported by network organizations, transplant centers, and other sources on all end stage renal disease patients in a manner that will permit—

(A) the preparation of the annual report to the Congress required under subsection (g);

(B) an identification of the economic impact, cost-effectiveness, and medical efficacy of alternative modalities of treatment;

(C) an evaluation with respect to the most appropriate allocation of resources for the treatment and research into the cause of end stage renal disease;

(D) the determination of patient mortality and morbidity rates, and trends in such rates, and other indices of quality of care; and

(E) such other analyses relating to the treatment and management of end stage renal disease as will assist the Congress in evaluating the end stage renal disease program under this section.

The Secretary shall provide for such coordination of data collection activities, and such consolidation of existing end stage renal disease data systems, as is necessary to achieve the purpose of such registry, shall determine the appropriate location of the registry, and shall provide for the appointment of a professional advisory group to assist the Secretary in the formulation of policies and procedures relevant to the management of such registry.

(8) The provisions of sections 1157 and 1160 shall apply with respect to network administrative organizations (including such organizations as medical review boards) with which the Secretary has entered into agreements under this subsection.

(d) Notwithstanding any provision to the contrary in section 226 any individual who donates a kidney for transplant surgery shall be entitled to benefits under parts A and B of this title with respect to such donation. Reimbursement for the reasonable expenses incurred by such an individual with respect to a kidney donation shall be made (without regard to the deductible, premium, and co-insurance provisions of this title), in such manner as may be prescribed by the Secretary in regulations, for all reasonable preparatory, operation, and postoperation recovery expenses associated with such donation, including but not limited to the expenses for which payment could be made if he were an eligible individual for purposes of parts A and B of this title without regard to this subsection. Payments for postoperation recovery expenses shall be limited to the actual period of recovery.

(e)(1) Notwithstanding any other provision of this title, the Secretary may, pursuant to agreements with approved providers of services, renal dialysis facilities, and nonprofit entities which the Secretary finds can furnish equipment economically and efficiently, reimburse such providers, facilities, and nonprofit entities (without regard to the deductible and coinsurance provisions of this title) for the reasonable cost of the purchase, installation, maintenance and reconditioning for subsequent use of artificial kidney and automated dialysis peritoneal machines (including supportive equipment) which are to be used exclusively by entitled individuals dialyzing at home.

(2) An agreement under this subsection shall require that the provider, facility, or other entity will—

(A) make the equipment available for use only by entitled individuals dialyzing at home;

(B) recondition the equipment, as needed, for reuse by such individuals throughout the useful life of the equipment, including modification of the equipment consistent with advances in research and technology;

(C) provide for full access for the Secretary to all records and information relating to the purchase, maintenance, and use of the equipment; and

(D) submit such reports, data, and information as the Secretary may require with respect to the cost, management, and use of the equipment.

(3) For purposes of this section, the term "supportive equipment" includes blood pumps, heparin pumps, bubble detectors, other alarm systems, and such other items as the Secretary may determine are medically necessary.

(f)(1) The Secretary shall initiate and carry out, at selected locations in the United States, pilot projects under which financial assistance in the purchase of new or used durable medical equipment for renal dialysis is provided to individuals suffering from end stage renal disease at the time home dialysis is begun, with provision for a trial period to assure successful adaptation to home dialysis before the actual purchase of such equipment.

(2) The Secretary shall conduct experiments to evaluate methods for reducing the costs of the end stage renal disease program. Such experiments shall include (without being limited to) reimbursement for nurses and dialysis technicians to assist with home dialysis, and reimbursement to family members assisting with home dialysis.

(3) The Secretary shall conduct experiments to evaluate methods of dietary control for reducing the costs of the end stage renal disease program, including (without being limited to) the use of protein-controlled products to delay the necessity for, or reduce the frequency of, dialysis in the treatment of end stage renal disease.

(4) The Secretary shall conduct a comprehensive study of methods for increasing public participation in kidney donation and other organ donation programs.

(5) The Secretary shall conduct a full and complete study of the reimbursement of physicians for services furnished to patients with end stage renal disease under this title, giving particular attention to the range of payments to physicians for such services, the average amounts of such payments, and the number of hours devoted to furnishing such services to patients at home, in renal disease facilities, in hospitals, and elsewhere.

(6) The Secretary shall conduct a study of the number of patients with end stage renal disease who are not eligible for benefits with respect to such disease under this title (by reason of this section or otherwise), and of the economic impact of such noneligibility of such individuals. Such study shall include consideration of mechanisms whereby governmental and other health plans might be instituted or modified to permit the purchase of actuarially sound coverage for the costs of end stage renal disease.

(7)(A) The Secretary shall establish protocols on standards and conditions for the reuse of dialyzer filters for those facilities and providers which voluntarily elect to reuse such filters.

(B) With respect to dialysis services furnished on or after January 1, 1988 (or July 1, 1988, with respect to protocols that relate to the reuse of bloodlines), no dialysis facility may reuse dialysis supplies (other than dialyzer filters) unless the Secretary has established a protocol with respect to the reuse of such supplies and the facility follows the protocol so established.

(C) The Secretary shall incorporate protocols established under this paragraph, and the requirement of subparagraph (B), into the requirements for facilities prescribed under subsection (b)(1)(A) and failure to follow such a protocol or requirement subjects such a facility to denial of participation in the program established under this section and to denial of payment for dialysis treatment not furnished in compliance with such a protocol or in violation of such requirement.

(8) The Secretary shall submit to the Congress no later than October 1, 1979, a full report on the experiments conducted under paragraphs (1), (2), (3), and (7), and the studies under paragraphs (4), (5), (6), and (7). Such report shall include any recommendations for legislative changes which the Secretary finds necessary or desirable as a result of such experiments and studies.

(g)(1) In any case where the Secretary—

(A) finds that a renal dialysis facility is not in substantial compliance with requirements for such facilities prescribed under subsection (b)(1)(A),

(B) finds that the facility's deficiencies do not immediately jeopardize the health and safety of patients, and

(C) has given the facility a reasonable opportunity to correct its deficiencies,

the Secretary may, in lieu of terminating approval of the facility, determine that payment under this title shall be made to the facility only for services furnished to individuals who were patients of the facility before the effective date of the notice.

(2) The Secretary's decision to restrict payments under this subsection shall be made effective only after such notice to the public and to the facility as may be prescribed in regulations, and shall remain in effect until (A) the Secretary finds that the facility is in substantial compliance with the requirements under subsection (b)(1)(A), or (B) the Secretary terminates the agreement under this title with the facility.

(3) A facility dissatisfied with a determination by the Secretary under paragraph (1) shall be entitled to a hearing thereon by the Secretary (after reasonable notice) to the same extent as is provided in section 205(b), and to judicial review of the Secretary's final decision after such hearing as is provided in section 205(g), except that, in so applying such sections and in applying section 205(l) thereto, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively.

(h) QUALITY INCENTIVES IN THE END-STAGE RENAL DISEASE PROGRAM.—

(1) QUALITY INCENTIVES.—

(A) IN GENERAL.—With respect to renal dialysis services (as defined in subsection (b)(14)(B)) furnished on or after January 1, 2012, in the case of a provider of services or a renal dialysis facility that does not meet the requirement described in subparagraph (B) with respect to the year, payments otherwise made to such provider or facility under the system under subsection (b)(14) for such services shall be reduced by up to 2.0 percent, as determined appropriate by the Secretary.

(B) REQUIREMENT.—The requirement described in this subparagraph is that the provider or facility meets (or exceeds) the total performance score under paragraph (3) with respect to performance standards established by the Secretary with respect to measures specified in paragraph (2).

(C) NO EFFECT IN SUBSEQUENT YEARS.—The reduction under subparagraph (A) shall apply only with respect to the year involved, and the Secretary shall not take into account such reduction in computing the single payment amount under the system under paragraph (14) in a subsequent year.

(2) MEASURES.—

(A) IN GENERAL.—The measures specified under this paragraph with respect to the year involved shall include—

(i) measures on anemia management that reflect the labeling approved by the Food and Drug Administration for such management and measures on dialysis adequacy;

(ii) to the extent feasible, such measure (or measures) of patient satisfaction as the Secretary shall specify;

(iii) for 2016 and subsequent years, measures described in subparagraph (E)(i); and

(iv) such other measures as the Secretary specifies, including, to the extent feasible, measures on—

(I) iron management;

(II) bone mineral metabolism; and

(III) vascular access, including for maximizing the placement of arterial venous fistula.

(B) USE OF ENDORSED MEASURES.—

(i) IN GENERAL.—Subject to clause (ii), any measure specified by the Secretary under subparagraph (A)(iv) must have been endorsed by the entity with a contract under section 1890(a).

(ii) EXCEPTION.—In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a), the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

(C) UPDATING MEASURES.—The Secretary shall establish a process for updating the measures specified under subparagraph (A) in consultation with interested parties.

(D) CONSIDERATION.—In specifying measures under subparagraph (A), the Secretary shall consider the availability of measures that address the unique treatment needs of children and young adults with kidney failure.

(E) MEASURES SPECIFIC TO THE CONDITIONS TREATED WITH ORAL-ONLY DRUGS.—

(i) IN GENERAL.—The measures described in this subparagraph are measures specified by the Secretary that are specific to the conditions treated with oral-only drugs. To the extent feasible, such measures shall be outcomes-based measures.

(ii) CONSULTATION.—In specifying the measures under clause (i), the Secretary shall consult with interested stakeholders.

(iii) USE OF ENDORSED MEASURES.—

(I) IN GENERAL.—Subject to subclause (I), any measures specified under clause (i) must have been endorsed by the entity with a contract under section 1890(a).

(II) EXCEPTION.—If the entity with a contract under section 1890(a) has not endorsed a measure for a specified area or topic related to measures described in clause (i) that the Secretary determines appropriate, the Secretary may specify a measure that is endorsed or adopted by a consensus organization recognized by the Secretary that has expertise in clinical guidelines for kidney disease.

(3) PERFORMANCE SCORES.—

(A) TOTAL PERFORMANCE SCORE.—

(i) IN GENERAL.—Subject to clause (ii), the Secretary shall develop a methodology for assessing the total performance of each provider of services and renal dialysis facility based on performance standards with respect to the measures selected under paragraph (2) for a performance period established under paragraph (4)(D) (in this subsection referred to as the “total performance score”).

(ii) APPLICATION.—For providers of services and renal dialysis facilities that do not meet (or exceed) the total performance score established by the Secretary, the Secretary shall ensure that the application of the methodology developed under clause (i) results in an appropriate distribution of reductions in payment under paragraph (1) among providers and facilities achieving different levels of total performance scores, with providers and facilities achieving the lowest total performance scores receiving the largest reduction in payment under paragraph (1)(A).

(iii) WEIGHTING OF MEASURES.—In calculating the total performance score, the Secretary shall weight the scores with respect to individual measures calculated under subparagraph (B) to reflect priorities for quality improvement, such as weighting scores to ensure that providers of services and renal dialysis facilities have strong incentives to meet or exceed anemia management and dialysis adequacy performance standards, as determined appropriate by the Secretary.

(B) PERFORMANCE SCORE WITH RESPECT TO INDIVIDUAL MEASURES.—The Secretary shall also calculate separate

performance scores for each measure, including for dialysis adequacy and anemia management.

(4) PERFORMANCE STANDARDS.—

(A) ESTABLISHMENT.—Subject to subparagraph (E), the Secretary shall establish performance standards with respect to measures selected under paragraph (2) for a performance period with respect to a year (as established under subparagraph (D)).

(B) ACHIEVEMENT AND IMPROVEMENT.—The performance standards established under subparagraph (A) shall include levels of achievement and improvement, as determined appropriate by the Secretary.

(C) TIMING.—The Secretary shall establish the performance standards under subparagraph (A) prior to the beginning of the performance period for the year involved.

(D) PERFORMANCE PERIOD.—The Secretary shall establish the performance period with respect to a year. Such performance period shall occur prior to the beginning of such year.

(E) SPECIAL RULE.—The Secretary shall initially use as the performance standard for the measures specified under paragraph (2)(A)(i) for a provider of services or a renal dialysis facility the lesser of—

(i) the performance of such provider or facility for such measures in the year selected by the Secretary under the second sentence of subsection (b)(14)(A)(ii); or

(ii) a performance standard based on the national performance rates for such measures in a period determined by the Secretary.

(5) LIMITATION ON REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise of the following:

(A) The determination of the amount of the payment reduction under paragraph (1).

(B) The establishment of the performance standards and the performance period under paragraph (4).

(C) The specification of measures under paragraph (2).

(D) The methodology developed under paragraph (3) that is used to calculate total performance scores and performance scores for individual measures.

(6) PUBLIC REPORTING.—

(A) IN GENERAL.—The Secretary shall establish procedures for making information regarding performance under this subsection available to the public, including—

(i) the total performance score achieved by the provider of services or renal dialysis facility under paragraph (3) and appropriate comparisons of providers of services and renal dialysis facilities to the national average with respect to such scores; and

(ii) the performance score achieved by the provider or facility with respect to individual measures.

(B) OPPORTUNITY TO REVIEW.—The procedures established under subparagraph (A) shall ensure that a provider of services and a renal dialysis facility has the oppor-

tunity to review the information that is to be made public with respect to the provider or facility prior to such data being made public.

(C) CERTIFICATES.—

(i) IN GENERAL.—The Secretary shall provide certificates to providers of services and renal dialysis facilities who furnish renal dialysis services under this section to display in patient areas. The certificate shall indicate the total performance score achieved by the provider or facility under paragraph (3).

(ii) DISPLAY.—Each facility or provider receiving a certificate under clause (i) shall prominently display the certificate at the provider or facility.

(D) WEB-BASED LIST.—The Secretary shall establish a list of providers of services and renal dialysis facilities who furnish renal dialysis services under this section that indicates the total performance score and the performance score for individual measures achieved by the provider and facility under paragraph (3). Such information shall be posted on the Internet website of the Centers for Medicare & Medicaid Services in an easily understandable format.

* * * * *

MEDICARE IMPROVEMENT FUND

SEC. 1898.

(a) ESTABLISHMENT.—The Secretary shall establish under this title a Medicare Improvement Fund (in this section referred to as the ‘Fund’) which shall be available to the Secretary to make improvements under the original Medicare fee-for-service program under parts A and B for individuals entitled to, or enrolled for, benefits under part or enrolled under part B including adjustments to payments for items and services furnished by providers of services and suppliers under such original Medicare fee-for-service program.

(b) FUNDING.—

(1) IN GENERAL.—There shall be available to the Fund, for expenditures from the Fund for services furnished ~~during and after fiscal year 2021, \$270,000,000~~ *during and after fiscal year 2021, \$245,000,000*

(2) PAYMENT FROM TRUST FUNDS.—The amount specified under paragraph (1) 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 such proportion as the Secretary determines appropriate.

(3) FUNDING LIMITATION.—Amounts in the Fund shall be available in advance of appropriations but only if the total amount obligated from the Fund does not exceed the amount available to the Fund under paragraph (1). The Secretary may obligate funds from the Fund 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 sufficient amounts to cover all such obligations incurred consistent with the previous sentence.

(4) NO EFFECT ON PAYMENTS IN SUBSEQUENT YEARS.—In the case that expenditures from the Fund are applied to, or otherwise affect, a payment rate for an item or service under this title for a year, the payment rate for such item or service shall be computed for a subsequent year as if such application or effect had never occurred.

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**MEDICARE IVIG ACCESS AND STRENGTHENING
MEDICARE AND REPAYING TAXPAYERS ACT OF 2012**

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TITLE I—MEDICARE IVIG ACCESS

SEC. 101. MEDICARE PATIENT IVIG ACCESS DEMONSTRATION PROJECT.

(a) ESTABLISHMENT.—The Secretary shall establish and implement a demonstration project under part B of title XVIII of the Social Security Act to evaluate the benefits of providing payment for items and services needed for the in-home administration of intravenous immune globin for the treatment of primary immune deficiency diseases.

(b) DURATION AND SCOPE.—

(1) DURATION.—Beginning not later than one year after the date of enactment of this Act, the Secretary shall conduct the demonstration project for a period of 3 years *and, subject to the availability of funds under subsection (g)—*

(A) if the date of enactment of the Medicare Part B Improvement Act of 2017 is on or before September 30, 2017, for the period beginning on October 1, 2017, and ending on December 31, 2020; and

(B) if the date of enactment of such Act is after September 30, 2017, for the period beginning on the date of enactment of such Act and ending on December 31, 2020

(2) SCOPE.—The Secretary shall enroll not more than 4,000 Medicare beneficiaries who have been diagnosed with primary immunodeficiency disease for participation in the demonstration project. A Medicare beneficiary may participate in the demonstration project on a voluntary basis and may terminate participation at any time. *Subject to the preceding sentence, a Medicare beneficiary enrolled in the demonstration project on September 30, 2017, shall be automatically enrolled during the period beginning on the date of the enactment of the Medicare Part B Improvement Act of 2017 and ending on December 31, 2020, without submission of another application.*

(c) COVERAGE.—Except as otherwise provided in this section, items and services for which payment may be made under the demonstration program shall be treated and covered under part B of title XVIII of the Social Security Act in the same manner as similar items and services covered under such part.

(d) PAYMENT.—The Secretary shall establish a per visit payment amount for items and services needed for the in-home administra-

tion of intravenous immune globin based on the national per visit low-utilization payment amount under the prospective payment system for home health services established under section 1895 of the Social Security Act (42 U.S.C. 1395fff).

(e) WAIVER AUTHORITY.—The Secretary may waive such requirements of title XVIII of the Social Security Act as may be necessary to carry out the demonstration project.

(f) STUDY AND REPORT TO CONGRESS.—

(1) INTERIM EVALUATION AND REPORT.—Not later than three years after the date of enactment of this Act, the Secretary shall submit to Congress a report that contains an interim evaluation of the impact of the demonstration project on access for Medicare beneficiaries to items and services needed for the in-home administration of intravenous immune globin.

(2) FINAL EVALUATION AND REPORT.—Not later than one year after the date of completion of the demonstration project, the Secretary shall submit to Congress a report that contains the following:

(A) A final evaluation of the impact of the demonstration project on access for Medicare beneficiaries to items and services needed for the in-home administration of intravenous immune globin.

(B) An analysis of the appropriateness of implementing a new methodology for payment for intravenous immune globulins in all care settings under part B of title XVIII of the Social Security Act (42 U.S.C. 1395k et seq.).

(C) An update to the report entitled “Analysis of Supply, Distribution, Demand, and Access Issues Associated with Immune Globulin Intravenous (IGIV)”, issued in February 2007 by the Office of the Assistant Secretary for Planning and Evaluation of the Department of Health and Human Services.

(g) FUNDING.—There shall be made available to the Secretary to carry out the demonstration project not more than \$45,000,000 from the Federal Supplementary Medical Insurance Trust Fund under section 1841 of the Social Security Act (42 U.S.C. 1395t).

(h) DEFINITIONS.—In this section:

(1) DEMONSTRATION PROJECT.—The term “demonstration project” means the demonstration project conducted under this section.

(2) MEDICARE BENEFICIARY.—The term “Medicare beneficiary” means an individual who is enrolled for benefits under part B of title XVIII of the Social Security Act.

(3) SECRETARY.—The term “Secretary” means the Secretary of Health and Human Services.

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**VII. EXCHANGES OF LETTERS WITH ADDITIONAL
COMMITTEES OF REFERRAL**

GREG WALDEN, OREGON
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FIFTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115
Majority (202) 225-2927
Minority (202) 225-3641

July 24, 2017

The Honorable Kevin Brady
Chairman
Committee on Ways and Means
1102 Longworth House Office Building
Washington, D.C. 20515

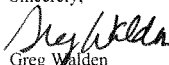
Dear Chairman Brady:

I write concerning H.R. 3178, Medicare Part B Improvement Act of 2017, on which the Committee on Energy and Commerce was granted the primary referral.

I wanted to notify you that the Committee will forgo action on H.R. 3178 so that it may proceed expeditiously to the House floor for consideration. This is done with the understanding that the Committee's jurisdictional interests over this and similar legislation are in no way diminished or altered. In addition, the Committee reserves the right to seek conferees on H.R. 3178 and requests your support when such a request is made.

I would appreciate your response confirming this understanding with respect to H.R. 3178 and ask that a copy of our exchange of letters on this matter be included in the Congressional Record during consideration of the bill on the House floor.

Sincerely,



Greg Walden
Chairman

COMMITTEE ON WAYS AND MEANS

U.S. HOUSE OF REPRESENTATIVES
WASHINGTON, DC 20515

July 24, 2017

The Honorable Greg Walden
Chairman
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Walden,

Thank you for your letter concerning H.R. 3178, the "Medicare Part B Improvement Act of 2017," on which the Energy and Commerce Committee was granted the primary referral.

I am most appreciative of your decision to waive formal consideration of H.R. 3178 so that it may proceed expeditiously to the House floor. I acknowledge that although you waived formal consideration of the bill, the Energy and Commerce Committee is in no way waiving its jurisdiction over the subject matter contained in those provisions of the bill that fall within your Rule X jurisdiction. I would support your effort to seek appointment of an appropriate number of conferees on any House-Senate conference involving this legislation.

I will include a copy of our letters in the *Congressional Record* during consideration of this legislation on the House floor.

Sincerely,


Kevin Brady
Chairman

cc: The Honorable Paul Ryan, Speaker
The Honorable Richard E. Neal
The Honorable Frank Pallone
Thomas J. Wickham, Jr., Parliamentarian