

PROVIDING FOR THE CONSIDERATION OF H.R. 2990, THE QUALITY CARE FOR THE UNINSURED ACT OF 1999, AND H.R. 2723, THE BIPARTISAN CONSENSUS MANAGED CARE IMPROVEMENT ACT OF 1999

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OCTOBER 5, 1999.—Referred to the House Calendar and ordered to be printed

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Mr. GOSS, from the Committee on Rules, submitted the following

## REPORT

[To accompany H. Res. 323]

The Committee on Rules, having had under consideration House Resolution 323, by a record vote of 9 to 3, report the same to the House with the recommendation that the resolution be adopted.

### SUMMARY OF PROVISIONS OF RESOLUTION

The resolution provides for the consideration of H.R. 2990, the Quality Care for the Uninsured Act of 1999, and H.R. 2723, Bipartisan Consensus Managed Care Improvement Act of 1999, under a structured rule.

The rule provides two hours of debate in the House on H.R. 2990, equally divided among and controlled by the chairmen and ranking minority members of the Committee on Commerce, the Committee on Education and the Workforce, and the Committee on Ways and Means. The rule waives all points of order against consideration of the bill. The rule provides one motion to recommit H.R. 2990.

The rule further provides three hours of general debate on H.R. 2723, equally divided among and controlled by the chairmen and ranking minority members of the Committee on Commerce, the Committee on Education and the Workforce, and the Committee on Ways and Means. All points of order against consideration of the bill are waived. The rule also provides that the amendments printed in part A of this report shall be considered as adopted upon adoption of the rule.

The rule provides for consideration of only the amendments printed in part B of this report. The amendments printed in part B shall be considered only in the order specified in this report, may be offered only by a Member designated in this report, shall be considered as read, shall be debatable for the time specified in this report equally divided and controlled by the proponent and an opponent, and shall not be subject to amendment. The rule also waives

all points of order against the amendments printed in part B of this report except that the adoption of an amendment in the nature of a substitute shall constitute the conclusion of consideration of the bill for amendment. The rule provides one motion to recommit H.R. 2723, with or without instructions.

Finally, the rule provides that in the engrossment of H.R. 2990, the clerk shall add the text of H.R. 2723, as passed by the House, as a new matter at the end of H.R. 2990, and then lay H.R. 2723 on the table.

#### COMMITTEE VOTES

Pursuant to clause 3(b) of House rule XIII the results of each record vote on an amendment or motion to report, together with the names of those voting for and against, and printed below:

##### *Rules Committee record vote No. 63*

Date: October 5, 1999.

Measure: H.R. 2990, the Quality Care for the Uninsured Act of 1999 and H.R. 2723, the Bipartisan Consensus Managed Care Improvement Act of 1999.

Motion by: Mr. Frost.

Summary of motion: To make in order amendment No. 27 to H.R. 2990 offered by Reps. Norwood, Dingell, Ganske, and Berry which would provide for revenue provisions designed to offset revenue losses from the bill. (Revenue losses are estimated to result from increased deductions for higher medical premiums.) The offsets would raise approximately \$7 billion over the period 2000–2004. Half of the offsets totaling \$3.5 billion were included in the tax bill that passed the Congress in this session. The remaining offsets consist of the elimination of corporate tax shelters. The provision codifies a court-developed doctrine that requires transactions to have economic substance in order to be respected for tax purposes. The provision would require that the transaction have a potential profit (and risk of loss) and that potential profit must be significant in relationship to the claimed tax benefits.

Results: Defeated 3 to 9.

Vote by Members: Goss—Nay; Linder—Nay; Pryce—Nay; Diaz-Balart—Nay; Hastings—Nay; Myrick—Nay; Sessions—Nay; Reynolds—Nay; Frost—Yea; Hall—Yea; Slaughter—Yea; Dreier—Nay.

##### *Rules Committee record vote No. 64*

Date: October 5, 1999.

Measure: H.R. 2990, the Quality Care for the Uninsured Act of 1999 and H.R. 2723, the Bipartisan Consensus Managed Care Improvement Act of 1999.

Motion by: Mr. Hall.

Summary of motion: To strike the provisions in the rule providing that H.R. 2990 and H.R. 2723 be engrossed together.

Results: Defeated 3 to 9.

Vote by Members: Goss—Nay; Linder—Nay; Pryce—Nay; Diaz-Balart—Nay; Hastings—Nay; Myrick—Nay; Sessions—Nay; Reynolds—Nay; Frost—Yea; Hall—Yea; Slaughter—Yea; Dreier—Nay.

*Rules Committee record vote No. 65*

Date: October 5, 1999.

Measure: H.R. 2990, the quality Care for the Uninsured Act of 1999 and H.R. 2723, the Bipartisan Consensus Managed Care Improvement Act of 1999.

Motion by: Mr. Goss.

Summary of motion: To report the rule.

Results: Adopted 9 to 3.

Vote by Members: Goss—Yea; Linder—Yea; Pryce—Yea; Diaz-Balart—Yea; Hastings—Yea; Myrick—Yea; Sessions—Yea; Reynolds—Yea; Frost—Nay; Hall—Nay; Slaughter—Nay; Dreier—Yea.

## PART A

SUMMARY OF AMENDMENTS CONSIDERED AS ADOPTED UNDER THE  
RULE

Amendments consisting of a variety of technical changes to H.R. 2723. Clarifies provisions in the bill to ensure that employers cannot be held liable unless they are making medical decisions.

TEXT OF THE AMENDMENTS CONSIDERED AS ADOPTED UNDER THE  
RULE

Page 17, beginning on line 24, strike “, as determined by the plan or issuer or as certified in writing by a treating health care professional,”.

Page 40, line 17, strike “enforce actions” and insert “enforce rights”.

Page 42, line 15, insert “or arrange to be offered” after “shall offer”.

Page 44, after line 8, insert the following:

(3) CONSTRUCTION.—Nothing in this subsection shall be construed as affecting the application of section 114 (relating to access to specialty care).

Page 47, amend lines 7 through 18 to read as follows:

(b) REIMBURSEMENT FOR MAINTENANCE CARE AND POST-STABILIZATION CARE.—In the case of services (other than emergency services) for which benefits are available under a group health plan, or under health insurance coverage offered by a health insurance issuer, the plan or issuer shall provide for reimbursement with respect to such services provided to a participant, beneficiary, or enrollee other than through a participating health care provider in a manner consistent with subsection (a)(1)(C) (and shall otherwise comply with the guidelines established under section 1852(d)(2) of the Social Security Act), if the services are maintenance care or post-stabilization care covered under such guidelines.

Page 86, amend lines 10 through 16 to read as follows:

(a) NO BENEFIT REQUIREMENTS.—Nothing in this title shall be construed to require a group health plan or a health insurance issuer offering health insurance coverage to provide items and services (including abortions) that are specifically excluded under the plan or coverage.

Page 102, line 25, strike “January 1, 2000” and insert “January 1, 2001”.

Page 96, strike line 20 and all that follows through line 15 on page 101 and insert the following (and conform the table of contents accordingly):

**SEC. 302. ERISA PREEMPTION NOT TO APPLY TO CERTAIN ACTIONS INVOLVING HEALTH INSURANCE POLICYHOLDERS.**

(a) IN GENERAL.—Section 514 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1144) is amended by adding at the end the following subsections:

“(e) PREEMPTION NOT TO APPLY TO CERTAIN ACTIONS ARISING OUT OF PROVISION OF HEALTH BENEFITS.—

“(1) NON-PREEMPTION OF CERTAIN CAUSES OF ACTION.—

“(A) IN GENERAL.—Except as provided in this subsection, nothing in this title shall be construed to invalidate, impair, or supersede any cause of action by a participant or beneficiary (or the estate of a participant or beneficiary) under State law to recover damages resulting from personal injury or for wrongful death against any person—

“(i) in connection with the provision of insurance, administrative services, or medical services by such person to or for a group health plan as defined in section 733), or

“(ii) that arises out of the arrangement by such person for the provision of such insurance, administrative services, or medical services by other persons.

“(B) LIMITATION ON PUNITIVE DAMAGES.—

“(i) IN GENERAL.—No person shall be liable for any punitive, exemplary, or similar damages in the case of a cause of action brought under subparagraph (A) if—

“(I) it relates to an externally appealable decision (as defined in subsection (a)(2) of section 103 of the Bipartisan Consensus Managed Care Improvement Act of 1999);

“(II) an external appeal with respect to such decision was completed under such section 103;

“(III) in the case such external appeal was initiated by the plan or issuer filing the request for the external appeal, the request was filed on a timely basis before the date the action was brought or, if later, within 30 days after the date the externally appealable decision was made; and

“(IV) the plan or issuer complied with the determination of the external appeal entity upon receipt of the determination of the external appeal entity.

The provisions of this clause supersede any State law or common law to the contrary.

“(ii) EXCEPTION.—Clause (i) shall not apply with respect to damages in the case of a cause of action for wrongful death if the applicable State law provides (or has been construed to provide) for damages in such a cause of action which are only punitive or exemplary in nature.

“(C) PERSONAL INJURY DEFINED.—For purposes of this subsection, the term ‘personal injury’ means a physical in-

jury and includes an injury arising out of the treatment (or failure to treat) a mental illness or disease.

“(2) EXCEPTION FOR GROUP HEALTH PLANS, EMPLOYERS, AND OTHER PLAN SPONSORS.—

“(A) IN GENERAL.—Subject to subparagraph (B), paragraph (1) does not authorize—

“(i) any cause of action against a group health plan or an employer or other plan sponsor maintaining the plan (or against an employee of such a plan, employer, or sponsor acting within the scope of employment), or

“(ii) a right of recovery, indemnity, or contribution by a person against a group health plan or an employer or other plan sponsor (or such an employee) for damages assessed against the person pursuant to a cause of action under paragraph (1).

“(B) SPECIAL RULE.—Subparagraph (A) shall not preclude any cause of action described in paragraph (1) against group health plan or an employer or other plan sponsor (or against an employee of such a plan, employer, or sponsor acting within the scope of employment) if—

“(i) such action is based on the exercise by the plan, employer, or sponsor (or employee) of discretionary authority to make a decision on a claim for benefits covered under the plan or health insurance coverage in the case at issue; and

“(ii) the exercise by the plan, employer, or sponsor (or employee) of such authority resulted in personal injury or wrongful death.

“(C) EXCEPTION.—The exercise of discretionary authority described in subparagraph (B)(i) shall not be construed to include—

“(i) the decision to include or exclude from the plan any specific benefit;

“(ii) any decision to provide extra-contractual benefits; or

“(iii) any decision not to consider the provision of a benefit while internal or external review is being conducted.

“(3) FUTILITY OF EXHAUSTION.—An individual bringing an action under this subsection is required to exhaust administrative processes under sections 102 and 103 of the Bipartisan Consensus Managed Care Improvement Act of 1999, unless the injury to or death of such individual has occurred before the completion of such processes.

“(4) CONSTRUCTION.—Nothing in this subsection shall be construed as—

“(A) permitting a cause of action under State law for the failure to provide an item or service which is specifically excluded under the group health plan involved;

“(B) as preempting a State law which requires an affidavit or certificate of merit in a civil action; or

“(C) permitting a cause of action or remedy under State law in connection with the provision or arrangement of ex-

cepted benefits (as defined in section 733(c)), other than those described in section 733(c)(2)(A).

“(f) RULES OF CONSTRUCTION RELATING TO HEALTH CARE.—Nothing in this title shall be construed as—

“(1) permitting the application of State laws that are otherwise superseded by this title and that mandate the provision of specific benefits by a group health plan (as defined in section 733(a)) or a multiple employer welfare arrangement (as defined in section 3(40)), or

“(2) affecting any State law which regulates the practice of medicine or provision of medical care, or affecting any action based upon such a State law.”.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to acts and omissions occurring on or after the date of the enactment of this Act from which a cause of action arises.

#### SEC. 303. LIMITATIONS ON ACTIONS.

Section 502 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1132) is amended by adding at the end the following new subsection:

“(n)(1) Except as provided in this subsection, no action may be brought under subsection (a)(1)(B), (a)(2), or (a)(3) by a participant or beneficiary seeking relief based on the application of any provision in section 101, subtitle B, or subtitle D of title I of the Bipartisan Consensus Managed Care Improvement Act of 1999 (as incorporated under section 714).

“(2) An action may be brought under subsection (a)(1)(B), (a)(2), or (a)(3) by a participant or beneficiary seeking relief based on the application of section 101, 113, 114, 115, 116, 117, 119, or 118(3) of the Bipartisan Consensus Managed Care Improvement Act of 1999 (as incorporated under section 714) to the individual circumstances of that participant or beneficiary, except that—

“(A) such an action may not be brought or maintained as a class action; and

“(B) in such an action, relief may only provide for the provision of (or payment of) benefits, items, or services denied to the individual participant or beneficiary involved (and for attorney’s fees and the costs of the action, at the discretion of the court) and shall not provide for any other relief to the participant or beneficiary or for any relief to any other person.

“(3) Nothing in this subsection shall be construed as affecting any action brought by the Secretary.”.

Page 102, line 20, and page 103, line 10, insert “303,” after “301,”.

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## PART B

### SUMMARY OF AMENDMENTS MADE IN ORDER UNDER THE RULE

1. Boehner No. 23: Amendment in the nature of a substitute. Provisions include: a prohibition on gag rules; access to emergency medical care; direct access to an OB/GYN; access to a pediatrician as a primary care provider; continuity of care for patients even if a provider leaves the plan; expanded plan information; a shortened group health plan review standard; a Health Care Access, Afford-

ability, and Quality Commission; health care lawsuit reform, including a limitation on “noneconomic damages”; and a patient choice of medical provider option. 60 minutes.

2. Goss/Coburn/Shadegg/Thomas/Greenwood No. 54: Amendment in the nature of a Substitute. Protects patients in managed care plans by: establishing utilization review procedures; requiring an internal appeals process within specified time lines; requiring independent external review of benefit disputes within specified time lines; allowing patients to sue health plans for benefit denials that cause harm; includes strong protection for employers; requires patients to exhaust the internal and external appeal prior to court action; includes caps on damages; allowing choice of medical professionals; establishing a prudent layperson standard for emergencies; allowing access to speciality care; allowing access to OB/GYNs without referral; allowing parents to designate a pediatrician as their primary care provider; prohibiting gag clauses; expanding access to cancer clinical trials; ensuring prompt payment of claims; simplifying paperwork requirements. 60 minutes.

3. Houghton/Graham/Hilleary/Gibbons No. 59: Amendment in the nature of a substitute. The amendment: gives people a way to get fair compensation when they are hurt by a bad decision and limit it to that; lets people sue only the final decision-maker who fails to exercise ordinary care; provides that patients would go to external review to get the benefits first, then go to court to seek compensation for any harm; and lets people sue the employer if the employer directly participates in the final decision. 60 minutes.

#### TEXT OF THE AMENDMENTS MADE IN ORDER UNDER THE RULE

#### 1. AN AMENDMENT TO BE OFFERED BY REPRESENTATIVE BOEHNER OF OHIO, OR A DESIGNEE, DEBATABLE FOR 60 MINUTES

Strike all after the enacting clause and insert the following:

#### **SECTION 1. SHORT TITLE AND TABLE OF CONTENTS.**

(a) **SHORT TITLE.**—This Act may be cited as the “Comprehensive Access and Responsibility in Health Care Act of 1999”.

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

Sec. 1. Short title and table of contents.

#### TITLE I—AMENDMENTS TO THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974

##### Subtitle A—Patient Protections

Sec. 101. Patient access to unrestricted medical advice, emergency medical care, obstetric and gynecological care, pediatric care, and continuity of care.

Sec. 102. Required disclosure to network providers.

Sec. 103. Effective date and related rules.

##### Subtitle B—Patient Access to Information

Sec. 111. Patient access to information regarding plan coverage, managed care procedures, health care providers, and quality of medical care.

Sec. 112. Effective date and related rules.

##### Subtitle C—Group Health Plan Review Standards

Sec. 121. Special rules for group health plans.

Sec. 122. Special rule for access to specialty care.

- Sec. 123. Protection for certain information developed to reduce mortality or morbidity or for improving patient care and safety.  
 Sec. 124. Effective date.

Subtitle E—Health Care Access, Affordability, and Quality Commission

- Sec. 131. Establishment of commission.  
 Sec. 132. Effective date.

TITLE II—AMENDMENTS TO THE PUBLIC HEALTH SERVICE ACT

- Sec. 201. Patient access to unrestricted medical advice, emergency medical care, obstetric and gynecological care, pediatric care, and continuity of care.  
 Sec. 202. Requiring health maintenance organizations to offer option of point-of-service coverage.  
 Sec. 203. Effective date and related rules.

Subtitle B—Patient Access to Information

- Sec. 211. Patient access to information regarding plan coverage, managed care procedures, health care providers, and quality of medical care.  
 Sec. 212. Effective date and related rules.

TITLE III—AMENDMENTS TO THE INTERNAL REVENUE CODE OF 1986

- Sec. 301. Patient access to unrestricted medical advice, emergency medical care, obstetric and gynecological care, pediatric care, and continuity of care.

TITLE IV—HEALTH CARE LAWSUIT REFORM

Subtitle A—General Provisions

- Sec. 401. Federal reform of health care liability actions.  
 Sec. 402. Definitions.  
 Sec. 403. Effective date.

Subtitle B—Uniform Standards for Health Care Liability Actions

- Sec. 411. Statute of limitations.  
 Sec. 412. Calculation and payment of damages.  
 Sec. 413. Alternative dispute resolution.  
 Sec. 414. Reporting on fraud and abuse enforcement activities.

## TITLE I—AMENDMENTS TO THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974

### Subtitle A—Patient Protections

**SEC. 101. PATIENT ACCESS TO UNRESTRICTED MEDICAL ADVICE, EMERGENCY MEDICAL CARE, OBSTETRIC AND GYNECOLOGICAL CARE, PEDIATRIC CARE, AND CONTINUITY OF CARE.**

(a) IN GENERAL.—Subpart B of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 is amended by adding at the end the following new section:

**“SEC. 714. PATIENT ACCESS TO UNRESTRICTED MEDICAL ADVICE, EMERGENCY MEDICAL CARE, OBSTETRIC AND GYNECOLOGICAL CARE, PEDIATRIC CARE, AND CONTINUITY OF CARE.**

**“(a) PATIENT ACCESS TO UNRESTRICTED MEDICAL ADVICE.—**

**“(1) IN GENERAL.—**In the case of any health care professional acting within the lawful scope of practice in the course of carrying out a contractual employment arrangement or other direct contractual arrangement between such professional and a group health plan or a health insurance issuer offering health

insurance coverage in connection with a group health plan, the plan or issuer with which such contractual employment arrangement or other direct contractual arrangement is maintained by the professional may not impose on such professional under such arrangement any prohibition or restriction with respect to advice, provided to a participant or beneficiary under the plan who is a patient, about the health status of the participant or beneficiary or the medical care or treatment for the condition or disease of the participant or beneficiary, regardless of whether benefits for such care or treatment are provided under the plan or health insurance coverage offered in connection with the plan.

“(2) HEALTH CARE PROFESSIONAL DEFINED.—For purposes of this paragraph, the term ‘health care professional’ means a physician (as defined in section 1861(r) of the Social Security Act) or other health care professional if coverage for the professional’s services is provided under the group health plan for the services of the professional. Such term includes a podiatrist, optometrist, chiropractor, psychologist, dentist, physician assistant, physical or occupational therapist and therapy assistant, speech-language pathologist, audiologist, registered or licensed practical nurse (including nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, and certified nurse-midwife), licensed certified social worker, registered respiratory therapist, and certified respiratory therapy technician.

“(3) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to require the sponsor of a group health plan or a health insurance issuer offering health insurance coverage in connection with the group health plan to engage in any practice that would violate its religious beliefs or moral convictions.

“(b) PATIENT ACCESS TO EMERGENCY MEDICAL CARE.—

“(1) COVERAGE OF EMERGENCY SERVICES.—

“(A) IN GENERAL.—If a group health plan, or health insurance coverage offered by a health insurance issuer, provides any benefits with respect to emergency services (as defined in subparagraph (B)(ii)), or ambulance services, the plan or issuer shall cover emergency services (including emergency ambulance services as defined in subparagraph (B)(iii)) furnished under the plan or coverage—

“(i) without the need for any prior authorization determination;

“(ii) whether or not the health care provider furnishing such services is a participating provider with respect to such services;

“(iii) in a manner so that, if such services are provided to a participant or beneficiary by a nonparticipating health care provider, the participant or beneficiary is not liable for amounts that exceed the amounts of liability that would be incurred if the services were provided by a participating provider; and

“(iv) without regard to any other term or condition of such plan or coverage (other than exclusion or co-

ordination of benefits, or an affiliation or waiting period, permitted under section 701 and other than applicable cost sharing).

“(B) DEFINITIONS.—In this subsection:

“(i) EMERGENCY MEDICAL CONDITION.—The term ‘emergency medical condition’ means—

“(I) a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act (42 U.S.C. 1395dd(e)(1)(A)); and

“(II) a medical condition manifesting itself in a neonate by acute symptoms of sufficient severity (including severe pain) such that a prudent health care professional could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act.

“(ii) EMERGENCY SERVICES.—The term ‘emergency services’ means—

“(I) with respect to an emergency medical condition described in clause (i)(I), a medical screening examination (as required under section 1867 of the Social Security Act, 42 U.S.C. 1395dd) that is within the capability of the emergency department of a hospital, including ancillary services routinely available to the emergency department to evaluate an emergency medical condition (as defined in clause (i)) and also, within the capabilities of the staff and facilities at the hospital, such further medical examination and treatment as are required under section 1867 of such Act to stabilize the patient; or

“(II) with respect to an emergency medical condition described in clause (i)(II), medical treatment for such condition rendered by a health care provider in a hospital to a neonate, including available hospital ancillary services in response to an urgent request of a health care professional and to the extent necessary to stabilize the neonate.

“(iii) EMERGENCY AMBULANCE SERVICES.—The term ‘emergency ambulance services’ means ambulance services (as defined for purposes of section 1861(s)(7) of the Social Security Act) furnished to transport an individual who has an emergency medical condition (as defined in clause (i)) to a hospital for the receipt of emergency services (as defined in clause (ii)) in a case in which appropriate emergency medical screening examinations are covered under the plan or cov-

erage pursuant to paragraph (1)(A) and a prudent layperson, with an average knowledge of health and medicine, could reasonably expect that the absence of such transport would result in placing the health of the individual in serious jeopardy, serious impairment of bodily function, or serious dysfunction of any bodily organ or part.

“(iv) STABILIZE.—The term ‘to stabilize’ means, with respect to an emergency medical condition, to provide such medical treatment of the condition as may be necessary to assure, within reasonable medical probability, that no material deterioration of the condition is likely to result from or occur during the transfer of the individual from a facility.

“(v) NONPARTICIPATING.—The term ‘nonparticipating’ means, with respect to a health care provider that provides health care items and services to a participant or beneficiary under group health plan or under group health insurance coverage, a health care provider that is not a participating health care provider with respect to such items and services.

“(vi) PARTICIPATING.—The term ‘participating’ means, with respect to a health care provider that provides health care items and services to a participant or beneficiary under group health plan or health insurance coverage offered by a health insurance issuer in connection with such a plan, a health care provider that furnishes such items and services under a contract or other arrangement with the plan or issuer.

“(c) PATIENT RIGHT TO OBSTETRIC AND GYNECOLOGICAL CARE.—

“(1) IN GENERAL.—In any case in which a group health plan (or a health insurance issuer offering health insurance coverage in connection with the plan)—

“(A) provides benefits under the terms of the plan consisting of—

“(i) gynecological care (such as preventive women’s health examinations); or

“(ii) obstetric care (such as pregnancy-related services),

provided by a participating health care professional who specializes in such care (or provides benefits consisting of payment for such care); and

“(B) requires or provides for designation by a participant or beneficiary of a participating primary care provider, if the primary care provider designated by such a participant or beneficiary is not such a health care professional, then the plan (or issuer) shall meet the requirements of paragraph (2).

“(2) REQUIREMENTS.—A group health plan (or a health insurance issuer offering health insurance coverage in connection with the plan) meets the requirements of this paragraph, in connection with benefits described in paragraph (1) consisting of care described in clause (i) or (ii) of paragraph (1)(A) (or consisting of payment therefor), if the plan (or issuer)—

“(A) does not require authorization or a referral by the primary care provider in order to obtain such benefits; and  
 “(B) treats the ordering of other care of the same type, by the participating health care professional providing the care described in clause (i) or (ii) of paragraph (1)(A), as the authorization of the primary care provider with respect to such care.

“(3) HEALTH CARE PROFESSIONAL DEFINED.—For purposes of this subsection, the term ‘health care professional’ means an individual (including, but not limited to, a nurse midwife or nurse practitioner) who is licensed, accredited, or certified under State law to provide obstetric and gynecological health care services and who is operating within the scope of such licensure, accreditation, or certification.

“(4) CONSTRUCTION.—Nothing in paragraph (1) shall be construed as preventing a plan from offering (but not requiring a participant or beneficiary to accept) a health care professional trained, credentialed, and operating within the scope of their licensure to perform obstetric and gynecological health care services. Nothing in paragraph (2)(B) shall waive any requirements of coverage relating to medical necessity or appropriateness with respect to coverage of gynecological or obstetric care so ordered.

“(5) TREATMENT OF MULTIPLE COVERAGE OPTIONS.—In the case of a plan providing benefits under two or more coverage options, the requirements of this subsection shall apply separately with respect to each coverage option.

“(d) PATIENT RIGHT TO PEDIATRIC CARE.—

“(1) IN GENERAL.—In any case in which a group health plan (or a health insurance issuer offering health insurance coverage in connection with the plan) provides benefits consisting of routine pediatric care provided by a participating health care professional who specializes in pediatrics (or consisting of payment for such care) and the plan requires or provides for designation by a participant or beneficiary of a participating primary care provider, the plan (or issuer) shall provide that such a participating health care professional may be designated, if available, by a parent or guardian of any beneficiary under the plan is who under 18 years of age, as the primary care provider with respect to any such benefits.

“(2) HEALTH CARE PROFESSIONAL DEFINED.—For purposes of this subsection, the term ‘health care professional’ means an individual (including, but not limited to, a nurse practitioner) who is licensed, accredited, or certified under State law to provide pediatric health care services and who is operating within the scope of such licensure, accreditation, or certification.

“(3) CONSTRUCTION.—Nothing in paragraph (1) shall be construed as preventing a plan from offering (but not requiring a participant or beneficiary to accept) a health care professional trained, credentialed, and operating within the scope of their licensure to perform pediatric health care services. Nothing in paragraph (1) shall waive any requirements of coverage relating to medical necessity or appropriateness with respect to coverage of pediatric care so ordered.

“(4) TREATMENT OF MULTIPLE COVERAGE OPTIONS.—In the case of a plan providing benefits under two or more coverage options, the requirements of this subsection shall apply separately with respect to each coverage option.

“(e) CONTINUITY OF CARE.—

“(1) IN GENERAL.—

“(A) TERMINATION OF PROVIDER.—If a contract between a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, and a health care provider is terminated (as defined in subparagraph (D)(ii)), or benefits or coverage provided by a health care provider are terminated because of a change in the terms of provider participation in a group health plan, and an individual who, at the time of such termination, is a participant or beneficiary in the plan and is scheduled to undergo surgery (including an organ transplantation), is undergoing treatment for pregnancy, or is determined to be terminally ill (as defined in section 1861(dd)(3)(A) of the Social Security Act) and is undergoing treatment for the terminal illness, the plan or issuer shall—

“(i) notify the individual on a timely basis of such termination and of the right to elect continuation of coverage of treatment by the provider under this subsection; and

“(ii) subject to paragraph (3), permit the individual to elect to continue to be covered with respect to treatment by the provider for such surgery, pregnancy, or illness during a transitional period (provided under paragraph (2)).

“(B) TREATMENT OF TERMINATION OF CONTRACT WITH HEALTH INSURANCE ISSUER.—If a contract for the provision of health insurance coverage between a group health plan and a health insurance issuer is terminated and, as a result of such termination, coverage of services of a health care provider is terminated with respect to an individual, the provisions of subparagraph (A) (and the succeeding provisions of this subsection) shall apply under the plan in the same manner as if there had been a contract between the plan and the provider that had been terminated, but only with respect to benefits that are covered under the plan after the contract termination.

“(C) TERMINATION DEFINED.—For purposes of this subsection, the term ‘terminated’ includes, with respect to a contract, the expiration or nonrenewal of the contract, but does not include a termination of the contract by the plan or issuer for failure to meet applicable quality standards or for fraud.

“(2) TRANSITIONAL PERIOD.—

“(A) IN GENERAL.—Except as provided in subparagraphs (B) through (D), the transitional period under this paragraph shall extend up to 90 days (as determined by the treating health care professional) after the date of the no-

tice described in paragraph (1)(A)(i) of the provider's termination.

“(B) SCHEDULED SURGERY.—If surgery was scheduled for an individual before the date of the announcement of the termination of the provider status under paragraph (1)(A)(i), the transitional period under this paragraph with respect to the surgery shall extend beyond the period under subparagraph (A) and until the date of discharge of the individual after completion of the surgery.

“(C) PREGNANCY.—If—

“(i) a participant or beneficiary was determined to be pregnant at the time of a provider's termination of participation, and

“(ii) the provider was treating the pregnancy before date of the termination,  
the transitional period under this paragraph with respect to provider's treatment of the pregnancy shall extend through the provision of post-partum care directly related to the delivery.

“(D) TERMINAL ILLNESS.—If—

“(i) a participant or beneficiary was determined to be terminally ill (as determined under section 1861(dd)(3)(A) of the Social Security Act) at the time of a provider's termination of participation, and

“(ii) the provider was treating the terminal illness before the date of termination,  
the transitional period under this paragraph shall extend for the remainder of the individual's life for care directly related to the treatment of the terminal illness or its medical manifestations.

“(3) PERMISSIBLE TERMS AND CONDITIONS.—A group health plan or health insurance issuer may condition coverage of continued treatment by a provider under paragraph (1)(A)(i) upon the individual notifying the plan of the election of continued coverage and upon the provider agreeing to the following terms and conditions:

“(A) The provider agrees to accept reimbursement from the plan or issuer and individual involved (with respect to cost-sharing) at the rates applicable prior to the start of the transitional period as payment in full (or, in the case described in paragraph (1)(B), at the rates applicable under the replacement plan or issuer after the date of the termination of the contract with the health insurance issuer) and not to impose cost-sharing with respect to the individual in an amount that would exceed the cost-sharing that could have been imposed if the contract referred to in paragraph (1)(A) had not been terminated.

“(B) The provider agrees to adhere to the quality assurance standards of the plan or issuer responsible for payment under subparagraph (A) and to provide to such plan or issuer necessary medical information related to the care provided.

“(C) The provider agrees otherwise to adhere to such plan's or issuer's policies and procedures, including proce-

dures regarding referrals and obtaining prior authorization and providing services pursuant to a treatment plan (if any) approved by the plan or issuer.

“(D) The provider agrees to provide transitional care to all participants and beneficiaries who are eligible for and elect to have coverage of such care from such provider.

“(E) If the provider initiates the termination, the provider has notified the plan within 30 days prior to the effective date of the termination of—

“(i) whether the provider agrees to permissible terms and conditions (as set forth in this paragraph) required by the plan, and

“(ii) if the provider agrees to the terms and conditions, the specific plan beneficiaries and participants undergoing a course of treatment from the provider who the provider believes, at the time of the notification, would be eligible for transitional care under this subsection.

“(4) CONSTRUCTION.—Nothing in this subsection shall be construed to—

“(A) require the coverage of benefits which would not have been covered if the provider involved remained a participating provider, or

“(B) prohibit a group health plan from conditioning a provider’s participation on the provider’s agreement to provide transitional care to all participants and beneficiaries eligible to obtain coverage of such care furnished by the provider as set forth under this subsection.

“(f) COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CANCER CLINICAL TRIALS.—

“(1) COVERAGE.—

“(A) IN GENERAL.—If a group health plan (or a health insurance issuer offering health insurance coverage in connection with the plan) provides coverage to a qualified individual (as defined in paragraph (2)), the plan or issuer—

“(i) may not deny the individual participation in the clinical trial referred to in paragraph (2)(B);

“(ii) subject to paragraphs (2), (3), and (4), may not deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and services furnished in connection with participation in the trial; and

“(iii) may not discriminate against the individual on the basis of the participation of the participant or beneficiary in such trial.

“(B) EXCLUSION OF CERTAIN COSTS.—For purposes of subparagraph (A)(ii), routine patient costs do not include the cost of the tests or measurements conducted primarily for the purpose of the clinical trial involved.

“(C) USE OF IN-NETWORK PROVIDERS.—If one or more participating providers is participating in a clinical trial, nothing in subparagraph (A) shall be construed as preventing a plan from requiring that a qualified individual participate in the trial through such a participating pro-

vider if the provider will accept the individual as a participant in the trial.

“(2) QUALIFIED INDIVIDUAL DEFINED.—For purposes of paragraph (1), the term ‘qualified individual’ means an individual who is a participant or beneficiary in a group health plan and who meets the following conditions:

“(A)(i) The individual has been diagnosed with cancer.

“(ii) The individual is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of cancer.

“(iii) The individual’s participation in the trial offers meaningful potential for significant clinical benefit for the individual.

“(B) Either—

“(i) the referring physician is a participating health care professional and has concluded that the individual’s participation in such trial would be appropriate based upon satisfaction by the individual of the conditions described in subparagraph (A); or

“(ii) the individual provides medical and scientific information establishing that the individual’s participation in such trial would be appropriate based upon the satisfaction by the individual of the conditions described in subparagraph (A).

“(3) PAYMENT.—

“(A) IN GENERAL.—A group health plan (or a health insurance issuer offering health insurance coverage in connection with the plan) shall provide for payment for routine patient costs described in paragraph (1)(B) but is not required to pay for costs of items and services that are reasonably expected to be paid for by the sponsors of an approved clinical trial.

“(B) ROUTINE PATIENT CARE COSTS.—

“(i) IN GENERAL.—For purposes of this paragraph, the term ‘routine patient care costs’ shall include the costs associated with the provision of items and services that—

“(I) would otherwise be covered under the group health plan if such items and services were not provided in connection with an approved clinical trial program; and

“(II) are furnished according to the protocol of an approved clinical trial program.

“(ii) EXCLUSION.—For purposes of this paragraph, ‘routine patient care costs’ shall not include the costs associated with the provision of—

“(I) an investigational drug or device, unless the Secretary has authorized the manufacturer of such drug or device to charge for such drug or device; or

“(II) any item or service supplied without charge by the sponsor of the approved clinical trial program.

“(C) PAYMENT RATE.—For purposes of this subsection—

“(i) PARTICIPATING PROVIDERS.—In the case of covered items and services provided by a participating provider, the payment rate shall be at the agreed upon rate.

“(ii) NONPARTICIPATING PROVIDERS.—In the case of covered items and services provided by a nonparticipating provider, the payment rate shall be at the rate the plan would normally pay for comparable items or services under clause (i).

“(4) APPROVED CLINICAL TRIAL DEFINED.—

“(A) IN GENERAL.—For purposes of this subsection, the term ‘approved clinical trial’ means a cancer clinical research study or cancer clinical investigation approved by an Institutional Review Board.

“(B) CONDITIONS FOR DEPARTMENTS.—The conditions described in this paragraph, for a study or investigation conducted by a Department, are that the study or investigation has been reviewed and approved through a system of peer review that the Secretary determines—

“(i) to be comparable to the system of peer review of studies and investigations used by the National Institutes of Health, and

“(ii) assures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review.

“(5) CONSTRUCTION.—Nothing in this subsection shall be construed to limit a plan’s coverage with respect to clinical trials.

“(6) PLAN SATISFACTION OF CERTAIN REQUIREMENTS; RESPONSIBILITIES OF FIDUCIARIES.—

“(A) IN GENERAL.—For purposes of this subsection, insofar as a group health plan provides benefits in the form of health insurance coverage through a health insurance issuer, the plan shall be treated as meeting the requirements of this subsection with respect to such benefits and not be considered as failing to meet such requirements because of a failure of the issuer to meet such requirements so long as the plan sponsor or its representatives did not cause such failure by the issuer.

“(B) CONSTRUCTION.—Nothing in this subsection shall be construed to affect or modify the responsibilities of the fiduciaries of a group health plan under part 4.

“(7) STUDY AND REPORT.—

“(A) STUDY.—The Secretary shall analyze cancer clinical research and its cost implications for managed care, including differentiation in—

“(i) the cost of patient care in trials versus standard care;

“(ii) the cost effectiveness achieved in different sites of service;

“(iii) research outcomes;

“(iv) volume of research subjects available in different sites of service;

“(v) access to research sites and clinical trials by cancer patients;

“(vi) patient cost sharing or copayment costs realized in different sites of service;

“(vii) health outcomes experienced in different sites of service;

“(viii) long term health care services and costs experienced in different sites of service;

“(ix) morbidity and mortality experienced in different sites of service; and

“(x) patient satisfaction and preference of sites of service.

“(B) REPORT TO CONGRESS.—Not later than January 1, 2005, the Secretary shall submit a report to Congress that contains—

“(i) an assessment of any incremental cost to group health plans resulting from the provisions of this section;

“(ii) a projection of expenditures to such plans resulting from this section;

“(iii) an assessment of any impact on premiums resulting from this section; and

“(iv) recommendations regarding action on other diseases.”.

(b) CONFORMING AMENDMENT.—The table of contents in section 1 of such Act is amended by adding at the end of the items relating to subpart B of part 7 of subtitle B of title I of such Act the following new item:

“Sec. 714. Patient access to unrestricted medical advice, emergency medical care, obstetric and gynecological care, pediatric care, and continuity of care.”.

**SEC. 102. REQUIRED DISCLOSURE TO NETWORK PROVIDERS.**

(a) IN GENERAL.—Subpart B of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 (as amended by section 101) is amended further by adding at the end the following new section:

**“SEC. 715. REQUIRED DISCLOSURE TO NETWORK PROVIDERS.**

“(a) IN GENERAL.—If a group health plan reimburses, through a contract or other arrangement, a health care provider at a discounted payment rate because the provider participates in a provider network, the plan shall disclose to the provider the following information before the provider furnishes covered items or services under the plan:

“(1) The identity of the plan sponsor or other entity that is to utilize the discounted payment rates in reimbursing network providers in that network.

“(2) The existence of any substantial benefit differentials established for the purpose of actively encouraging participants or beneficiaries under the plan to utilize the providers in that network.

“(3) The methods and materials by which providers in the network are identified to such participants or beneficiaries as part of the network.

“(b) PERMITTED MEANS OF DISCLOSURE.—Disclosure required under subsection (a) by a plan may be made—

“(1) by another entity under a contract or other arrangement between the plan and the entity; and

“(2) by making such information available in written format, in an electronic format, on the Internet, or on a proprietary computer network which is readily accessible to the network providers.

“(c) CONSTRUCTION.—Nothing in this section shall be construed to require, directly or indirectly, disclosure of specific fee arrangements or other reimbursement arrangements—

“(1) between (i) group health plans or provider networks and (ii) health care providers, or

“(2) among health care providers.

“(d) DEFINITIONS.—For purposes of this subsection:

“(1) BENEFIT DIFFERENTIAL.—The term ‘benefit differential’ means, with respect to a group health plan, differences in the case of any participant or beneficiary, in the financial responsibility for payment of coinsurance, copayments, deductibles, balance billing requirements, or any other charge, based upon whether a health care provider from whom covered items or services are obtained is a network provider.

“(2) DISCOUNTED PAYMENT RATE.—The term ‘discounted payment rate’ means, with respect to a provider, a payment rate that is below the charge imposed by the provider.

“(3) NETWORK PROVIDER.—The term ‘network provider’ means, with respect to a group health plan, a health care provider that furnishes health care items and services to participants or beneficiaries under the plan pursuant to a contract or other arrangement with a provider network in which the provider is participating.

“(4) PROVIDER NETWORK.—The term ‘provider network’ means, with respect to a group health plan offering health insurance coverage, an association of network providers through whom the plan provides, through contract or other arrangement, health care items and services to participants and beneficiaries.”.

(b) CONFORMING AMENDMENT.—The table of contents in section 1 of such Act is amended by adding at the end of the items relating to subpart B of part 7 of subtitle B of title I of such Act the following new item:

“Sec. 715. Required disclosure to network providers.”.

**SEC. 103. EFFECTIVE DATE AND RELATED RULES.**

(a) IN GENERAL.—The amendments made by this subtitle shall apply with respect to plan years beginning on or after January 1 of the second calendar year following the date of the enactment of this Act, except that the Secretary of Labor may issue regulations before such date under such amendments. The Secretary shall first issue regulations necessary to carry out the amendments made by this subtitle before the effective date thereof.

(b) LIMITATION ON ENFORCEMENT ACTIONS.—No enforcement action shall be taken, pursuant to the amendments made by this subtitle, against a group health plan or health insurance issuer with respect to a violation of a requirement imposed by such amendments before the date of issuance of regulations issued in connec-

tion with such requirement, if the plan or issuer has sought to comply in good faith with such requirement.

(c) **SPECIAL RULE FOR COLLECTIVE BARGAINING AGREEMENTS.**—In the case of a group health plan maintained pursuant to one or more collective bargaining agreements between employee representatives and one or more employers ratified before the date of the enactment of this Act, the amendments made by this subtitle shall not apply with respect to plan years beginning before the later of—

(1) the date on which the last of the collective bargaining agreements relating to the plan terminates (determined without regard to any extension thereof agreed to after the date of the enactment of this Act); or

(2) January 1, 2002.

For purposes of this subsection, any plan amendment made pursuant to a collective bargaining agreement relating to the plan which amends the plan solely to conform to any requirement added by this subtitle shall not be treated as a termination of such collective bargaining agreement.

## **Subtitle B—Patient Access to Information**

### **SEC. 111. PATIENT ACCESS TO INFORMATION REGARDING PLAN COVERAGE, MANAGED CARE PROCEDURES, HEALTH CARE PROVIDERS, AND QUALITY OF MEDICAL CARE.**

(a) **IN GENERAL.**—Part 1 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 is amended—

(1) by redesignating section 111 as section 112; and

(2) by inserting after section 110 the following new section:

#### **“DISCLOSURE BY GROUP HEALTH PLANS**

**“SEC. 111. (a) DISCLOSURE REQUIREMENT.**—The administrator of each group health plan shall take such actions as are necessary to ensure that the summary plan description of the plan required under section 102 (or each summary plan description in any case in which different summary plan descriptions are appropriate under part 1 for different options of coverage) contains, among any information otherwise required under this part, the information required under subsections (b), (c), (d), and (e)(2)(A).

**“(b) PLAN BENEFITS.**—The information required under subsection (a) includes the following:

**“(1) COVERED ITEMS AND SERVICES.**—

**“(A) CATEGORIZATION OF INCLUDED BENEFITS.**—A description of covered benefits, categorized by—

**“(i) types of items and services (including any special disease management program); and**

**“(ii) types of health care professionals providing such items and services.**

**“(B) EMERGENCY MEDICAL CARE.**—A description of the extent to which the plan covers emergency medical care (including the extent to which the plan provides for access to urgent care centers), and any definitions provided under the plan for the relevant plan terminology referring to such care.

“(C) PREVENTATIVE SERVICES.—A description of the extent to which the plan provides benefits for preventative services.

“(D) DRUG FORMULARIES.—A description of the extent to which covered benefits are determined by the use or application of a drug formulary and a summary of the process for determining what is included in such formulary.

“(E) COBRA CONTINUATION COVERAGE.—A description of the benefits available under the plan pursuant to part 6.

“(2) LIMITATIONS, EXCLUSIONS, AND RESTRICTIONS ON COVERED BENEFITS.—

“(A) CATEGORIZATION OF EXCLUDED BENEFITS.—A description of benefits specifically excluded from coverage, categorized by types of items and services.

“(B) UTILIZATION REVIEW AND PREAUTHORIZATION REQUIREMENTS.—Whether coverage for medical care is limited or excluded on the basis of utilization review or preauthorization requirements.

“(C) LIFETIME, ANNUAL, OR OTHER PERIOD LIMITATIONS.—A description of the circumstances under which, and the extent to which, coverage is subject to lifetime, annual, or other period limitations, categorized by types of benefits.

“(D) CUSTODIAL CARE.—A description of the circumstances under which, and the extent to which, the coverage of benefits for custodial care is limited or excluded, and a statement of the definition used by the plan for custodial care.

“(E) EXPERIMENTAL TREATMENTS.—Whether coverage for any medical care is limited or excluded because it constitutes an investigational item or experimental treatment or technology, and any definitions provided under the plan for the relevant plan terminology referring to such limited or excluded care.

“(F) MEDICAL APPROPRIATENESS OR NECESSITY.—Whether coverage for medical care may be limited or excluded by reason of a failure to meet the plan’s requirements for medical appropriateness or necessity, and any definitions provided under the plan for the relevant plan terminology referring to such limited or excluded care.

“(G) SECOND OR SUBSEQUENT OPINIONS.—A description of the circumstances under which, and the extent to which, coverage for second or subsequent opinions is limited or excluded.

“(H) SPECIALTY CARE.—A description of the circumstances under which, and the extent to which, coverage of benefits for specialty care is conditioned on referral from a primary care provider.

“(I) CONTINUITY OF CARE.—A description of the circumstances under which, and the extent to which, coverage of items and services provided by any health care professional is limited or excluded by reason of the departure by the professional from any defined set of providers.

“(J) RESTRICTIONS ON COVERAGE OF EMERGENCY SERVICES.—A description of the circumstances under which,

and the extent to which, the plan, in covering emergency medical care furnished to a participant or beneficiary of the plan imposes any financial responsibility described in subsection (c) on participants or beneficiaries or limits or conditions benefits for such care subject to any other term or condition of such plan.

“(3) NETWORK CHARACTERISTICS.—If the plan (or health insurance issuer offering health insurance coverage in connection with the plan) utilizes a defined set of providers under contract with the plan (or issuer), a detailed list of the names of such providers and their geographic location, set forth separately with respect to primary care providers and with respect to specialists.

“(c) PARTICIPANT’S FINANCIAL RESPONSIBILITIES.—The information required under subsection (a) includes an explanation of—

“(1) a participant’s financial responsibility for payment of premiums, coinsurance, copayments, deductibles, and any other charges; and

“(2) the circumstances under which, and the extent to which, the participant’s financial responsibility described in paragraph (1) may vary, including any distinctions based on whether a health care provider from whom covered benefits are obtained is included in a defined set of providers.

“(d) DISPUTE RESOLUTION PROCEDURES.—The information required under subsection (a) includes a description of the processes adopted by the plan pursuant to section 503, including—

“(1) descriptions thereof relating specifically to—

“(A) coverage decisions;

“(B) internal review of coverage decisions; and

“(C) any external review of coverage decisions; and

“(2) the procedures and time frames applicable to each step of the processes referred to in subparagraphs (A), (B), and (C) of paragraph (1).

“(e) INFORMATION ON PLAN PERFORMANCE.—Any information required under subsection (a) shall include information concerning the number of external reviews under section 503 that have been completed during the prior plan year and the number of such reviews in which a recommendation is made for modification or reversal of an internal review decision under the plan.

“(f) INFORMATION INCLUDED WITH ADVERSE COVERAGE DECISIONS.—A group health plan shall provide to each participant and beneficiary, together with any notification of the participant or beneficiary of an adverse coverage decision, the following information:

“(1) PREAUTHORIZATION AND UTILIZATION REVIEW PROCEDURES.—A description of the basis on which any preauthorization requirement or any utilization review requirement has resulted in the adverse coverage decision.

“(2) PROCEDURES FOR DETERMINING EXCLUSIONS BASED ON MEDICAL NECESSITY OR ON INVESTIGATIONAL ITEMS OR EXPERIMENTAL TREATMENTS.—If the adverse coverage decision is based on a determination relating to medical necessity or to an investigational item or an experimental treatment or technology, a description of the procedures and medically-based criteria used in such decision.

“(g) INFORMATION AVAILABLE ON REQUEST.—

“(1) ACCESS TO PLAN BENEFIT INFORMATION IN ELECTRONIC FORM.—

“(A) IN GENERAL.—In addition to the information required to be provided under section 104(b)(4), a group health plan may, upon written request (made not more frequently than annually), make available to participants and beneficiaries, in a generally recognized electronic format—

“(i) the latest summary plan description, including the latest summary of material modifications, and

“(ii) the actual plan provisions setting forth the benefits available under the plan,

to the extent such information relates to the coverage options under the plan available to the participant or beneficiary. A reasonable charge may be made to cover the cost of providing such information in such generally recognized electronic format. The Secretary may by regulation prescribe a maximum amount which will constitute a reasonable charge under the preceding sentence.

“(B) ALTERNATIVE ACCESS.—The requirements of this paragraph may be met by making such information generally available (rather than upon request) on the Internet or on a proprietary computer network in a format which is readily accessible to participants and beneficiaries.

“(2) ADDITIONAL INFORMATION TO BE PROVIDED ON REQUEST.—

“(A) INCLUSION IN SUMMARY PLAN DESCRIPTION OF SUMMARY OF ADDITIONAL INFORMATION.—The information required under subsection (a) includes a summary description of the types of information required by this subsection to be made available to participants and beneficiaries on request.

“(B) INFORMATION REQUIRED FROM PLANS AND ISSUERS ON REQUEST.—In addition to information required to be included in summary plan descriptions under this subsection, a group health plan shall provide the following information to a participant or beneficiary on request:

“(i) CARE MANAGEMENT INFORMATION.—A description of the circumstances under which, and the extent to which, the plan has special disease management programs or programs for persons with disabilities, indicating whether these programs are voluntary or mandatory and whether a significant benefit differential results from participation in such programs.

“(ii) INCLUSION OF DRUGS AND BIOLOGICALS IN FORMULARIES.—A statement of whether a specific drug or biological is included in a formulary used to determine benefits under the plan and a description of the procedures for considering requests for any patient-specific waivers.

“(iii) ACCREDITATION STATUS OF HEALTH INSURANCE ISSUERS AND SERVICE PROVIDERS.—A description of the accreditation and licensing status (if any) of each health insurance issuer offering health insurance cov-

erage in connection with the plan and of any utilization review organization utilized by the issuer or the plan, together with the name and address of the accrediting or licensing authority.

“(iv) QUALITY PERFORMANCE MEASURES.—The latest information (if any) maintained by the plan relating to quality of performance of the delivery of medical care with respect to coverage options offered under the plan and of health care professionals and facilities providing medical care under the plan.

“(C) INFORMATION REQUIRED FROM HEALTH CARE PROFESSIONALS.—

“(i) QUALIFICATIONS, PRIVILEGES, AND METHOD OF COMPENSATION.—Any health care professional treating a participant or beneficiary under a group health plan shall provide to the participant or beneficiary, on request, a description of his or her professional qualifications (including board certification status, licensing status, and accreditation status, if any), privileges, and experience and a general description by category (including salary, fee-for-service, capitation, and such other categories as may be specified in regulations of the Secretary) of the applicable method by which such professional is compensated in connection with the provision of such medical care.

“(ii) COST OF PROCEDURES.—Any health care professional who recommends an elective procedure or treatment while treating a participant or beneficiary under a group health plan that requires a participant or beneficiary to share in the cost of treatment shall inform such participant or beneficiary of each cost associated with the procedure or treatment and an estimate of the magnitude of such costs.

“(D) INFORMATION REQUIRED FROM HEALTH CARE FACILITIES ON REQUEST.—Any health care facility from which a participant or beneficiary has sought treatment under a group health plan shall provide to the participant or beneficiary, on request, a description of the facility’s corporate form or other organizational form and all forms of licensing and accreditation status (if any) assigned to the facility by standard-setting organizations.

“(h) ACCESS TO INFORMATION RELEVANT TO THE COVERAGE OPTIONS UNDER WHICH THE PARTICIPANT OR BENEFICIARY IS ELIGIBLE TO ENROLL.—In addition to information otherwise required to be made available under this section, a group health plan shall, upon written request (made not more frequently than annually), make available to a participant (and an employee who, under the terms of the plan, is eligible for coverage but not enrolled) in connection with a period of enrollment the summary plan description for any coverage option under the plan under which the participant is eligible to enroll and any information described in clauses (i), (ii), (iii), (vi), (vii), and (viii) of subsection (e)(2)(B).

“(i) ADVANCE NOTICE OF CHANGES IN DRUG FORMULARIES.—Not later than 30 days before the effective of date of any exclusion of

a specific drug or biological from any drug formulary under the plan that is used in the treatment of a chronic illness or disease, the plan shall take such actions as are necessary to reasonably ensure that plan participants are informed of such exclusion. The requirements of this subsection may be satisfied—

“(1) by inclusion of information in publications broadly distributed by plan sponsors, employers, or employee organizations;

“(2) by electronic means of communication (including the Internet or proprietary computer networks in a format which is readily accessible to participants);

“(3) by timely informing participants who, under an ongoing program maintained under the plan, have submitted their names for such notification; or

“(4) by any other reasonable means of timely informing plan participants.

“(j) DEFINITIONS AND RELATED RULES.—

“(1) IN GENERAL.—For purposes of this section—

“(A) GROUP HEALTH PLAN.—The term ‘group health plan’ has the meaning provided such term under section 733(a)(1).

“(B) MEDICAL CARE.—The term ‘medical care’ has the meaning provided such term under section 733(a)(2).

“(C) HEALTH INSURANCE COVERAGE.—The term ‘health insurance coverage’ has the meaning provided such term under section 733(b)(1).

“(D) HEALTH INSURANCE ISSUER.—The term ‘health insurance issuer’ has the meaning provided such term under section 733(b)(2).

“(2) APPLICABILITY ONLY IN CONNECTION WITH INCLUDED GROUP HEALTH PLAN BENEFITS.—

“(A) IN GENERAL.—The requirements of this section shall apply only in connection with included group health plan benefits.

“(B) INCLUDED GROUP HEALTH PLAN BENEFIT.—For purposes of subparagraph (A), the term ‘included group health plan benefit’ means a benefit which is not an excepted benefit (as defined in section 733(c)).”.

(b) CONFORMING AMENDMENTS.—

(1) Section 102(b) of such Act (29 U.S.C. 1022(b)) is amended by inserting before the period at the end the following: “; and, in the case of a group health plan (as defined in section 112(j)(1)(A)) providing included group health plan benefits (as defined in section 111(j)(2)(B)), the information required to be included under section 111(a)”.

(2) The table of contents in section 1 of such Act is amended by striking the item relating to section 111 and inserting the following new items:

“Sec. 111. Disclosure by group health plans.

“Sec. 112. Repeal and effective date.”.

**SEC. 112. EFFECTIVE DATE AND RELATED RULES.**

(a) IN GENERAL.—The amendments made by this subtitle shall apply with respect to plan years beginning on or after January 1 of the second calendar year following the date of the enactment of

this Act. The Secretary of Labor shall first issue all regulations necessary to carry out the amendments made by this subtitle before such date.

(b) **LIMITATION ON ENFORCEMENT ACTIONS.**—No enforcement action shall be taken, pursuant to the amendments made by this subtitle, against a group health plan or health insurance issuer with respect to a violation of a requirement imposed by such amendments before the date of issuance of final regulations issued in connection with such requirement, if the plan or issuer has sought to comply in good faith with such requirement.

## **Subtitle C—Group Health Plan Review Standards**

### **SEC. 121. SPECIAL RULES FOR GROUP HEALTH PLANS.**

(a) **IN GENERAL.**—Section 503 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1133) is amended—

(1) by inserting “(a) **IN GENERAL.**—” after “SEC. 503.”;

(2) by inserting (after and below paragraph (2)) the following new flush-left sentence:

“This subsection does not apply in the case of included group health plan benefits (as defined in subsection (b)(10)(S)).”; and

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

“(b) **SPECIAL RULES FOR GROUP HEALTH PLANS.**—

“(1) **COVERAGE DETERMINATIONS.**—Every group health plan shall, in the case of included group health plan benefits—

“(A) provide adequate notice in writing in accordance with this subsection to any participant or beneficiary of any adverse coverage decision with respect to such benefits of such participant or beneficiary under the plan, setting forth the specific reasons for such coverage decision and any rights of review provided under the plan, written in a manner calculated to be understood by the average participant;

“(B) provide such notice in writing also to any treating medical care provider of such participant or beneficiary, if such provider has claimed reimbursement for any item or service involved in such coverage decision, or if a claim submitted by the provider initiated the proceedings leading to such decision;

“(C) afford a reasonable opportunity to any participant or beneficiary who is in receipt of the notice of such adverse coverage decision, and who files a written request for review of the initial coverage decision within 90 days after receipt of the notice of the initial decision, for a full and fair review of the decision by an appropriate named fiduciary who did not make the initial decision; and

“(D) meet the additional requirements of this subsection, which shall apply solely with respect to such benefits.

“(2) **TIME LIMITS FOR MAKING INITIAL COVERAGE DECISIONS FOR BENEFITS AND COMPLETING INTERNAL APPEALS.**—

“(A) **TIME LIMITS FOR DECIDING REQUESTS FOR BENEFIT PAYMENTS, REQUESTS FOR ADVANCE DETERMINATION OF**

COVERAGE, AND REQUESTS FOR REQUIRED DETERMINATION OF MEDICAL NECESSITY.—Except as provided in subparagraph (B)—

“(i) INITIAL DECISIONS.—If a request for benefit payments, a request for advance determination of coverage, or a request for required determination of medical necessity is submitted to a group health plan in such reasonable form as may be required under the plan, the plan shall issue in writing an initial coverage decision on the request before the end of the initial decision period under paragraph (10)(I) following the filing completion date. Failure to issue a coverage decision on such a request before the end of the period required under this clause shall be treated as an adverse coverage decision for purposes of internal review under clause (ii).

“(ii) INTERNAL REVIEWS OF INITIAL DENIALS.—Upon the written request of a participant or beneficiary for review of an initial adverse coverage decision under clause (i), a review by an appropriate named fiduciary (subject to paragraph (3)) of the initial coverage decision shall be completed, including issuance by the plan of a written decision affirming, reversing, or modifying the initial coverage decision, setting forth the grounds for such decision, before the end of the internal review period following the review filing date. Such decision shall be treated as the final decision of the plan, subject to any applicable reconsideration under paragraph (4). Failure to issue before the end of such period such a written decision requested under this clause shall be treated as a final decision affirming the initial coverage decision.

“(B) TIME LIMITS FOR MAKING COVERAGE DECISIONS RELATING TO ACCELERATED NEED MEDICAL CARE AND FOR COMPLETING INTERNAL APPEALS.—

“(i) INITIAL DECISIONS.—A group health plan shall issue in writing an initial coverage decision on any request for expedited advance determination of coverage or for expedited required determination of medical necessity submitted, in such reasonable form as may be required under the plan before the end of the accelerated need decision period under paragraph (10)(K), in cases involving accelerated need medical care, following the filing completion date. Failure to approve or deny such a request before the end of the applicable decision period shall be treated as a denial of the request for purposes of internal review under clause (ii).

“(ii) INTERNAL REVIEWS OF INITIAL DENIALS.—Upon the written request of a participant or beneficiary for review of an initial adverse coverage decision under clause (i), a review by an appropriate named fiduciary (subject to paragraph (3)) of the initial coverage decision shall be completed, including issuance by the plan of a written decision affirming, reversing, or modifying

the initial converge decision, setting forth the grounds for the decision before the end of the accelerated need decision period under paragraph (10)(K) following the review filing date. Such decision shall be treated as the final decision of the plan, subject to any applicable reconsideration under paragraph (4). Failure to issue before the end of the applicable decision period such a written decision requested under this clause shall be treated as a final decision affirming the initial coverage decision.

“(3) PHYSICIANS MUST REVIEW INITIAL COVERAGE DECISIONS INVOLVING MEDICAL APPROPRIATENESS OR NECESSITY OR INVESTIGATIONAL ITEMS OR EXPERIMENTAL TREATMENT.—If an initial coverage decision under paragraph (2)(A)(i) or (2)(B)(i) is based on a determination that provision of a particular item or service is excluded from coverage under the terms of the plan because the provision of such item or service does not meet the requirements for medical appropriateness or necessity or would constitute provision of investigational items or experimental treatment or technology, the review under paragraph (2)(A)(ii) or (2)(B)(ii), to the extent that it relates to medical appropriateness or necessity or to investigational items or experimental treatment or technology, shall be conducted by a physician who is selected by the plan and who did not make the initial denial.

“(4) ELECTIVE EXTERNAL REVIEW BY INDEPENDENT MEDICAL EXPERT AND RECONSIDERATION OF INITIAL REVIEW DECISION.—

“(A) IN GENERAL.—In any case in which a participant or beneficiary, who has received an adverse coverage decision which is not reversed upon review conducted pursuant to paragraph (1)(C) (including review under paragraph (2)(A)(ii) or (2)(B)(ii)) and who has not commenced review of the coverage decision under section 502, makes a request in writing, within 30 days after the date of such review decision, for reconsideration of such review decision, the requirements of subparagraphs (B), (C), (D) and (E) shall apply in the case of such adverse coverage decision, if the requirements of clause (i) or (ii) are met, subject to clause (iii).

“(i) MEDICAL APPROPRIATENESS OR INVESTIGATIONAL ITEM OR EXPERIMENTAL TREATMENT OR TECHNOLOGY.—The requirements of this clause are met if such coverage decision is based on a determination that provision of a particular item or service that would otherwise be covered is excluded from coverage because the provision of such item or service—

“(I) is not medically appropriate or necessary; or

“(II) would constitute provision of an investigational item or experimental treatment or technology.

“(ii) EXCLUSION OF ITEM OR SERVICE REQUIRING EVALUATION OF MEDICAL FACTS OR EVIDENCE.—The requirements of this clause are met if—

“(I) such coverage decision is based on a determination that a particular item or service is not

covered under the terms of the plan because provision of such item or service is specifically or categorically excluded from coverage under the terms of the plan, and

“(II) an independent contract expert finds under subparagraph (C), in advance of any review of the decision under subparagraph (D), that such determination primarily requires the evaluation of medical facts or medical evidence by a health professional.

“(iii) MATTERS SPECIFICALLY NOT SUBJECT TO REVIEW.—The requirements of subparagraphs (B), (C), (D), and (E) shall not apply in the case of any adverse coverage decision if such decision is based on—

“(I) a determination of eligibility for benefits,

“(II) the application of explicit plan limits on the number, cost, or duration of any benefit, or

“(III) a limitation on the amount of any benefit payment or a requirement to make copayments under the terms of the plan.

Review under this paragraph shall not be available for any coverage decision that has previously undergone review under this paragraph.

“(B) LIMITS ON ALLOWABLE ADVANCE PAYMENTS.—The review under this paragraph in connection with an adverse coverage decision shall be available subject to any requirement of the plan (unless waived by the plan for financial or other reasons) for payment in advance to the plan by the participant or beneficiary seeking review of an amount not to exceed the greater of—

“(i) the lesser of \$100 or 10 percent of the cost of the medical care involved in the decision, or

“(ii) \$25,

with such dollar amount subject to compounded annual adjustments in the same manner and to the same extent as apply under section 215(i) of the Social Security Act, except that, for any calendar year, such amount as so adjusted shall be deemed, solely for such calendar year, to be equal to such amount rounded to the nearest \$10. No such payment may be required in the case of any participant or beneficiary whose enrollment under the plan is paid for, in whole or in part, under a State plan under title XIX or XXI of the Social Security Act. Any such advance payment shall be subject to reimbursement if the recommendation of the independent medical expert (or panel of such experts) under subparagraph (D)(ii)(IV) is to reverse or modify the coverage decision.

“(C) REQUEST TO INDEPENDENT CONTRACT EXPERT FOR DETERMINATION OF WHETHER COVERAGE DECISION REQUIRED EVALUATION OF MEDICAL FACTS OR EVIDENCE.—

“(i) IN GENERAL.—In the case of a request for review made by a participant or beneficiary as described in subparagraph (A), if the requirements of subparagraph (A)(ii) are met (and review is not otherwise pre-

cluded under subparagraph (A)(iii)), the terms of the plan shall provide for a procedure for initial review by an independent contract expert selected in accordance with subparagraph (H) under which the expert will determine whether the coverage decision requires the evaluation of medical facts or evidence by a health professional. If the expert determines that the coverage decision requires such evaluation, reconsideration of such adverse decision shall proceed under this paragraph. If the expert determines that the coverage decision does not require such evaluation, the adverse decision shall remain the final decision of the plan.

“(ii) INDEPENDENT CONTRACT EXPERTS.—For purposes of this subparagraph, the term ‘independent contract expert’ means a professional—

“(I) who has appropriate credentials and has attained recognized expertise in the applicable area of contract interpretation;

“(II) who was not involved in the initial decision or any earlier review thereof; and

“(III) who is selected in accordance with subparagraph (H)(i) and meets the requirements of subparagraph (H)(iii).

“(D) RECONSIDERATION OF INITIAL REVIEW DECISION.—

“(i) IN GENERAL.—In the case of a request for review made by a participant or beneficiary as described in subparagraph (A), if the requirements of subparagraph (A)(i) are met or reconsideration proceeds under this paragraph pursuant to subparagraph (C), the terms of the plan shall provide for a procedure for such reconsideration in accordance with clause (ii).

“(ii) PROCEDURE FOR RECONSIDERATION.—The procedure required under clause (i) shall include the following—

“(I) An independent medical expert (or a panel of such experts, as determined necessary) will be selected in accordance with subparagraph (H) to reconsider any coverage decision described in subparagraph (A) to determine whether such decision was in accordance with the terms of the plan and this title.

“(II) The record for review (including a specification of the terms of the plan and other criteria serving as the basis for the initial review decision) will be presented to such expert (or panel) and maintained in a manner which will ensure confidentiality of such record.

“(III) Such expert (or panel) will reconsider the initial review decision to determine whether such decision was in accordance with the terms of the plan and this title. The expert (or panel) in its reconsideration will take into account the medical condition of the patient, the recommendation of the treating physician, the initial coverage deci-

sion (including the reasons for such decision) and the decision upon review conducted pursuant to paragraph (1)(C) (including review under paragraph (2)(A)(ii) or (2)(B)(ii)), any guidelines adopted by the plan through a process involving medical practitioners and peer-reviewed medical literature identified as such under criteria established by the Food and Drug Administration, and any other valid, relevant, scientific or clinical evidence the expert (or panel) determines appropriate for its review. The expert (or panel) may consult the participant or beneficiary, the treating physician, the medical director of the plan, or any other party who, in the opinion of the expert (or panel), may have relevant information for consideration.

“(E) ISSUANCE OF BINDING FINAL DECISION.—Upon completion of the procedure for review under subparagraph (D), the independent medical expert (or panel of such experts) shall issue a written decision affirming, modifying, or reversing the initial review decision, setting forth the grounds for the decision. Such decision shall be the final decision of the plan and shall be binding on the plan. Such decision shall set forth specifically the determination of the expert (or panel) of the appropriate period for timely compliance by the plan with the decision. Such decision shall be issued concurrently to the participant or beneficiary, to the treating physician, and to the plan, shall constitute conclusive, written authorization for the provision of benefits under the plan in accordance with the decision, and shall be treated as terms of the plan for purposes of any action by the participant or beneficiary under section 502.

“(F) TIME LIMITS FOR RECONSIDERATION.—Any review under this paragraph (including any review under subparagraph (C)) shall be completed before the end of the reconsideration period (as defined in paragraph (10)(L)) following the review filing date in connection with such review. Failure to issue a written decision before the end of the reconsideration period in any reconsideration requested under this paragraph shall be treated as a final decision affirming the initial review decision of the plan.

“(G) INDEPENDENT MEDICAL EXPERTS.—

“(i) IN GENERAL.—For purposes of this paragraph, the term ‘independent medical expert’ means, in connection with any coverage decision by a group health plan, a professional—

“(I) who is a physician or, if appropriate, another medical professional,

“(II) who has appropriate credentials and has attained recognized expertise in the applicable medical field,

“(III) who was not involved in the initial decision or any earlier review thereof,

“(IV) who has no history of disciplinary action or sanctions (including, but not limited to, loss of staff privileges or participation restriction) taken or pending by any hospital, health carrier, government, or regulatory body, and

“(V) who is selected in accordance with subparagraph (H)(i) and meets the requirements of subparagraph (H)(iii).

“(H) SELECTION OF EXPERTS.—

“(i) IN GENERAL.—An independent contract expert or independent medical expert (or each member of any panel of independent medical experts selected under subparagraph (D)(ii)) is selected in accordance with this clause if—

“(I) the expert is selected by an intermediary which itself meets the requirements of clauses (ii) and (iii), by means of a method which ensures that the identity of the expert is not disclosed to the plan, any health insurance issuer offering health insurance coverage to the aggrieved participant or beneficiary in connection with the plan, and the aggrieved participant or beneficiary under the plan, and the identities of the plan, the issuer, and the aggrieved participant or beneficiary are not disclosed to the expert;

“(II) the expert is selected by an appropriately credentialed panel of physicians meeting the requirements of clauses (ii) and (iii) established by a fully accredited teaching hospital meeting such requirements;

“(III) the expert is selected by an organization described in section 1152(1)(A) of the Social Security Act which meets the requirements of clauses (ii) and (iii);

“(IV) the expert is selected by an external review organization which meets the requirements of clauses (ii) and (iii) and is accredited by a private standard-setting organization meeting such requirements;

“(V) the expert is selected by a State agency which is established for the purpose of conducting independent external reviews and which meets the requirements of clauses (ii) and (iii); or

“(VI) the expert is selected, by an intermediary or otherwise, in a manner that is, under regulations issued pursuant to negotiated rulemaking, sufficient to ensure the expert’s independence, and the method of selection is devised to reasonably ensure that the expert selected meets the requirements of clauses (ii) and (iii).

“(ii) STANDARDS OF PERFORMANCE FOR INTERMEDIARIES.—The Secretary shall prescribe by regulation standards (in addition to the requirements of clause (iii)) which entities making selections under

subclause (I), (II), (III), (IV), (V), or (VI) of clause (ii) must meet in order to be eligible for making such selections. Such standards shall include (but are not limited to)—

“(I) assurance that the entity will carry out specified duties in the course of exercising the entity’s responsibilities under clause (i)(I),

“(II) assurance that applicable deadlines will be met in the exercise of such responsibilities, and

“(III) assurance that the entity meets appropriate indicators of solvency and fiscal integrity.

Each such entity shall provide to the Secretary, in such manner and at such times as the Secretary may prescribe, information relating the volume of claims with respect to which the entity has served under this subparagraph, the types of such claims, and such other information regarding such claims as the Secretary may determine appropriate.

“(iii) INDEPENDENCE REQUIREMENTS.—An independent contract expert or independent medical expert or another entity described in clause (i) meets the independence requirements of this clause if—

“(I) the expert or entity is not affiliated with any related party;

“(II) any compensation received by such expert or entity in connection with the external review is reasonable and not contingent on any decision rendered by the expert or entity;

“(III) under the terms of the plan and any health insurance coverage offered in connection with the plan, the plan and the issuer (if any) have no recourse against the expert or entity in connection with the external review; and

“(IV) the expert or entity does not otherwise have a conflict of interest with a related party as determined under any regulations which the Secretary may prescribe.

“(iv) RELATED PARTY.—For purposes of clause (i)(I), the term ‘related party’ means—

“(I) the plan or any health insurance issuer offering health insurance coverage in connection with the plan (or any officer, director, or management employee of such plan or issuer);

“(II) the physician or other medical care provider that provided the medical care involved in the coverage decision;

“(III) the institution at which the medical care involved in the coverage decision is provided;

“(IV) the manufacturer of any drug or other item that was included in the medical care involved in the coverage decision; or

“(V) any other party determined under any regulations which the Secretary may prescribe to

have a substantial interest in the coverage decision.

“(v) AFFILIATED.—For purposes of clause (ii)(I), the term ‘affiliated’ means, in connection with any entity, having a familial, financial, or professional relationship with, or interest in, such entity.

“(I) MISBEHAVIOR BY EXPERTS.—Any action by the expert or experts in applying for their selection under this paragraph or in the course of carrying out their duties under this paragraph which constitutes—

“(i) fraud or intentional misrepresentation by such expert or experts, or

“(ii) demonstrates failure to adhere to the standards for selection set forth in subparagraph (H)(iii), shall be treated as a failure to meet the requirements of this paragraph and therefore as a cause of action which may be brought by a fiduciary under section 502(a)(3).

“(J) BENEFIT EXCLUSIONS MAINTAINED.—Nothing in this paragraph shall be construed as providing for or requiring the coverage of items or services for which benefits are specifically excluded under the group health plan or any health insurance coverage offered in connection with the plan.

“(5) PERMITTED ALTERNATIVES TO REQUIRED FORMS OF REVIEW.—

“(A) IN GENERAL.—In accordance with such regulations (if any) as may be prescribed by the Secretary for purposes of this paragraph, in the case of any initial coverage decision or any decision upon review thereof under paragraph (2)(A)(ii) or (2)(B)(ii), a group health plan may provide an alternative dispute resolution procedure meeting the requirements of subparagraph (B) for use in lieu of the procedures set forth under the preceding provisions of this subsection relating review of such decision. Such procedure may be provided in one form for all participants and beneficiaries or in a different form for each group of similarly situated participants and beneficiaries. Upon voluntary election of such procedure by the plan and by the aggrieved participant or beneficiary in connection with the decision, the plan may provide under such procedure (in a manner consistent with such regulations as the Secretary may prescribe to ensure equitable procedures) for waiver of the review of the decision under paragraph (3) or waiver of further review of the decision under paragraph (4) or section 502 or for election by such parties of an alternative means of external review (other than review under paragraph (4)).

“(B) REQUIREMENTS.—An alternative dispute resolution procedure meets the requirements of this subparagraph, in connection with any decision, if—

“(i) such procedure is utilized solely—

“(I) in accordance with the applicable terms of a bona fide collective bargaining agreement pursuant to which the plan (or the applicable portion

thereof governed by the agreement) is established or maintained, or

“(II) upon election by both the aggrieved participant or beneficiary and the plan,

“(i) the procedure incorporates any otherwise applicable requirement for review by a physician under paragraph (3), unless waived by the participant or beneficiary (in a manner consistent with such regulations as the Secretary may prescribe to ensure equitable procedures); and

“(iii) the means of resolution of dispute allow for adequate presentation by each party of scientific and medical evidence supporting the position of such party.

“(6) REVIEW REQUIREMENTS.—In any review of a decision issued under this subsection—

“(A) the record shall be maintained for purposes of any further review in accordance with standards which shall be prescribed in regulations of the Secretary designed to facilitate such further review, and

“(B) any decision upon review which modifies or reverses a decision below shall specifically set forth a determination that the record upon review is sufficient to rebut a presumption in favor of the decision below.

“(7) COMPLIANCE WITH FIDUCIARY STANDARDS.—The issuance of a decision under a plan upon review in good faith compliance with the requirements of this subsection shall not be treated as a violation of part 4 of subtitle B of title I of the Employee Retirement Income Security Act of 1974.

“(8) LIMITATION ON APPLICABILITY OF SPECIAL RULES.—The provisions of this subsection shall not apply with respect to employee benefit plans that are not group health plans or with respect to benefits that are not included group health plan benefits (as defined in paragraph (10)(S)).

“(9) GROUP HEALTH PLAN DEFINED.—For purposes of this section—

“(A) IN GENERAL.—The term ‘group health plan’ shall have the meaning provided in section 733(a).

“(B) TREATMENT OF PARTNERSHIPS.—The provisions of paragraphs (1), (2), and (3) of section 732(d) shall apply.

“(10) OTHER DEFINITIONS.—For purposes of this subsection—

“(A) REQUEST FOR BENEFIT PAYMENTS.—The term ‘request for benefit payments’ means a request, for payment of benefits by a group health plan for medical care, which is made by, or (if expressly authorized) on behalf of, a participant or beneficiary after such medical care has been provided.

“(B) REQUIRED DETERMINATION OF MEDICAL NECESSITY.—The term ‘required determination of medical necessity’ means a determination required under a group health plan solely that proposed medical care meets, under the facts and circumstances at the time of the determination, the requirements for medical appropriateness or necessity (which may be subject to exceptions under the plan for

fraud or misrepresentation), irrespective of whether the proposed medical care otherwise meets other terms and conditions of coverage, but only if such determination does not constitute an advance determination of coverage (as defined in subparagraph (C)).

“(C) ADVANCE DETERMINATION OF COVERAGE.—The term ‘advance determination of coverage’ means a determination under a group health plan that proposed medical care meets, under the facts and circumstances at the time of the determination, the plan’s terms and conditions of coverage (which may be subject to exceptions under the plan for fraud or misrepresentation).

“(D) REQUEST FOR ADVANCE DETERMINATION OF COVERAGE.—The term ‘request for advance determination of coverage of medical care which is made by, or (if expressly authorized) on behalf of, a participant or beneficiary before such medical care is provided.

“(E) REQUEST FOR EXPEDITED ADVANCE DETERMINATION OF COVERAGE.—The term ‘request for expedited advance determination of coverage’ means a request for advance determination of coverage, in any case in which the proposed medical care constitutes accelerated need medical care.

“(F) REQUEST FOR REQUIRED DETERMINATION OF MEDICAL NECESSITY.—The term ‘request for required determination of medical necessity’ means a request for a required determination of medical necessity for medical care which is made by or on behalf of a participant or beneficiary before the medical care is provided.

“(G) REQUEST FOR EXPEDITED REQUIRED DETERMINATION OF MEDICAL NECESSITY.—The term ‘request for expedited required determination of medical necessity’ means a request for required determination of medical necessity in any case in which the proposed medical care constitutes accelerated need medical care.

“(H) ACCELERATED NEED MEDICAL CARE.—The term ‘accelerated need medical care’ means medical care in any case in which an appropriate physician has certified in writing (or as otherwise provided in regulations of the Secretary) that the participant or beneficiary is stabilized and—

“(i) that failure to immediately provide the care to the participant or beneficiary could reasonably be expected to result in—

“(I) placing the health of such participant or beneficiary (or, with respect to such a participant or beneficiary who is a pregnant woman, the health of the woman or her unborn child) in serious jeopardy;

“(II) serious impairment to bodily functions; or

“(III) serious dysfunction of any bodily organ or part; or

“(ii) that immediate provision of the care is necessary because the participant or beneficiary has made

or is at serious risk of making an attempt to harm himself or herself or another individual.

“(I) INITIAL DECISION PERIOD.—The term ‘initial decision period’ means a period of 30 days, or such period as may be prescribed in regulations of the Secretary.

“(J) INTERNAL REVIEW PERIOD.—The term ‘internal review period’ means a period of 30 days, or such period as may be prescribed in regulations of the Secretary.

“(K) ACCELERATED NEED DECISION PERIOD.—The term ‘accelerated need decision period’ means a period of 3 days, or such period as may be prescribed in regulations of the Secretary.

“(L) RECONSIDERATION PERIOD.—The term ‘reconsideration period’ means a period of 25 days, or such period as may be prescribed in regulations of the Secretary, except that, in the case of a decision involving accelerated need medical care, such term means the accelerated need decision period.

“(M) FILING COMPLETION DATE.—The term ‘filing completion date’ means, in connection with a group health plan, the date as of which the plan is in receipt of all information reasonably required (in writing or in such other reasonable form as may be specified by the plan) to make an initial coverage decision.

“(N) REVIEW FILING DATE.—The term ‘review filing date’ means, in connection with a group health plan, the date as of which the appropriate named fiduciary (or the independent medical expert or panel of such experts in the case of a review under paragraph (4)) is in receipt of all information reasonably required (in writing or in such other reasonable form as may be specified by the plan) to make a decision to affirm, modify, or reverse a coverage decision.

“(O) MEDICAL CARE.—The term ‘medical care’ has the meaning provided such term by section 733(a)(2).

“(P) HEALTH INSURANCE COVERAGE.—The term ‘health insurance coverage’ has the meaning provided such term by section 733(b)(1).

“(Q) HEALTH INSURANCE ISSUER.—The term ‘health insurance issuer’ has the meaning provided such term by section 733(b)(2).

“(R) WRITTEN OR IN WRITING.—

“(i) IN GENERAL.—A request or decision shall be deemed to be ‘written’ or ‘in writing’ if such request or decision is presented in a generally recognized printable or electronic format. The Secretary may by regulation provide for presentation of information otherwise required to be in written form in such other forms as may be appropriate under the circumstances.

“(ii) MEDICAL APPROPRIATENESS OR INVESTIGATIONAL ITEMS OR EXPERIMENTAL TREATMENT DETERMINATIONS.—For purposes of this subparagraph, in the case of a request for advance determination of coverage, a request for expedited advance determination of cov-

erage, a request for required determination of medical necessity, or a request for expedited required determination of medical necessity, if the decision on such request is conveyed to the provider of medical care or to the participant or beneficiary by means of telephonic or other electronic communications, such decision shall be treated as a written decision.

“(S) INCLUDED GROUP HEALTH PLAN BENEFIT.—The term ‘included group health plan benefit’ means a benefit under a group health plan which is not an excepted benefit (as defined in section 733(c)).”.

(b) CIVIL PENALTIES.—

(1) IN GENERAL.—Section 502(c) of such Act (29 U.S.C. 1132(c)) is amended by redesignating paragraphs (6) and (7) as paragraphs (7) and (8), respectively, and by inserting after paragraph (5) the following new paragraph:

“(6)(A)(i) In the case of any failure to timely provide an included group health plan benefit (as defined in section 503(b)(10)(S)) to a participant or beneficiary, which occurs after the issuance of, and in violation of, a final decision rendered upon completion of external review (under section 503(b)(4)) of an adverse coverage decision by the plan relating to such benefit, any person acting in the capacity of a fiduciary of the plan so as to cause such failure may, in the court’s discretion, be liable to the aggrieved participant or beneficiary for a civil penalty.

“(ii) Except as provided in clause (iii), such civil penalty shall be in an amount of up to \$1,000 a day from the date that occurs on or after the date of the issuance of the decision under section 503(b)(4) and upon which the plan otherwise could have been reasonably expected to commence compliance with the decision until the date the failure to provide the benefit is corrected.

“(iii) In any case in which it is proven by clear and convincing evidence that the person referred to in clause (i) acted willfully and in bad faith, the daily penalty under clause (ii) shall be increased to an amount of up to \$5,000 a day.

“(iv) In any case in which it is further proven by clear and convincing evidence that—

“(I) the plan is not in full compliance with the decision of the independent medical expert (or panel of such experts) under section 503(b)(4)(E)) within the appropriate period specified in such decision, and

“(II) the failure to be in full compliance was caused by the plan or by a health insurance issuer offering health insurance coverage in connection with the plan,

the plan shall pay the cost of all medical care which was not provided by reason of such failure to fully comply and which is otherwise obtained by the participant or beneficiary from any provider.

“(B) For purposes of subparagraph (A), the plan, and any health insurance issuer offering health insurance coverage in connection with the plan, shall be deemed to be in compliance with any decision of an independent medical expert (or panel of such experts) under section 503(b)(4) with respect to any participant or beneficiary upon transmission to such entity (or panel) and to such participant or beneficiary by the plan or issuer of timely notice of an

authorization of coverage by the plan or issuer which is consistent with such decision.

“(C) In any action commenced under subsection (a) by a participant or beneficiary with respect to an included group health plan benefit in which the plaintiff alleges that a person, in the capacity of a fiduciary and in violation of the terms of the plan or this title, has taken an action resulting in an adverse coverage decision in violation of the terms of the plan, or has failed to take an action for which such person is responsible under the plan and which is necessary under the plan for a favorable coverage decision, upon finding in favor of the plaintiff, if such action was commenced after a final decision of the plan upon review which included a review under section 503(b)(4) or such action was commenced under subsection (b)(4) of this section, the court shall cause to be served on the defendant an order requiring the defendant—

“(i) to cease and desist from the alleged action or failure to act; and

“(ii) to pay to the plaintiff a reasonable attorney’s fee and other reasonable costs relating to the prosecution of the action on the charges on which the plaintiff prevails.

The remedies provided under this subparagraph shall be in addition to remedies otherwise provided under this section.

“(D)(i) The Secretary may assess a civil penalty against a person acting in the capacity of a fiduciary of one or more group health plans (as defined in section 503(b)(9)) for—

“(I) any pattern or practice of repeated adverse coverage decisions in connection with included group health plan benefits in violation of the terms of the plan or plans or this title; or

“(II) any pattern or practice of repeated violations of the requirements of section 503 in connection with such benefits.

Such penalty shall be payable only upon proof by clear and convincing evidence of such pattern or practice.

“(ii) Such penalty shall be in an amount not to exceed the lesser of—

“(I) 5 percent of the aggregate value of benefits shown by the Secretary to have not been provided, or unlawfully delayed in violation of section 503, under such pattern or practice; or

“(II) \$100,000.

“(iii) Any person acting in the capacity of a fiduciary of a group health plan or plans who has engaged in any such pattern or practice in connection with included group health plan benefits, upon the petition of the Secretary, may be removed by the court from that position, and from any other involvement, with respect to such plan or plans, and may be precluded from returning to any such position or involvement for a period determined by the court.

“(E) For purposes of this paragraph, the term ‘included group health plan benefit’ has the meaning provided in section 503(b)(10)(S).

“(F) The preceding provisions of this paragraph shall not apply with respect to employee benefit plans that are not group health plans or with respect to benefits that are not included group health plan benefits (as defined in paragraph (10)(S)).”.

(2) CONFORMING AMENDMENT.—Section 502(a)(6) of such Act (29 U.S.C. 1132(a)(6)) is amended by striking “, or (6)” and inserting “, (6), or (7)”.

(c) EXPEDITED COURT REVIEW.—Section 502 of such Act (29 U.S.C. 1132) is amended—

(1) in subsection (a)(8), by striking “or” at the end;

(2) in subsection (a)(9), by striking the period and inserting “, or”;

(3) by adding at the end of subsection (a) the following new paragraph:

“(10) by a participant or beneficiary for appropriate relief under subsection (b)(4).”.

(4) by adding at the end of subsection (b) the following new paragraph:

“(4) In the case of a group health plan, if exhaustion of administrative remedies in accordance with paragraph (2)(A)(ii) or (2)(B)(ii) of section 503(b) otherwise necessary for an action for relief under paragraph (1)(B) or (3) of subsection (a) has not been obtained and it is demonstrated to the court by means of certification by an appropriate physician that such exhaustion is not reasonably attainable under the facts and circumstances without undue risk of irreparable harm to the health of the participant or beneficiary, a civil action may be brought by the participant or beneficiary to obtain appropriate equitable relief. Any determinations made under paragraph (2)(A)(ii) or (2)(B)(ii) of section 503(b) made while an action under this paragraph is pending shall be given due consideration by the court in any such action. This paragraph shall not apply with respect to benefits that are not included group health plan benefits (as defined in section 503(b)(10)(S)).”.

(d) ATTORNEY’S FEES.—Section 502(g) of such Act (29 U.S.C. 1132(g)) is amended—

(1) in paragraph (1), by striking “paragraph (2)” and inserting “paragraph (2) or (3)”; and

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

“(3) In any action under this title by a participant or beneficiary in connection with an included group health plan benefit (as defined in section 503(b)(10)(S)) in which judgment in favor of the participant or beneficiary is awarded, the court shall allow a reasonable attorney’s fee and costs of action to the participant or beneficiary.”.

(e) STANDARD OF REVIEW UNAFFECTED.—The standard of review under section 502 of the Employee Retirement Income Security Act of 1974 (as amended by this section) shall continue on and after the date of the enactment of this Act to be the standard of review which was applicable under such section as of immediately before such date.

(f) CONCURRENT JURISDICTION.—Section 502(e)(1) of such Act (29 U.S.C. 1132(e)(1)) is amended—

(1) in the first sentence, by striking “under subsection (a)(1)(B) of this section” and inserting “under subsection (a)(1)(A) for relief under subsection (c)(6), under subsection (a)(1)(B), and under subsection (b)(4)”; and

(2) in the last sentence, by striking “of actions under paragraphs (1)(B) and (7) of subsection (a) of this section” and in-

serting “of actions under paragraph (1)(A) of subsection (a) for relief under subsection (c)(6) and of actions under paragraphs (1)(B) and (7) of subsection (a) and paragraph (4) of subsection (b)”.

**SEC. 122. SPECIAL RULE FOR ACCESS TO SPECIALTY CARE.**

Section 503(b) of such Act (as added by the preceding provisions of this subtitle) is amended by adding at the end the following new paragraph:

“(11) SPECIAL RULE FOR ACCESS TO SPECIALTY CARE.—

“(A) IN GENERAL.—In the case of a request for advance determination of coverage consisting of a request by a physician for a determination of coverage of the services of a specialist with respect to any condition, if coverage of the services of such specialist for such condition is otherwise provided under the plan, the initial coverage decision referred to in subparagraph (A)(i) or (B)(i) of paragraph (2) shall be issued within the accelerated need decision period.

“(B) SPECIALIST.—For purposes of this paragraph, the term ‘specialist’ means, with respect to a condition, a physician who has a high level of expertise through appropriate training and experience (including, in the case of a patient who is a child, appropriate pediatric expertise) to treat the condition.”.

**SEC. 123. PROTECTION FOR CERTAIN INFORMATION DEVELOPED TO REDUCE MORTALITY OR MORBIDITY OR FOR IMPROVING PATIENT CARE AND SAFETY.**

(a) PROTECTION OF CERTAIN INFORMATION.—Notwithstanding any other provision of Federal or State law, health care response information shall be exempt from any disclosure requirement (regardless of whether the requirement relates to subpoenas, discovery, introduction of evidence, testimony, or any other form of disclosure), in connection with a civil or administrative proceeding under Federal or State law, to the same extent as information developed by a health care provider with respect to any of the following:

- (1) Peer review.
- (2) Utilization review.
- (3) Quality management or improvement.
- (4) Quality control.
- (5) Risk management.
- (6) Internal review for purposes of reducing mortality, morbidity, or for improving patient care or safety.

(b) NO WAIVER OF PROTECTION THROUGH INTERACTION WITH ACCREDITING BODY.—Notwithstanding any other provision of Federal or State law, the protection of health care response information from disclosure provided under subsection (a) shall not be deemed to be modified or in any way waived by—

- (1) the development of such information in connection with a request or requirement of an accrediting body; or
- (2) the transfer of such information to an accrediting body.

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

- (1) The term “accrediting body” means a national, not-for-profit organization that—
  - (A) accredits health care providers; and

(B) is recognized as an accrediting body by statute or by a Federal or State agency that regulates health care providers.

(2) The term “health care provider” has the meaning given such term in section 1188 of the Social Security Act (as added by section 5001 of this Act).

(3) The term “health care response information” means information (including any data, report, record, memorandum, analysis, statement, or other communication) developed by, or on behalf of, a health care provider in response to a serious, adverse, patient-related event—

(A) during the course of analyzing or studying the event and its causes; and

(B) for purposes of—

(i) reducing mortality or morbidity; or

(ii) improving patient care or safety (including the provider’s notification to an accrediting body and the provider’s plans of action in response to such event).

(5) The term “State” includes the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

**SEC. 124. EFFECTIVE DATE.**

(a) **IN GENERAL.**—The amendments made by sections 801 and 802 shall apply with respect to grievances arising in plan years beginning on or after January 1 of the second calendar year following 12 months after the date the Secretary of Labor issues all regulations necessary to carry out amendments made by this title. The amendments made by section 803 shall take effect on such January 1.

(b) **LIMITATION ON ENFORCEMENT ACTIONS.**—No enforcement action shall be taken, pursuant to the amendments made by this title, against a group health plan or health insurance issuer with respect to a violation of a requirement imposed by such amendments before the date of issuance of final regulations issued in connection with such requirement, if the plan or issuer has sought to comply in good faith with such requirement.

(c) **COLLECTIVE BARGAINING AGREEMENTS.**—Any plan amendment made pursuant to a collective bargaining agreement relating to the plan which amends the plan solely to conform to any requirement added by this title shall not be treated as a termination of such collective bargaining agreement.

## **Subtitle D—Health Care Access, Affordability, and Quality Commission**

**SEC. 131. ESTABLISHMENT OF COMMISSION.**

Part 5 of the Employee Retirement Income Security Act of 1974 is amended by adding at the end the following new section:

“SEC. 518. HEALTH POLICY COMMISSION.

“(a) **ESTABLISHMENT.**—There is hereby established a commission to be known as the Health Care Access, Affordability, and Quality

Commission (hereinafter in this Act referred to as the “Commission”).

“(b) DUTIES OF COMMISSION.—The duties of the Commission shall be as follows:

“(1) STUDIES OF CRITICAL AREAS.—Based on information gathered by appropriate Federal agencies, advisory groups, and other appropriate sources for health care information, studies, and data, the Commission shall study and report on in each of the following areas:

“(A) Independent expert external review programs.

“(B) Consumer friendly information programs.

“(C) The extent to which the following affect patient quality and satisfaction:

“(i) health plan enrollees’ attitudes based on surveys;

“(ii) outcomes measurements; and

“(iii) accreditation by private organizations.

“(D) Available systems to ensure the timely processing of claims.

“(2) ESTABLISHMENT OF FORM FOR REMITTANCE OF CLAIMS TO PROVIDERS.—Not later than 2 years after the date of the first meeting of the Commission, the Commission shall develop and transmit to the Secretary a proposed form for use by health insurance issuers (as defined in section 733(b)(2)) for the remittance of claims to health care providers. Effective for plan years beginning after 5 years after the date of the Comprehensive Access and Responsibility in Health Care Act of 1999, a health insurance issuer offering health insurance coverage in connection with a group health plan shall use such form for the remittance of all claims to providers.

“(3) EVALUATION OF HEALTH BENEFITS MANDATES.—At the request of the chairmen or ranking minority members of the appropriate committees of Congress, the Commission shall evaluate, taking into consideration the overall cost effect, availability of treatment, and the effect on the health of the general population, existing and proposed benefit requirements for group health plans.

“(4) COMMENTS ON CERTAIN SECRETARIAL REPORTS.—If the Secretary submits to Congress (or a committee of Congress) a report that is required by law and that relates to policies under this section, the Secretary shall transmit a copy of the report to the Commission. The Commission shall review the report and, not later than 6 months after the date of submittal of the Secretary’s report to Congress, shall submit to the appropriate committees of Congress written comments on such report. Such comments may include such recommendations as the Commission deems appropriate.

“(5) AGENDA AND ADDITIONAL REVIEW.—The Commission shall consult periodically with the chairmen and ranking minority members of the appropriate committees of Congress regarding the Commission’s agenda and progress toward achieving the agenda. The Commission may conduct additional reviews, and submit additional reports to the appropriate committees of Congress, from time to time on such topics as may

be requested by such chairmen and members and as the Commission deems appropriate.

“(6) AVAILABILITY OF REPORTS.—The Commission shall transmit to the Secretary a copy of each report submitted under this subsection and shall make such reports available to the public.

“(c) MEMBERSHIP.—

“(1) NUMBER AND APPOINTMENT.—The Commission shall be composed of 11 members appointed by the Comptroller General.

“(2) QUALIFICATIONS.—

“(A) IN GENERAL.—The membership of the Commission shall include—

“(i) physicians and other health professionals;

“(ii) representatives of employers, including multi-employer plans;

“(iii) representatives of insured employees;

“(iv) third-party payers; and

“(v) health services and health economics researchers with expertise in outcomes and effectiveness research and technology assessment.

“(B) ETHICAL DISCLOSURE.—The Comptroller General shall establish a system for public disclosure by members of the Commission of financial and other potential conflicts of interest relating to such members.

“(3) TERMS.—

“(A) IN GENERAL.—Each member shall be appointed for a term of 3 years, except that the Comptroller shall designate staggered terms for the members first appointed.

“(B) VACANCIES.—Any member appointed to fill a vacancy occurring before the expiration of the term for which the member’s predecessor was appointed shall be appointed only for the remainder of that term. A member may serve after the expiration of that member’s term until a successor has taken office. A vacancy in the Commission shall be filled in the manner in which the original appointment was made.

“(4) BASIC PAY.—

“(A) RATES OF PAY.—Except as provided in subparagraph (B), members shall each be paid at a rate equal to the rate of basic pay payable for level IV of the Executive Schedule for each day (including travel time) during which they are engaged in the actual performance of duties vested in the Commission.

“(B) PROHIBITION OF COMPENSATION OF FEDERAL EMPLOYEES.—Members of the Commission who are full-time officers or employees of the United States (or Members of Congress) may not receive additional pay, allowances, or benefits by reason of their service on the Commission.

“(5) TRAVEL EXPENSES.—Each member shall receive travel expenses, including per diem in lieu of subsistence, in accordance with sections 5702 and 5703 of title 5, United States Code.

“(6) CHAIRPERSON.—The Chairperson of the Commission shall be designated by the Comptroller at the time of the ap-

pointment. The term of office of the Chairperson shall be 3 years.

“(7) MEETINGS.—The Commission shall meet 4 times each year.

“(d) DIRECTOR AND STAFF OF COMMISSION.—

“(1) DIRECTOR.—The Commission shall have a Director who shall be appointed by the Chairperson. The Director shall be paid at a rate not to exceed the maximum rate of basic pay payable for GS–13 of the General Schedule.

“(2) STAFF.—The Director may appoint 2 additional staff members.

“(3) APPLICABILITY OF CERTAIN CIVIL SERVICE LAWS.—The Director and staff of the Commission shall be appointed subject to the provisions of title 5, United States Code, governing appointments in the competitive service, and shall be paid in accordance with the provisions of chapter 51 and subchapter III of chapter 53 of that title relating to classification and General Schedule pay rates.

“(e) POWERS OF COMMISSION.—

“(1) HEARINGS AND SESSIONS.—The Commission may, for the purpose of carrying out this Act, hold hearings, sit and act at times and places, take testimony, and receive evidence as the Commission considers appropriate. The Commission may administer oaths or affirmations to witnesses appearing before it.

“(2) POWERS OF MEMBERS AND AGENTS.—Any member or agent of the Commission may, if authorized by the Commission, take any action which the Commission is authorized to take by this section.

“(3) OBTAINING OFFICIAL DATA.—The Commission may secure directly from any department or agency of the United States information necessary to enable it to carry out this Act. Upon request of the Chairperson of the Commission, the head of that department or agency shall furnish that information to the Commission.

“(4) MAILS.—The Commission may use the United States mails in the same manner and under the same conditions as other departments and agencies of the United States.

“(5) ADMINISTRATIVE SUPPORT SERVICES.—Upon the request of the Commission, the Administrator of General Services shall provide to the Commission, on a reimbursable basis, the administrative support services necessary for the Commission to carry out its responsibilities under this Act.

“(6) CONTRACT AUTHORITY.—The Commission may contract with and compensate government and private agencies or persons for services, without regard to section 3709 of the Revised Statutes (41 U.S.C. 5).

“(f) REPORTS.—Beginning December 31, 2000, and each year thereafter, the Commission shall submit to the Congress an annual report detailing the following information:

“(1) Access to care, affordability to employers and employees, and quality of care under employer-sponsored health plans and recommendations for improving such access, affordability, and quality.

“(2) Any issues the Commission deems appropriate or any issues (such as the appropriateness and availability of particular medical treatment) that the chairmen or ranking members of the appropriate committees of Congress requested the Commission to evaluate.

“(g) DEFINITION OF APPROPRIATE COMMITTEES OF CONGRESS.—For purposes of this section the term ‘appropriate committees of Congress’ means any committee in the Senate or House of Representatives having jurisdiction over the Employee Retirement Income Security Act of 1974.

“(h) TERMINATION.—Section 14(a)(2)(B) of the Federal Advisory Committee Act (5 U.S.C. App.; relating to the termination of advisory committees) shall not apply to the Commission.

“(i) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated for fiscal years 2000 through 2004 such sums as may be necessary to carry out this section.”.

**SEC. 132. EFFECTIVE DATE.**

This subtitle shall be effective 6 months after the date of the enactment of this Act.

## **TITLE II—AMENDMENTS TO THE PUBLIC HEALTH SERVICE ACT**

### **Subtitle A—Patient Protections and Point of Service Coverage Requirements**

**SEC. 201. PATIENT ACCESS TO UNRESTRICTED MEDICAL ADVICE, EMERGENCY MEDICAL CARE, OBSTETRIC AND GYNECOLOGICAL CARE, PEDIATRIC CARE, AND CONTINUITY OF CARE.**

(a) IN GENERAL.—Subpart 2 of part A of title XXVII of the Public Health Service Act is amended by adding at the end the following new section:

**“SEC. 2707. PATIENT ACCESS TO UNRESTRICTED MEDICAL ADVICE, EMERGENCY MEDICAL CARE, OBSTETRIC AND GYNECOLOGICAL CARE, PEDIATRIC CARE, AND CONTINUITY OF CARE.**

“(a) PATIENT ACCESS TO UNRESTRICTED MEDICAL ADVICE.—

“(1) IN GENERAL.—In the case of any health care professional acting within the lawful scope of practice in the course of carrying out a contractual employment arrangement or other direct contractual arrangement between such professional and a group health plan or a health insurance issuer offering health insurance coverage in connection with a group health plan, the plan or issuer with which such contractual employment arrangement or other direct contractual arrangement is maintained by the professional may not impose on such professional under such arrangement any prohibition or restriction with respect to advice, provided to a participant or beneficiary under the plan who is a patient, about the health status of the participant or beneficiary or the medical care or treatment for the condition or disease of the participant or beneficiary, regard-

less of whether benefits for such care or treatment are provided under the plan or health insurance coverage offered in connection with the plan.

“(2) HEALTH CARE PROFESSIONAL DEFINED.—For purposes of this paragraph, the term ‘health care professional’ means a physician (as defined in section 1861(r) of the Social Security Act) or other health care professional if coverage for the professional’s services is provided under the group health plan for the services of the professional. Such term includes a podiatrist, optometrist, chiropractor, psychologist, dentist, physician assistant, physical or occupational therapist and therapy assistant, speech-language pathologist, audiologist, registered or licensed practical nurse (including nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, and certified nurse-midwife), licensed certified social worker, registered respiratory therapist, and certified respiratory therapy technician.

“(3) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to require the sponsor of a group health plan or a health insurance issuer offering health insurance coverage in connection with the group health plan to engage in any practice that would violate its religious beliefs or moral convictions.

“(b) PATIENT ACCESS TO EMERGENCY MEDICAL CARE.—

“(1) COVERAGE OF EMERGENCY SERVICES.—

“(A) IN GENERAL.—If a group health plan, or health insurance coverage offered by a health insurance issuer, provides any benefits with respect to emergency services (as defined in subparagraph (B)(ii)), or ambulance services, the plan or issuer shall cover emergency services (including emergency ambulance services as defined in subparagraph (B)(iii)) furnished under the plan or coverage—

“(i) without the need for any prior authorization determination;

“(ii) whether or not the health care provider furnishing such services is a participating provider with respect to such services;

“(iii) in a manner so that, if such services are provided to a participant, beneficiary, or enrollee by a nonparticipating health care provider, the participant, beneficiary, or enrollee is not liable for amounts that exceed the amounts of liability that would be incurred if the services were provided by a participating provider; and

“(iv) without regard to any other term or condition of such plan or coverage (other than exclusion or coordination of benefits, or an affiliation or waiting period, permitted under section 2701 and other than applicable cost sharing).

“(B) DEFINITIONS.—In this subsection:

“(i) EMERGENCY MEDICAL CONDITION.—The term ‘emergency medical condition’ means—

“(I) a medical condition manifesting itself by acute symptoms of sufficient severity (including

severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act (42 U.S.C. 1395dd(e)(1)(A)); and

“(II) a medical condition manifesting itself in a neonate by acute symptoms of sufficient severity (including severe pain) such that a prudent health care professional could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act.

“(ii) EMERGENCY SERVICES.—The term ‘emergency services’ means—

“(I) with respect to an emergency medical condition described in clause (i)(I), a medical screening examination (as required under section 1867 of the Social Security Act, 42 U.S.C. 1395dd) that is within the capability of the emergency department of a hospital, including ancillary services routinely available to the emergency department to evaluate an emergency medical condition (as defined in clause (i)) and also, within the capabilities of the staff and facilities at the hospital, such further medical examination and treatment as are required under section 1867 of such Act to stabilize the patient; or

“(II) with respect to an emergency medical condition described in clause (i)(II), medical treatment for such condition rendered by a health care provider in a hospital to a neonate, including available hospital ancillary services in response to an urgent request of a health care professional and to the extent necessary to stabilize the neonate.

“(iii) EMERGENCY AMBULANCE SERVICES.—The term ‘emergency ambulance services’ means ambulance services (as defined for purposes of section 1861(s)(7) of the Social Security Act) furnished to transport an individual who has an emergency medical condition (as defined in clause (i)) to a hospital for the receipt of emergency services (as defined in clause (ii)) in a case in which appropriate emergency medical screening examinations are covered under the plan or coverage pursuant to paragraph (1)(A) and a prudent layperson, with an average knowledge of health and medicine, could reasonably expect that the absence of such transport would result in placing the health of the individual in serious jeopardy, serious impairment of bodily function, or serious dysfunction of any bodily organ or part.

“(iv) STABILIZE.—The term ‘to stabilize’ means, with respect to an emergency medical condition, to provide such medical treatment of the condition as may be necessary to assure, within reasonable medical probability, that no material deterioration of the condition is likely to result from or occur during the transfer of the individual from a facility.

“(v) NONPARTICIPATING.—The term ‘nonparticipating’ means, with respect to a health care provider that provides health care items and services to a participant or beneficiary under group health plan or under group health insurance coverage, a health care provider that is not a participating health care provider with respect to such items and services.

“(vi) PARTICIPATING.—The term ‘participating’ means, with respect to a health care provider that provides health care items and services to a participant or beneficiary under group health plan or health insurance coverage offered by a health insurance issuer in connection with such a plan, a health care provider that furnishes such items and services under a contract or other arrangement with the plan or issuer.

“(c) PATIENT RIGHT TO OBSTETRIC AND GYNECOLOGICAL CARE.—

“(1) IN GENERAL.—In any case in which a group health plan (or a health insurance issuer offering health insurance coverage in connection with the plan)—

“(A) provides benefits under the terms of the plan consisting of—

“(i) gynecological care (such as preventive women’s health examinations); or

“(ii) obstetric care (such as pregnancy-related services),

provided by a participating health care professional who specializes in such care (or provides benefits consisting of payment for such care); and

“(B) requires or provides for designation by a participant or beneficiary of a participating primary care provider, if the primary care provider designated by such a participant or beneficiary is not such a health care professional, then the plan (or issuer) shall meet the requirements of paragraph (2).

“(1) REQUIREMENTS.—A group health plan (or a health insurance issuer offering health insurance coverage in connection with the plan) meets the requirements of this paragraph, in connection with benefits described in paragraph (1) consisting of care described in clause (i) or (ii) of paragraph (1)(A) (or consisting of payment therefor), if the plan (or issuer)—

“(A) does not require authorization or a referral by the primary care provider in order to obtain such benefits; and

“(B) treats the ordering of other care of the same type, by the participating health care professional providing the care described in clause (i) or (ii) of paragraph (1)(A), as the authorization of the primary care provider with respect to such care.

“(3) HEALTH CARE PROFESSIONAL DEFINED.—For purposes of this subsection, the term ‘health care professional’ means an individual (including, but not limited to, a nurse midwife or nurse practitioner) who is licensed, accredited, or certified under State law to provide obstetric and gynecological health care services and who is operating within the scope of such licensure, accreditation, or certification.

“(4) CONSTRUCTION.—Nothing in paragraph (1) shall be construed as preventing a plan from offering (but not requiring a participant or beneficiary to accept) a health care professional trained, credentialed, and operating within the scope of their licensure to perform obstetric and gynecological health care services. Nothing in paragraph (2)(B) shall waive any requirements of coverage relating to medical necessity or appropriateness with respect to coverage of gynecological or obstetric care so ordered.

“(5) TREATMENT OF MULTIPLE COVERAGE OPTIONS.—In the case of a plan providing benefits under two or more coverage options, the requirements of this subsection shall apply separately with respect to each coverage option.

“(d) PATIENT RIGHT TO PEDIATRIC CARE.—

“(1) IN GENERAL.—In any case in which a group health plan (or a health insurance issuer offering health insurance coverage in connection with the plan) provides benefits consisting of routine pediatric care provided by a participating health care professional who specializes in pediatrics (or consisting of payment for such care) and the plan requires or provides for designation by a participant or beneficiary of a participating primary care provider, the plan (or issuer) shall provide that such a participating health care professional may be designated, if available, by a parent or guardian of any beneficiary under the plan is who under 18 years of age, as the primary care provider with respect to any such benefits.

“(2) HEALTH CARE PROFESSIONAL DEFINED.—For purposes of this subsection, the term ‘health care professional’ means an individual (including, but not limited to, a nurse practitioner) who is licensed, accredited, or certified under State law to provide pediatric health care services and who is operating within the scope of such licensure, accreditation, or certification.

“(3) CONSTRUCTION.—Nothing in paragraph (1) shall be construed as preventing a plan from offering (but not requiring a participant or beneficiary to accept) a health care professional trained, credentialed, and operating within the scope of their licensure to perform pediatric health care services. Nothing in paragraph (1) shall waive any requirements of coverage relating to medical necessity or appropriateness with respect to coverage of pediatric care so ordered.

“(4) TREATMENT OF MULTIPLE COVERAGE OPTIONS.—In the case of a plan providing benefits under two or more coverage options, the requirements of this subsection shall apply separately with respect to each coverage option.

“(e) CONTINUITY OF CARE.—

“(1) IN GENERAL.—

“(A) TERMINATION OF PROVIDER.—If a contract between a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, and a health care provider is terminated (as defined in subparagraph (D)(ii)), or benefits or coverage provided by a health care provider are terminated because of a change in the terms of provider participation in a group health plan, and an individual who, at the time of such termination, is a participant or beneficiary in the plan and is scheduled to undergo surgery (including an organ transplantation), is undergoing treatment for pregnancy, or is determined to be terminally ill (as defined in section 1861(dd)(3)(A) of the Social Security Act) and is undergoing treatment for the terminal illness, the plan or issuer shall—

“(i) notify the individual on a timely basis of such termination and of the right to elect continuation of coverage of treatment by the provider under this subsection; and

“(ii) subject to paragraph (3), permit the individual to elect to continue to be covered with respect to treatment by the provider for such surgery, pregnancy, or illness during a transitional period (provided under paragraph (2)).

“(B) TREATMENT OF TERMINATION OF CONTRACT WITH HEALTH INSURANCE ISSUER.—If a contract for the provision of health insurance coverage between a group health plan and a health insurance issuer is terminated and, as a result of such termination, coverage of services of a health care provider is terminated with respect to an individual, the provisions of subparagraph (A) (and the succeeding provisions of this subsection) shall apply under the plan in the same manner as if there had been a contract between the plan and the provider that had been terminated, but only with respect to benefits that are covered under the plan after the contract termination.

“(C) TERMINATION DEFINED.—For purposes of this subsection, the term ‘terminated’ includes, with respect to a contract, the expiration or nonrenewal of the contract, but does not include a termination of the contract by the plan or issuer for failure to meet applicable quality standards or for fraud.

“(2) TRANSITIONAL PERIOD.—

“(A) IN GENERAL.—Except as provided in subparagraphs (B) through (D), the transitional period under this paragraph shall extend up to 90 days (as determined by the treating health care professional) after the date of the notice described in paragraph (1)(A)(i) of the provider’s termination.

“(B) SCHEDULED SURGERY.—If surgery was scheduled for an individual before the date of the announcement of the termination of the provider status under paragraph (1)(A)(i), the transitional period under this paragraph with respect to the surgery shall extend beyond the period

under subparagraph (A) and until the date of discharge of the individual after completion of the surgery.

“(C) PREGNANCY.—If—

“(i) a participant or beneficiary was determined to be pregnant at the time of a provider’s termination of participation, and

“(ii) the provider was treating the pregnancy before date of the termination,

the transitional period under this paragraph with respect to provider’s treatment of the pregnancy shall extend through the provision of post-partum care directly related to the delivery.

“(D) TERMINAL ILLNESS.—If—

“(i) a participant or beneficiary was determined to be terminally ill (as determined under section 1861(dd)(3)(A) of the Social Security Act) at the time of a provider’s termination of participation, and

“(ii) the provider was treating the terminal illness before the date of termination,

the transitional period under this paragraph shall extend for the remainder of the individual’s life for care directly related to the treatment of the terminal illness or its medical manifestations.

“(3) PERMISSIBLE TERMS AND CONDITIONS.—A group health plan or health insurance issuer may condition coverage of continued treatment by a provider under paragraph (1)(A)(i) upon the individual notifying the plan of the election of continued coverage and upon the provider agreeing to the following terms and conditions:

“(A) The provider agrees to accept reimbursement from the plan or issuer and individual involved (with respect to cost-sharing) at the rates applicable prior to the start of the transitional period as payment in full (or, in the case described in paragraph (1)(B), at the rates applicable under the replacement plan or issuer after the date of the termination of the contract with the health insurance issuer) and not to impose cost-sharing with respect to the individual in an amount that would exceed the cost-sharing that could have been imposed if the contract referred to in paragraph (1)(A) had not been terminated.

“(B) The provider agrees to adhere to the quality assurance standards of the plan or issuer responsible for payment under subparagraph (A) and to provide to such plan or issuer necessary medical information related to the care provided.

“(C) The provider agrees otherwise to adhere to such plan’s or issuer’s policies and procedures, including procedures regarding referrals and obtaining prior authorization and providing services pursuant to a treatment plan (if any) approved by the plan or issuer.

“(D) The provider agrees to provide transitional care to all participants and beneficiaries who are eligible for and elect to have coverage of such care from such provider.

“(E) If the provider initiates the termination, the provider has notified the plan within 30 days prior to the effective date of the termination of—

“(i) whether the provider agrees to permissible terms and conditions (as set forth in this paragraph) required by the plan, and

“(ii) if the provider agrees to the terms and conditions, the specific plan beneficiaries and participants undergoing a course of treatment from the provider who the provider believes, at the time of the notification, would be eligible for transitional care under this subsection.

“(4) CONSTRUCTION.—Nothing in this subsection shall be construed to—

“(A) require the coverage of benefits which would not have been covered if the provider involved remained a participating provider, or

“(B) prohibit a group health plan from conditioning a provider’s participation on the provider’s agreement to provide transitional care to all participants and beneficiaries eligible to obtain coverage of such care furnished by the provider as set forth under this subsection.

“(f) COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CANCER CLINICAL TRIALS.—

“(1) COVERAGE.—

“(A) IN GENERAL.—If a group health plan (or a health insurance issuer offering health insurance coverage) provides coverage to a qualified individual (as defined in paragraph (2)), the plan or issuer—

“(i) may not deny the individual participation in the clinical trial referred to in paragraph (2)(B);

“(ii) subject to paragraphs (2), (3), and (4), may not deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and services furnished in connection with participation in the trial; and

“(iii) may not discriminate against the individual on the basis of the participation of the participant or beneficiary in such trial.

“(B) EXCLUSION OF CERTAIN COSTS.—For purposes of subparagraph (A)(ii), routine patient costs do not include the cost of the tests or measurements conducted primarily for the purpose of the clinical trial involved.

“(C) USE OF IN-NETWORK PROVIDERS.—If one or more participating providers is participating in a clinical trial, nothing in subparagraph (A) shall be construed as preventing a plan from requiring that a qualified individual participate in the trial through such a participating provider if the provider will accept the individual as a participant in the trial.

“(2) QUALIFIED INDIVIDUAL DEFINED.—For purposes of paragraph (1), the term ‘qualified individual’ means an individual who is a participant or beneficiary in a group health plan and who meets the following conditions:

“(A)(i) The individual has been diagnosed with cancer.

“(ii) The individual is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of cancer.

“(iii) The individual’s participation in the trial offers meaningful potential for significant clinical benefit for the individual.

“(B) Either—

“(i) the referring physician is a participating health care professional and has concluded that the individual’s participation in such trial would be appropriate based upon satisfaction by the individual of the conditions described in subparagraph (A); or

“(ii) the individual provides medical and scientific information establishing that the individual’s participation in such trial would be appropriate based upon the satisfaction by the individual of the conditions described in subparagraph (A).

“(3) PAYMENT.—

“(A) IN GENERAL.—A group health plan (or a health insurance issuer offering health insurance coverage) shall provide for payment for routine patient costs described in paragraph (1)(B) but is not required to pay for costs of items and services that are reasonably expected to be paid for by the sponsors of an approved clinical trial.

“(B) ROUTINE PATIENT CARE COSTS.—

“(i) IN GENERAL.—For purposes of this paragraph, the term ‘routine patient care costs’ shall include the costs associated with the provision of items and services that—

“(I) would otherwise be covered under the group health plan if such items and services were not provided in connection with an approved clinical trial program; and

“(II) are furnished according to the protocol of an approved clinical trial program.

“(ii) EXCLUSION.—For purposes of this paragraph, ‘routine patient care costs’ shall not include the costs associated with the provision of—

“(I) an investigational drug or device, unless the Secretary has authorized the manufacturer of such drug or device to charge for such drug or device; or

“(II) any item or service supplied without charge by the sponsor of the approved clinical trial program.

“(C) PAYMENT RATE.—For purposes of this subsection—

“(i) PARTICIPATING PROVIDERS.—In the case of covered items and services provided by a participating provider, the payment rate shall be at the agreed upon rate.

“(ii) NONPARTICIPATING PROVIDERS.—In the case of covered items and services provided by a nonparticipating provider, the payment rate shall be at the rate

the plan would normally pay for comparable items or services under clause (i).

“(4) APPROVED CLINICAL TRIAL DEFINED.—

“(A) IN GENERAL.—For purposes of this subsection, the term ‘approved clinical trial’ means a cancer clinical research study or cancer clinical investigation approved by an Institutional Review Board.

“(B) CONDITIONS FOR DEPARTMENTS.—The conditions described in this paragraph, for a study or investigation conducted by a Department, are that the study or investigation has been reviewed and approved through a system of peer review that the Secretary determines—

“(i) to be comparable to the system of peer review of studies and investigations used by the National Institutes of Health, and

“(ii) assures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review.

“(5) CONSTRUCTION.—Nothing in this subsection shall be construed to limit a plan’s coverage with respect to clinical trials.

“(6) PLAN SATISFACTION OF CERTAIN REQUIREMENTS; RESPONSIBILITIES OF FIDUCIARIES.—

“(A) IN GENERAL.—For purposes of this subsection, insofar as a group health plan provides benefits in the form of health insurance coverage through a health insurance issuer, the plan shall be treated as meeting the requirements of this subsection with respect to such benefits and not be considered as failing to meet such requirements because of a failure of the issuer to meet such requirements so long as the plan sponsor or its representatives did not cause such failure by the issuer.

“(B) CONSTRUCTION.—Nothing in this subsection shall be construed to affect or modify the responsibilities of the fiduciaries of a group health plan under part 4 of subtitle B of title I of the Employee Retirement Income Security Act of 1974.

“(7) STUDY AND REPORT.—

“(A) STUDY.—The Secretary shall analyze cancer clinical research and its cost implications for managed care, including differentiation in—

“(i) the cost of patient care in trials versus standard care;

“(ii) the cost effectiveness achieved in different sites of service;

“(iii) research outcomes;

“(iv) volume of research subjects available in different sites of service;

“(v) access to research sites and clinical trials by cancer patients;

“(vi) patient cost sharing or copayment costs realized in different sites of service;

“(vii) health outcomes experienced in different sites of service;

“(viii) long term health care services and costs experienced in different sites of service;

“(ix) morbidity and mortality experienced in different sites of service; and

“(x) patient satisfaction and preference of sites of service.

“(B) REPORT TO CONGRESS.—Not later than January 1, 2005, the Secretary shall submit a report to Congress that contains—

“(i) an assessment of any incremental cost to group health plans resulting from the provisions of this section;

“(ii) a projection of expenditures to such plans resulting from this section;

“(iii) an assessment of any impact on premiums resulting from this section; and

“(iv) recommendations regarding action on other diseases.”.

**SEC. 202. REQUIRING HEALTH MAINTENANCE ORGANIZATIONS TO OFFER OPTION OF POINT-OF-SERVICE COVERAGE.**

Title XXVII of the Public Health Service Act is amended by inserting after section 2713 the following new section:

**“SEC. 2714. REQUIRING OFFERING OF OPTION OF POINT-OF-SERVICE COVERAGE.**

“(a) REQUIREMENT TO OFFER COVERAGE OPTION TO CERTAIN EMPLOYERS.—Except as provided in subsection (c), any health insurance issuer which—

“(1) is a health maintenance organization (as defined in section 2791(b)(3)); and

“(2) which provides for coverage of services of one or more classes of health care professionals under health insurance coverage offered in connection with a group health plan only if such services are furnished exclusively through health care professionals within such class or classes who are members of a closed panel of health care professionals,

the issuer shall make available to the plan sponsor in connection with such a plan a coverage option which provides for coverage of such services which are furnished through such class (or classes) of health care professionals regardless of whether or not the professionals are members of such panel.

“(b) REQUIREMENT TO OFFER SUPPLEMENTAL COVERAGE TO PARTICIPANTS IN CERTAIN CASES.—Except as provided in subsection (c), if a health insurance issuer makes available a coverage option under and described in subsection (a) to a plan sponsor of a group health plan and the sponsor declines to contract for such coverage option, then the issuer shall make available in the individual insurance market to each participant in the group health plan optional separate supplemental health insurance coverage in the individual health insurance market which consists of services identical to those provided under such coverage provided through the closed panel under the group health plan but are furnished exclusively by health care professionals who are not members of such a closed panel.

“(c) EXCEPTIONS.—

“(1) OFFERING OF NON-PANEL OPTION.—Subsections (a) and (b) shall not apply with respect to a group health plan if the plan offers a coverage option that provides coverage for services that may be furnished by a class or classes of health care professionals who are not in a closed panel. This paragraph shall be applied separately to distinguishable groups of employees under the plan.

“(2) AVAILABILITY OF COVERAGE THROUGH HEALTHMART.—Subsections (a) and (b) shall not apply to a group health plan if the health insurance coverage under the plan is made available through a HealthMart (as defined in section 2801) and if any health insurance coverage made available through the HealthMart provides for coverage of the services of any class of health care professionals other than through a closed panel of professionals.

“(3) RELICENSURE EXEMPTION.—Subsections (a) and (b) shall not apply to a health maintenance organization in a State in any case in which—

“(A) the organization demonstrates to the applicable authority that the organization has made a good faith effort to obtain (but has failed to obtain) a contract between the organization and any other health insurance issuer providing for the coverage option or supplemental coverage described in subsection (a) or (b), as the case may be, within the applicable service area of the organization; and

“(B) the State requires the organization to receive or qualify for a separate license, as an indemnity insurer or otherwise, in order to offer such coverage option or supplemental coverage, respectively.

The applicable authority may require that the organization demonstrate that it meets the requirements of the previous sentence no more frequently than once every 2 years.

“(4) COLLECTIVE BARGAINING AGREEMENTS.—Subsections (a) and (b) shall not apply in connection with a group health plan if the plan is established or maintained pursuant to one or more collective bargaining agreements.

“(5) SMALL ISSUERS.—Subsections (a) and (b) shall not apply in the case of a health insurance issuer with 25,000 or fewer covered lives.

“(d) APPLICABILITY.—The requirements of this section shall apply only in connection with included group health plan benefits.

“(e) DEFINITIONS.—For purposes of this section:

“(1) COVERAGE THROUGH CLOSED PANEL.—Health insurance coverage for a class of health care professionals shall be treated as provided through a closed panel of such professionals only if such coverage consists of coverage of items or services consisting of professionals services which are reimbursed for or provided only within a limited network of such professionals.

“(2) HEALTH CARE PROFESSIONAL.—The term ‘health care professional’ has the meaning given such term in section 2707(a)(2).

“(3) INCLUDED GROUP HEALTH PLAN BENEFIT.—The term ‘included group health plan benefit’ means a benefit which is not an excepted benefit (as defined in section 2791(c)).”

**SEC. 203. EFFECTIVE DATE AND RELATED RULES.**

(a) **IN GENERAL.**—The amendments made by this title shall apply with respect to plan years beginning on or after January 1 of the second calendar year following the date of the enactment of this Act, except that the Secretary of Health and Human Services may issue regulations before such date under such amendments. The Secretary shall first issue regulations necessary to carry out the amendments made by this title before the effective date thereof.

(b) **LIMITATION ON ENFORCEMENT ACTIONS.**—No enforcement action shall be taken, pursuant to the amendments made by this title, against a group health plan or health insurance issuer with respect to a violation of a requirement imposed by such amendments before the date of issuance of regulations issued in connection with such requirement, if the plan or issuer has sought to comply in good faith with such requirement.

(c) **SPECIAL RULE FOR COLLECTIVE BARGAINING AGREEMENTS.**—In the case of a group health plan maintained pursuant to one or more collective bargaining agreements between employee representatives and one or more employers ratified before the date of the enactment of this Act, the amendments made by this title shall not apply with respect to plan years beginning before the later of—

(1) the date on which the last of the collective bargaining agreements relating to the plan terminates (determined without regard to any extension thereof agreed to after the date of the enactment of this Act); or

(2) January 1, 2002.

For purposes of this subsection, any plan amendment made pursuant to a collective bargaining agreement relating to the plan which amends the plan solely to conform to any requirement added by this title shall not be treated as a termination of such collective bargaining agreement.

## **Subtitle B—Patient Access to Information**

### **SEC. 111. PATIENT ACCESS TO INFORMATION REGARDING PLAN COVERAGE, MANAGED CARE PROCEDURES, HEALTH CARE PROVIDERS, AND QUALITY OF MEDICAL CARE.**

(a) **IN GENERAL.**—Subpart 2 of part A of title XXVII of the Public Health Service Act (as amended by subtitle A) is amended further by adding at the end the following new section:

#### **“SEC. 2708. DISCLOSURE BY GROUP HEALTH PLANS.**

“(a) **DISCLOSURE REQUIREMENT.**—Each health insurance issuer offering health insurance coverage in connection with a group health plan shall provide the plan administrator on a timely basis with the information necessary to enable the administrator to provide participants and beneficiaries with information in a manner and to an extent consistent with the requirements of section 111 of the Employee Retirement Income Security Act of 1974. To the extent that any such issuer provides such information on a timely basis to plan participants and beneficiaries, the requirements of this subsection shall be deemed satisfied in the case of such plan with respect to such information.

“(b) PLAN BENEFITS.—The information required under subsection (a) includes the following:

“(1) COVERED ITEMS AND SERVICES.—

“(A) CATEGORIZATION OF INCLUDED BENEFITS.—A description of covered benefits, categorized by—

“(i) types of items and services (including any special disease management program); and

“(ii) types of health care professionals providing such items and services.

“(B) EMERGENCY MEDICAL CARE.—A description of the extent to which the plan covers emergency medical care (including the extent to which the plan provides for access to urgent care centers), and any definitions provided under the plan for the relevant plan terminology referring to such care.

“(C) PREVENTATIVE SERVICES.—A description of the extent to which the plan provides benefits for preventative services.

“(D) DRUG FORMULARIES.—A description of the extent to which covered benefits are determined by the use or application of a drug formulary and a summary of the process for determining what is included in such formulary.

“(E) COBRA CONTINUATION COVERAGE.—A description of the benefits available under the plan pursuant to part 6.

“(2) LIMITATIONS, EXCLUSIONS, AND RESTRICTIONS ON COVERED BENEFITS.—

“(A) CATEGORIZATION OF EXCLUDED BENEFITS.—A description of benefits specifically excluded from coverage, categorized by types of items and services.

“(B) UTILIZATION REVIEW AND PREAUTHORIZATION REQUIREMENTS.—Whether coverage for medical care is limited or excluded on the basis of utilization review or preauthorization requirements.

“(C) LIFETIME, ANNUAL, OR OTHER PERIOD LIMITATIONS.—A description of the circumstances under which, and the extent to which, coverage is subject to lifetime, annual, or other period limitations, categorized by types of benefits.

“(D) CUSTODIAL CARE.—A description of the circumstances under which, and the extent to which, the coverage of benefits for custodial care is limited or excluded, and a statement of the definition used by the plan for custodial care.

“(E) EXPERIMENTAL TREATMENTS.—Whether coverage for any medical care is limited or excluded because it constitutes an investigational item or experimental treatment or technology, and any definitions provided under the plan for the relevant plan terminology referring to such limited or excluded care.

“(F) MEDICAL APPROPRIATENESS OR NECESSITY.—Whether coverage for medical care may be limited or excluded by reason of a failure to meet the plan’s requirements for medical appropriateness or necessity, and any definitions provided under the plan for the relevant plan terminology referring to such limited or excluded care.

“(G) SECOND OR SUBSEQUENT OPINIONS.—A description of the circumstances under which, and the extent to which, coverage for second or subsequent opinions is limited or excluded.

“(H) SPECIALTY CARE.—A description of the circumstances under which, and the extent to which, coverage of benefits for specialty care is conditioned on referral from a primary care provider.

“(I) CONTINUITY OF CARE.—A description of the circumstances under which, and the extent to which, coverage of items and services provided by any health care professional is limited or excluded by reason of the departure by the professional from any defined set of providers.

“(J) RESTRICTIONS ON COVERAGE OF EMERGENCY SERVICES.—A description of the circumstances under which, and the extent to which, the plan, in covering emergency medical care furnished to a participant or beneficiary of the plan imposes any financial responsibility described in subsection (c) on participants or beneficiaries or limits or conditions benefits for such care subject to any other term or condition of such plan.

“(3) NETWORK CHARACTERISTICS.—If the plan (or issuer) utilizes a defined set of providers under contract with the plan (or issuer), a detailed list of the names of such providers and their geographic location, set forth separately with respect to primary care providers and with respect to specialists.

“(c) PARTICIPANT’S FINANCIAL RESPONSIBILITIES.—The information required under subsection (a) includes an explanation of—

“(1) a participant’s financial responsibility for payment of premiums, coinsurance, copayments, deductibles, and any other charges; and

“(2) the circumstances under which, and the extent to which, the participant’s financial responsibility described in paragraph (1) may vary, including any distinctions based on whether a health care provider from whom covered benefits are obtained is included in a defined set of providers.

“(d) DISPUTE RESOLUTION PROCEDURES.—The information required under subsection (a) includes a description of the processes adopted by the plan of the type described in section 503 of the Employee Retirement Income Security Act of 1974, including—

“(1) descriptions thereof relating specifically to—

“(A) coverage decisions;

“(B) internal review of coverage decisions; and

“(C) any external review of coverage decisions; and

“(2) the procedures and time frames applicable to each step of the processes referred to in subparagraphs (A), (B), and (C) of paragraph (1).

“(e) INFORMATION ON PLAN PERFORMANCE.—Any information required under subsection (a) shall include information concerning the number of external reviews of the type described in section 503 of the Employee Retirement Income Security Act of 1974 that have been completed during the prior plan year and the number of such reviews in which a recommendation is made for modification or reversal of an internal review decision under the plan.

“(f) INFORMATION INCLUDED WITH ADVERSE COVERAGE DECISIONS.—A health insurance issuer offering health insurance coverage in connection with a group health plan shall provide to each participant and beneficiary, together with any notification of the participant or beneficiary of an adverse coverage decision, the following information:

“(1) PREAUTHORIZATION AND UTILIZATION REVIEW PROCEDURES.—A description of the basis on which any preauthorization requirement or any utilization review requirement has resulted in the adverse coverage decision.

“(2) PROCEDURES FOR DETERMINING EXCLUSIONS BASED ON MEDICAL NECESSITY OR ON INVESTIGATIONAL ITEMS OR EXPERIMENTAL TREATMENTS.—If the adverse coverage decision is based on a determination relating to medical necessity or to an investigational item or an experimental treatment or technology, a description of the procedures and medically-based criteria used in such decision.

“(g) INFORMATION AVAILABLE ON REQUEST.—

“(1) ACCESS TO PLAN BENEFIT INFORMATION IN ELECTRONIC FORM.—

“(A) IN GENERAL.—A health insurance issuer offering health insurance coverage in connection with a group health plan may, upon written request (made not more frequently than annually), make available to participants and beneficiaries, in a generally recognized electronic format—

“(i) the latest summary plan description, including the latest summary of material modifications, and

“(ii) the actual plan provisions setting forth the benefits available under the plan,

to the extent such information relates to the coverage options under the plan available to the participant or beneficiary. A reasonable charge may be made to cover the cost of providing such information in such generally recognized electronic format. The Secretary may by regulation prescribe a maximum amount which will constitute a reasonable charge under the preceding sentence.

“(B) ALTERNATIVE ACCESS.—The requirements of this paragraph may be met by making such information generally available (rather than upon request) on the Internet or on a proprietary computer network in a format which is readily accessible to participants and beneficiaries.

“(2) ADDITIONAL INFORMATION TO BE PROVIDED ON REQUEST.—

“(A) INCLUSION IN SUMMARY PLAN DESCRIPTION OF SUMMARY OF ADDITIONAL INFORMATION.—The information required under subsection (a) includes a summary description of the types of information required by this subsection to be made available to participants and beneficiaries on request.

“(B) INFORMATION REQUIRED FROM PLANS AND ISSUERS ON REQUEST.—In addition to information otherwise required to be provided under this subsection, a health insurance issuer offering health insurance coverage in connection with a group health plan shall provide the fol-

lowing information to a participant or beneficiary on request:

“(i) CARE MANAGEMENT INFORMATION.—A description of the circumstances under which, and the extent to which, the plan has special disease management programs or programs for persons with disabilities, indicating whether these programs are voluntary or mandatory and whether a significant benefit differential results from participation in such programs.

“(ii) INCLUSION OF DRUGS AND BIOLOGICALS IN FORMULARIES.—A statement of whether a specific drug or biological is included in a formulary used to determine benefits under the plan and a description of the procedures for considering requests for any patient-specific waivers.

“(iii) ACCREDITATION STATUS OF HEALTH INSURANCE ISSUERS AND SERVICE PROVIDERS.—A description of the accreditation and licensing status (if any) of each health insurance issuer offering health insurance coverage in connection with the plan and of any utilization review organization utilized by the issuer or the plan, together with the name and address of the accrediting or licensing authority.

“(iv) QUALITY PERFORMANCE MEASURES.—The latest information (if any) maintained by the health insurance issuer relating to quality of performance of the delivery of medical care with respect to coverage options offered under the plan and of health care professionals and facilities providing medical care under the plan.

“(C) INFORMATION REQUIRED FROM HEALTH CARE PROFESSIONALS.—

“(i) QUALIFICATIONS, PRIVILEGES, AND METHOD OF COMPENSATION.—Any health care professional treating a participant or beneficiary under a group health plan shall provide to the participant or beneficiary, on request, a description of his or her professional qualifications (including board certification status, licensing status, and accreditation status, if any), privileges, and experience and a general description by category (including salary, fee-for-service, capitation, and such other categories as may be specified in regulations of the Secretary) of the applicable method by which such professional is compensated in connection with the provision of such medical care.

“(ii) COST OF PROCEDURES.—Any health care professional who recommends an elective procedure or treatment while treating a participant or beneficiary under a group health plan that requires a participant or beneficiary to share in the cost of treatment shall inform such participant or beneficiary of each cost associated with the procedure or treatment and an estimate of the magnitude of such costs.

“(D) INFORMATION REQUIRED FROM HEALTH CARE FACILITIES ON REQUEST.—Any health care facility from which a participant or beneficiary has sought treatment under a group health plan shall provide to the participant or beneficiary, on request, a description of the facility’s corporate form or other organizational form and all forms of licensing and accreditation status (if any) assigned to the facility by standard-setting organizations.

“(h) ACCESS TO INFORMATION RELEVANT TO THE COVERAGE OPTIONS UNDER WHICH THE PARTICIPANT OR BENEFICIARY IS ELIGIBLE TO ENROLL.—In addition to information otherwise required to be made available under this section, a health insurance issuer offering health insurance coverage in connection with a group health plan shall, upon written request (made not more frequently than annually), make available to a participant (and an employee who, under the terms of the plan, is eligible for coverage but not enrolled) in connection with a period of enrollment the summary plan description for any coverage option under the plan under which the participant is eligible to enroll and any information described in clauses (i), (ii), (iii), (vi), (vii), and (viii) of subsection (e)(2)(B).

“(i) ADVANCE NOTICE OF CHANGES IN DRUG FORMULARIES.—Not later than 30 days before the effective date of any exclusion of a specific drug or biological from any drug formulary under health insurance coverage offered by a health insurance issuer in connection with a group health plan that is used in the treatment of a chronic illness or disease, the issuer shall take such actions as are necessary to reasonably ensure that plan participants are informed of such exclusion. The requirements of this subsection may be satisfied—

“(1) by inclusion of information in publications broadly distributed by plan sponsors, employers, or employee organizations;

“(2) by electronic means of communication (including the Internet or proprietary computer networks in a format which is readily accessible to participants);

“(3) by timely informing participants who, under an ongoing program maintained under the plan, have submitted their names for such notification; or

“(4) by any other reasonable means of timely informing plan participants.

“(j) DEFINITIONS AND RELATED RULES.—

“(1) IN GENERAL.—For purposes of this section—

“(A) GROUP HEALTH PLAN.—The term ‘group health plan’ has the meaning provided such term under section 733(a)(1).

“(B) MEDICAL CARE.—The term ‘medical care’ has the meaning provided such term under section 733(a)(2).

“(C) HEALTH INSURANCE COVERAGE.—The term ‘health insurance coverage’ has the meaning provided such term under section 733(b)(1).

“(D) HEALTH INSURANCE ISSUER.—The term ‘health insurance issuer’ has the meaning provided such term under section 733(b)(2).

“(2) APPLICABILITY ONLY IN CONNECTION WITH INCLUDED GROUP HEALTH PLAN BENEFITS.—

“(A) IN GENERAL.—The requirements of this section shall apply only in connection with included group health plan benefits.

“(B) INCLUDED GROUP HEALTH PLAN BENEFIT.—For purposes of subparagraph (A), the term ‘included group health plan benefit’ means a benefit which is not an excepted benefit (as defined in section 2791(c)).”.

**SEC. 212. EFFECTIVE DATE AND RELATED RULES.**

(a) IN GENERAL.—The amendments made by section 211 shall apply with respect to plan years beginning on or after January 1 of the second calendar year following the date of the enactment of this Act. The Secretary of Labor shall first issue all regulations necessary to carry out the amendments made by this title before such date.

(b) LIMITATION ON ENFORCEMENT ACTIONS.—No enforcement action shall be taken, pursuant to the amendments made by this title, against a health insurance issuer with respect to a violation of a requirement imposed by such amendments before the date of issuance of final regulations issued in connection with such requirement, if the issuer has sought to comply in good faith with such requirement.

### **TITLE III—AMENDMENTS TO THE INTERNAL REVENUE CODE OF 1986**

**SEC. 301. PATIENT ACCESS TO UNRESTRICTED MEDICAL ADVICE, EMERGENCY MEDICAL CARE, OBSTETRIC AND GYNECOLOGICAL CARE, PEDIATRIC CARE, AND CONTINUITY OF CARE.**

Subchapter B of chapter 100 of the Internal Revenue Code of 1986 is amended—

(1) in the table of sections, by inserting after the item relating to section 9812 the following new item:

“Sec. 9813. Patient access to unrestricted medical advice, emergency medical care, obstetric and gynecological care, pediatric care, and continuity of care.”; and

(2) by inserting after section 9812 the following:

**“SEC. 9813. PATIENT ACCESS TO UNRESTRICTED MEDICAL ADVICE, EMERGENCY MEDICAL CARE, OBSTETRIC AND GYNECOLOGICAL CARE, PEDIATRIC CARE, AND CONTINUITY OF CARE.**

“(a) PATIENT ACCESS TO UNRESTRICTED MEDICAL ADVICE.—

“(1) IN GENERAL.—In the case of any health care professional acting within the lawful scope of practice in the course of carrying out a contractual employment arrangement or other direct contractual arrangement between such professional and a group health plan, the plan with which such contractual employment arrangement or other direct contractual arrangement is maintained by the professional may not impose on such professional under such arrangement any prohibition or restriction with respect to advice, provided to a participant or bene-

ficiary under the plan who is a patient, about the health status of the participant or beneficiary or the medical care or treatment for the condition or disease of the participant or beneficiary, regardless of whether benefits for such care or treatment are provided under the plan.

“(2) HEALTH CARE PROFESSIONAL DEFINED.—For purposes of this paragraph, the term ‘health care professional’ means a physician (as defined in section 1861(r) of the Social Security Act) or other health care professional if coverage for the professional’s services is provided under the group health plan for the services of the professional. Such term includes a podiatrist, optometrist, chiropractor, psychologist, dentist, physician assistant, physical or occupational therapist and therapy assistant, speech-language pathologist, audiologist, registered or licensed practical nurse (including nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, and certified nurse-midwife), licensed certified social worker, registered respiratory therapist, and certified respiratory therapy technician.

“(3) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to require the sponsor of a group health plan to engage in any practice that would violate its religious beliefs or moral convictions.

“(b) PATIENT ACCESS TO EMERGENCY MEDICAL CARE.—

“(1) COVERAGE OF EMERGENCY SERVICES.—

“(A) IN GENERAL.—If a group health plan provides any benefits with respect to emergency services (as defined in subparagraph (B)(ii)), or ambulance services, the plan shall cover emergency services (including emergency ambulance services as defined in subparagraph (B)(iii)) furnished under the plan—

“(i) without the need for any prior authorization determination;

“(ii) whether or not the health care provider furnishing such services is a participating provider with respect to such services;

“(iii) in a manner so that, if such services are provided to a participant or beneficiary by a nonparticipating health care provider, the participant or beneficiary is not liable for amounts that exceed the amounts of liability that would be incurred if the services were provided by a participating provider; and

“(iv) without regard to any other term or condition of such plan (other than exclusion or coordination of benefits, or an affiliation or waiting period, permitted under section 701 and other than applicable cost sharing).

“(B) DEFINITIONS.—In this subsection:

“(i) EMERGENCY MEDICAL CONDITION.—The term ‘emergency medical condition’ means—

“(I) a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and

medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act (42 U.S.C. 1395dd(e)(1)(A)); and

“(II) a medical condition manifesting itself in a neonate by acute symptoms of sufficient severity (including severe pain) such that a prudent health care professional could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act.

“(ii) EMERGENCY SERVICES.—The term ‘emergency services’ means—

“(I) with respect to an emergency medical condition described in clause (i)(I), a medical screening examination (as required under section 1867 of the Social Security Act, 42 U.S.C. 1395dd) that is within the capability of the emergency department of a hospital, including ancillary services routinely available to the emergency department to evaluate an emergency medical condition (as defined in clause (i)) and also, within the capabilities of the staff and facilities at the hospital, such further medical examination and treatment as are required under section 1867 of such Act to stabilize the patient; or

“(II) with respect to an emergency medical condition described in clause (i)(II), medical treatment for such condition rendered by a health care provider in a hospital to a neonate, including available hospital ancillary services in response to an urgent request of a health care professional and to the extent necessary to stabilize the neonate.

“(iii) EMERGENCY AMBULANCE SERVICES.—The term ‘emergency ambulance services’ means ambulance services (as defined for purposes of section 1861(s)(7) of the Social Security Act) furnished to transport an individual who has an emergency medical condition (as defined in clause (i)) to a hospital for the receipt of emergency services (as defined in clause (ii)) in a case in which appropriate emergency medical screening examinations are covered under the plan pursuant to paragraph (1)(A) and a prudent layperson, with an average knowledge of health and medicine, could reasonably expect that the absence of such transport would result in placing the health of the individual in serious jeopardy, serious impairment of bodily function, or serious dysfunction of any bodily organ or part.

“(iv) STABILIZE.—The term ‘to stabilize’ means, with respect to an emergency medical condition, to provide such medical treatment of the condition as may be

necessary to assure, within reasonable medical probability, that no material deterioration of the condition is likely to result from or occur during the transfer of the individual from a facility.

“(v) NONPARTICIPATING.—The term ‘nonparticipating’ means, with respect to a health care provider that provides health care items and services to a participant or beneficiary under group health plan, a health care provider that is not a participating health care provider with respect to such items and services.

“(vi) PARTICIPATING.—The term ‘participating’ means, with respect to a health care provider that provides health care items and services to a participant or beneficiary under group health plan, a health care provider that furnishes such items and services under a contract or other arrangement with the plan.

“(c) PATIENT RIGHT TO OBSTETRIC AND GYNECOLOGICAL CARE.—

“(1) IN GENERAL.—In any case in which a group health plan—

“(A) provides benefits under the terms of the plan consisting of—

“(i) gynecological care (such as preventive women’s health examinations); or

“(ii) obstetric care (such as pregnancy-related services),

provided by a participating health care professional who specializes in such care (or provides benefits consisting of payment for such care); and

“(B) requires or provides for designation by a participant or beneficiary of a participating primary care provider, if the primary care provider designated by such a participant or beneficiary is not such a health care professional, then the plan shall meet the requirements of paragraph (2).

“(2) REQUIREMENTS.—A group health plan meets the requirements of this paragraph, in connection with benefits described in paragraph (1) consisting of care described in clause (i) or (ii) of paragraph (1)(A) (or consisting of payment therefor), if the plan—

“(A) does not require authorization or a referral by the primary care provider in order to obtain such benefits; and

“(B) treats the ordering of other care of the same type, by the participating health care professional providing the care described in clause (i) or (ii) of paragraph (1)(A), as the authorization of the primary care provider with respect to such care.

“(3) HEALTH CARE PROFESSIONAL DEFINED.—For purposes of this subsection, the term ‘health care professional’ means an individual (including, but not limited to, a nurse midwife or nurse practitioner) who is licensed, accredited, or certified under State law to provide obstetric and gynecological health care services and who is operating within the scope of such licensure, accreditation, or certification.

“(4) CONSTRUCTION.—Nothing in paragraph (1) shall be construed as preventing a plan from offering (but not requiring a

participant or beneficiary to accept) a health care professional trained, credentialed, and operating within the scope of their licensure to perform obstetric and gynecological health care services. Nothing in paragraph (2)(B) shall waive any requirements of coverage relating to medical necessity or appropriateness with respect to coverage of gynecological or obstetric care so ordered.

“(5) TREATMENT OF MULTIPLE COVERAGE OPTIONS.—In the case of a plan providing benefits under two or more coverage options, the requirements of this subsection shall apply separately with respect to each coverage option.

“(d) PATIENT RIGHT TO PEDIATRIC CARE.—

“(1) IN GENERAL.—In any case in which a group health plan provides benefits consisting of routine pediatric care provided by a participating health care professional who specializes in pediatrics (or consisting of payment for such care) and the plan requires or provides for designation by a participant or beneficiary of a participating primary care provider, the plan shall provide that such a participating health care professional may be designated, if available, by a parent or guardian of any beneficiary under the plan is who under 18 years of age, as the primary care provider with respect to any such benefits.

“(2) HEALTH CARE PROFESSIONAL DEFINED.—For purposes of this subsection, the term ‘health care professional’ means an individual (including, but not limited to, a nurse practitioner) who is licensed, accredited, or certified under State law to provide pediatric health care services and who is operating within the scope of such licensure, accreditation, or certification.

“(3) CONSTRUCTION.—Nothing in paragraph (1) shall be construed as preventing a plan from offering (but not requiring a participant or beneficiary to accept) a health care professional trained, credentialed, and operating within the scope of their licensure to perform pediatric health care services. Nothing in paragraph (1) shall waive any requirements of coverage relating to medical necessity or appropriateness with respect to coverage of pediatric care so ordered.

“(4) TREATMENT OF MULTIPLE COVERAGE OPTIONS.—In the case of a plan providing benefits under two or more coverage options, the requirements of this subsection shall apply separately with respect to each coverage option.

“(e) CONTINUITY OF CARE.—

“(1) IN GENERAL.—

“(A) TERMINATION OF PROVIDER.—If a contract between a group health plan and a health care provider is terminated (as defined in subparagraph (D)(ii)), or benefits provided by a health care provider are terminated because of a change in the terms of provider participation in a group health plan, and an individual who, at the time of such termination, is a participant or beneficiary in the plan and is scheduled to undergo surgery (including an organ transplantation), is undergoing treatment for pregnancy, or is determined to be terminally ill (as defined in section 1861(dd)(3)(A) of the Social Security Act) and is undergoing treatment for the terminal illness, the plan shall—

“(i) notify the individual on a timely basis of such termination and of the right to elect continuation of coverage of treatment by the provider under this subsection; and

“(ii) subject to paragraph (3), permit the individual to elect to continue to be covered with respect to treatment by the provider for such surgery, pregnancy, or illness during a transitional period (provided under paragraph (2)).

“(B) TREATMENT OF TERMINATION OF CONTRACT WITH HEALTH INSURANCE ISSUER.—If a contract for the provision of health insurance coverage between a group health plan and a health insurance issuer is terminated and, as a result of such termination, coverage of services of a health care provider is terminated with respect to an individual, the provisions of subparagraph (A) (and the succeeding provisions of this subsection) shall apply under the plan in the same manner as if there had been a contract between the plan and the provider that had been terminated, but only with respect to benefits that are covered under the plan after the contract termination.

“(C) TERMINATION DEFINED.—For purposes of this subsection, the term ‘terminated’ includes, with respect to a contract, the expiration or nonrenewal of the contract, but does not include a termination of the contract by the plan for failure to meet applicable quality standards or for fraud.

“(2) TRANSITIONAL PERIOD.—

“(A) IN GENERAL.—Except as provided in subparagraphs (B) through (D), the transitional period under this paragraph shall extend up to 90 days (as determined by the treating health care professional) after the date of the notice described in paragraph (1)(A)(i) of the provider’s termination.

“(B) SCHEDULED SURGERY.—If surgery was scheduled for an individual before the date of the announcement of the termination of the provider status under paragraph (1)(A)(i), the transitional period under this paragraph with respect to the surgery or transplantation.

“(C) PREGNANCY.—If—

“(i) a participant or beneficiary was determined to be pregnant at the time of a provider’s termination of participation, and

“(ii) the provider was treating the pregnancy before date of the termination,  
the transitional period under this paragraph with respect to provider’s treatment of the pregnancy shall extend through the provision of post-partum care directly related to the delivery.

“(D) TERMINAL ILLNESS.—If—

“(i) a participant or beneficiary was determined to be terminally ill (as determined under section 1861(dd)(3)(A) of the Social Security Act) at the time of a provider’s termination of participation, and

“(ii) the provider was treating the terminal illness before the date of termination, the transitional period under this paragraph shall extend for the remainder of the individual’s life for care directly related to the treatment of the terminal illness or its medical manifestations.

“(3) PERMISSIBLE TERMS AND CONDITIONS.—A group health plan may condition coverage of continued treatment by a provider under paragraph (1)(A)(i) upon the individual notifying the plan of the election of continued coverage and upon the provider agreeing to the following terms and conditions:

“(A) The provider agrees to accept reimbursement from the plan and individual involved (with respect to cost-sharing) at the rates applicable prior to the start of the transitional period as payment in full (or, in the case described in paragraph (1)(B), at the rates applicable under the replacement plan after the date of the termination of the contract with the health insurance issuer) and not to impose cost-sharing with respect to the individual in an amount that would exceed the cost-sharing that could have been imposed if the contract referred to in paragraph (1)(A) had not been terminated.

“(B) The provider agrees to adhere to the quality assurance standards of the plan responsible for payment under subparagraph (A) and to provide to such plan necessary medical information related to the care provided.

“(C) The provider agrees otherwise to adhere to such plan’s policies and procedures, including procedures regarding referrals and obtaining prior authorization and providing services pursuant to a treatment plan (if any) approved by the plan.

“(D) The provider agrees to provide transitional care to all participants and beneficiaries who are eligible for and elect to have coverage of such care from such provider.

“(E) If the provider initiates the termination, the provider has notified the plan within 30 days prior to the effective date of the termination of—

“(i) whether the provider agrees to permissible terms and conditions (as set forth in this paragraph) required by the plan, and

“(ii) if the provider agrees to the terms and conditions, the specific plan beneficiaries and participants undergoing a course of treatment from the provider who the provider believes, at the time of the notification, would be eligible for transitional care under this subsection.

“(4) CONSTRUCTION.—Nothing in this subsection shall be construed to—

“(A) require the coverage of benefits which would not have been covered if the provider involved remained a participating provider, or

“(B) prohibit a group health plan from conditioning a provider’s participation on the provider’s agreement to provide transitional care to all participants and beneficiaries

eligible to obtain coverage of such care furnished by the provider as set forth under this subsection.

“(f) COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CANCER CLINICAL TRIALS.—

“(1) COVERAGE.—

“(A) IN GENERAL.—If a group health plan provides coverage to a qualified individual (as defined in paragraph (2)), the plan—

“(i) may not deny the individual participation in the clinical trial referred to in paragraph (2)(B);

“(ii) subject to paragraphs (2), (3), and (4), may not deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and services furnished in connection with participation in the trial; and

“(iii) may not discriminate against the individual on the basis of the participation of the participant or beneficiary in such trial.

“(B) EXCLUSION OF CERTAIN COSTS.—For purposes of subparagraph (A)(ii), routine patient costs do not include the cost of the tests or measurements conducted primarily for the purpose of the clinical trial involved.

“(C) USE OF IN-NETWORK PROVIDERS.—If one or more participating providers is participating in a clinical trial, nothing in subparagraph (A) shall be construed as preventing a plan from requiring that a qualified individual participate in the trial through such a participating provider if the provider will accept the individual as a participant in the trial.

“(2) QUALIFIED INDIVIDUAL DEFINED.—For purposes of paragraph (1), the term ‘qualified individual’ means an individual who is a participant or beneficiary in a group health plan and who meets the following conditions:

“(A)(i) The individual has been diagnosed with cancer.

“(ii) The individual is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of cancer.

“(iii) The individual’s participation in the trial offers meaningful potential for significant clinical benefit for the individual.

“(B) Either—

“(i) the referring physician is a participating health care professional and has concluded that the individual’s participation in such trial would be appropriate based upon satisfaction by the individual of the conditions described in subparagraph (A); or

“(ii) the individual provides medical and scientific information establishing that the individual’s participation in such trial would be appropriate based upon the satisfaction by the individual of the conditions described in subparagraph (A).

“(3) PAYMENT.—

“(A) IN GENERAL.—A group health plan shall provide for payment for routine patient costs described in paragraph

(1)(B) but is not required to pay for costs of items and services that are reasonably expected to be paid for by the sponsors of an approved clinical trial.

“(B) ROUTINE PATIENT CARE COSTS.—

“(i) IN GENERAL.—For purposes of this paragraph, the term ‘routine patient care costs’ shall include the costs associated with the provision of items and services that—

“(I) would otherwise be covered under the group health plan if such items and services were not provided in connection with an approved clinical trial program; and

“(II) are furnished according to the protocol of an approved clinical trial program.

“(ii) EXCLUSION.—For purposes of this paragraph, ‘routine patient care costs’ shall not include the costs associated with the provision of—

“(I) an investigational drug or device, unless the Secretary has authorized the manufacturer of such drug or device to charge for such drug or device; or

“(II) any item or service supplied without charge by the sponsor of the approved clinical trial program.

“(C) PAYMENT RATE.—For purposes of this subsection—

“(i) PARTICIPATING PROVIDERS.—In the case of covered items and services provided by a participating provider, the payment rate shall be at the agreed upon rate.

“(ii) NONPARTICIPATING PROVIDERS.—In the case of covered items and services provided by a nonparticipating provider, the payment rate shall be at the rate the plan would normally pay for comparable items or services under clause (i).

“(4) APPROVED CLINICAL TRIAL DEFINED.—

“(A) IN GENERAL.—For purposes of this subsection, the term ‘approved clinical trial’ means a cancer clinical research study or cancer clinical investigation approved by an Institutional Review Board.

“(B) CONDITIONS FOR DEPARTMENTS.—The conditions described in this paragraph, for a study or investigation conducted by a Department, are that the study or investigation has been reviewed and approved through a system of peer review that the Secretary determines—

“(i) to be comparable to the system of peer review of studies and investigations used by the National Institutes of Health, and

“(ii) assures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review.

“(5) CONSTRUCTION.—Nothing in this subsection shall be construed to limit a plan’s coverage with respect to clinical trials.

“(6) PLAN SATISFACTION OF CERTAIN REQUIREMENTS; RESPONSIBILITIES OF FIDUCIARIES.—

“(A) IN GENERAL.—For purposes of this subsection, insofar as a group health plan provides benefits in the form of health insurance coverage through a health insurance issuer, the plan shall be treated as meeting the requirements of this subsection with respect to such benefits and not be considered as failing to meet such requirements because of a failure of the issuer to meet such requirements so long as the plan sponsor or its representatives did not cause such failure by the issuer.

“(B) CONSTRUCTION.—Nothing in this subsection shall be construed to affect or modify the responsibilities of the fiduciaries of a group health plan under part 4 of subtitle B of title I of the Employee Retirement Income Security Act of 1974.

“(7) STUDY AND REPORT.—

“(A) STUDY.—The Secretary shall analyze cancer clinical research and its cost implications for managed care, including differentiation in—

“(i) the cost of patient care in trials versus standard care;

“(ii) the cost effectiveness achieved in different sites of service;

“(iii) research outcomes;

“(iv) volume of research subjects available in different sites of service;

“(v) access to research sites and clinical trials by cancer patients;

“(vi) patient cost sharing or copayment costs realized in different sites of service;

“(vii) health outcomes experienced in different sites of service;

“(viii) long term health care services and costs experienced in different sites of service;

“(ix) morbidity and mortality experienced in different sites of service; and

“(x) patient satisfaction and preference of sites of service.

“(B) REPORT TO CONGRESS.—Not later than January 1, 2005, the Secretary shall submit a report to Congress that contains—

“(i) an assessment of any incremental cost to group health plans resulting from the provisions of this section;

“(ii) a projection of expenditures to such plans resulting from this section;

“(iii) an assessment of any impact on premiums resulting from this section; and

“(iv) recommendations regarding action on other diseases.”.

**SEC. 302. EFFECTIVE DATE AND RELATED RULES.**

(a) IN GENERAL.—The amendments made by this title shall apply with respect to plan years beginning on or after January 1 of the second calendar year following the date of the enactment of this Act, except that the Secretary of the Treasury may issue regula-

tions before such date under such amendments. The Secretary shall first issue regulations necessary to carry out the amendments made by this title before the effective date thereof.

(b) **LIMITATION ON ENFORCEMENT ACTIONS.**—No enforcement action shall be taken, pursuant to the amendments made by this title, against a group health plan with respect to a violation of a requirement imposed by such amendments before the date of issuance of regulations issued in connection with such requirement, if the plan has sought to comply in good faith with such requirement.

(c) **SPECIAL RULE FOR COLLECTIVE BARGAINING AGREEMENTS.**—In the case of a group health plan maintained pursuant to one or more collective bargaining agreements between employee representatives and one or more employers ratified before the date of the enactment of this Act, the amendments made by this title shall not apply with respect to plan years beginning before the later of—

(1) the date on which the last of the collective bargaining agreements relating to the plan terminates (determined without regard to any extension thereof agreed to after the date of the enactment of this Act); or

(2) January 1, 2002.

For purposes of this subsection, any plan amendment made pursuant to a collective bargaining agreement relating to the plan which amends the plan solely to conform to any requirement added by this title shall not be treated as a termination of such collective bargaining agreement.

## **TITLE IV—HEALTH CARE LAWSUIT REFORM**

### **Subtitle A—General Provisions**

#### **SEC. 401. FEDERAL REFORM OF HEALTH CARE LIABILITY ACTIONS.**

(a) **APPLICABILITY.**—This title shall apply with respect to any health care liability action brought in any State or Federal court, except that this title shall not apply to—

(1) an action for damages arising from a vaccine-related injury or death to the extent that title XXI of the Public Health Service Act applies to the action;

(2) an action under the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1001 et seq.); or

(3) an action in connection with benefits which are not included group health plan benefits (as defined in section 402(14)).

(b) **PREEMPTION.**—This title shall preempt any State law to the extent such law is inconsistent with the limitations contained in this title. This title shall not preempt any State law that provides for defenses or places limitations on a person's liability in addition to those contained in this title or otherwise imposes greater restrictions than those provided in this title.

(c) **EFFECT ON SOVEREIGN IMMUNITY AND CHOICE OF LAW OR VENUE.**—Nothing in subsection (b) shall be construed to—

(1) waive or affect any defense of sovereign immunity asserted by any State under any provision of law;

(2) waive or affect any defense of sovereign immunity asserted by the United States;

(3) affect the applicability of any provision of the Foreign Sovereign Immunities Act of 1976;

(4) preempt State choice-of-law rules with respect to claims brought by a foreign nation or a citizen of a foreign nation; or

(5) affect the right of any court to transfer venue or to apply the law of a foreign nation or to dismiss a claim of a foreign nation or of a citizen of a foreign nation on the ground of inconvenient forum.

(d) AMOUNT IN CONTROVERSY.—In an action to which this title applies and which is brought under section 1332 of title 28, United States Code, the amount of non-economic damages or punitive damages, and attorneys' fees or costs, shall not be included in determining whether the matter in controversy exceeds the sum or value of \$50,000.

(e) FEDERAL COURT JURISDICTION NOT ESTABLISHED ON FEDERAL QUESTION GROUNDS.—Nothing in this title shall be construed to establish any jurisdiction in the district courts of the United States over health care liability actions on the basis of section 1331 or 1337 of title 28, United States Code.

#### SEC. 402. DEFINITIONS.

As used in this title:

(1) ACTUAL DAMAGES.—The term “actual damages” means damages awarded to pay for economic loss.

(2) ALTERNATIVE DISPUTE RESOLUTION SYSTEM; ADR.—The term “alternative dispute resolution system” or “ADR” means a system established under Federal or State law that provides for the resolution of health care liability claims in a manner other than through health care liability actions.

(3) CLAIMANT.—The term “claimant” means any person who brings a health care liability action and any person on whose behalf such an action is brought. If such action is brought through or on behalf of an estate, the term includes the claimant's decedent. If such action is brought through or on behalf of a minor or incompetent, the term includes the claimant's legal guardian.

(4) CLEAR AND CONVINCING EVIDENCE.—The term “clear and convincing evidence” is that measure or degree of proof that will produce in the mind of the trier of fact a firm belief or conviction as to the truth of the allegations sought to be established. Such measure or degree of proof is more than that required under preponderance of the evidence but less than that required for proof beyond a reasonable doubt.

(5) COLLATERAL SOURCE PAYMENTS.—The term “collateral source payments” means any amount paid or reasonably likely to be paid in the future to or on behalf of a claimant, or any service, product, or other benefit provided or reasonably likely to be provided in the future to or on behalf of a claimant, as a result of an injury or wrongful death, pursuant to—

(A) any State or Federal health, sickness, income-disability, accident or workers' compensation Act;

(B) any health, sickness, income-disability, or accident insurance that provides health benefits or income-disability coverage;

(C) any contract or agreement of any group, organization, partnership, or corporation to provide, pay for, or reimburse the cost of medical, hospital, dental, or income disability benefits; and

(D) any other publicly or privately funded program.

(6) DRUG.—The term “drug” has the meaning given such term in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)).

(7) ECONOMIC LOSS.—The term “economic loss” means any pecuniary loss resulting from injury (including the loss of earnings or other benefits related to employment, medical expense loss, replacement services loss, loss due to death, burial costs, and loss of business or employment opportunities), to the extent recovery for such loss is allowed under applicable State law.

(8) HARM.—The term “harm” means any legally cognizable wrong or injury for which punitive damages may be imposed.

(9) HEALTH BENEFIT PLAN.—The term “health benefit plan” means—

(A) a hospital or medical expense incurred policy or certificate;

(B) a hospital or medical service plan contract;

(C) a health maintenance subscriber contract; or

(D) a Medicare+Choice plan (offered under part C of title XVIII of the Social Security Act),

that provides benefits with respect to health care services.

(10) HEALTH CARE LIABILITY ACTION.—The term “health care liability action” means a civil action brought in a State or Federal court against—

(A) a health care provider;

(B) an entity which is obligated to provide or pay for health benefits under any health benefit plan (including any person or entity acting under a contract or arrangement to provide or administer any health benefit); or

(C) the manufacturer, distributor, supplier, marketer, promoter, or seller of a medical product,

in which the claimant alleges a claim (including third party claims, cross claims, counter claims, or contribution claims) based upon the provision of (or the failure to provide or pay for) health care services or the use of a medical product, regardless of the theory of liability on which the claim is based or the number of plaintiffs, defendants, or causes of action.

(11) HEALTH CARE LIABILITY CLAIM.—The term “health care liability claim” means a claim in which the claimant alleges that injury was caused by the provision of (or the failure to provide) health care services.

(12) HEALTH CARE PROVIDER.—The term “health care provider” means any person that is engaged in the delivery of health care services in a State and that is required by the laws or regulations of the State to be licensed or certified by the State to engage in the delivery of such services in the State.

(13) **HEALTH CARE SERVICE.**—The term “health care service” means any service eligible for payment under a health benefit plan, including services related to the delivery or administration of such service.

(14) **INCLUDED GROUP HEALTH PLAN BENEFIT.**—The term ‘included group health plan benefit’ means a benefit under a group health plan which is not an excepted benefit (as defined in section 733(c) of the Employee Retirement Income Security Act of 1974).

(15) **MEDICAL DEVICE.**—The term “medical device” has the meaning given such term in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)).

(16) **NON-ECONOMIC DAMAGES.**—The term “non-economic damages” means damages paid to an individual for pain and suffering, inconvenience, emotional distress, mental anguish, loss of consortium, injury to reputation, humiliation, and other nonpecuniary losses.

(17) **PERSON.**—The term “person” means any individual, corporation, company, association, firm, partnership, society, joint stock company, or any other entity, including any governmental entity.

(18) **PRODUCT SELLER.**—

(A) **IN GENERAL.**—Subject to subparagraph (B), the term “product seller” means a person who, in the course of a business conducted for that purpose—

(i) sells, distributes, rents, leases, prepares, blends, packages, labels, or is otherwise involved in placing, a product in the stream of commerce; or

(ii) installs, repairs, or maintains the harm-causing aspect of a product.

(B) **EXCLUSION.**—Such term does not include—

(i) a seller or lessor of real property;

(ii) a provider of professional services in any case in which the sale or use of a product is incidental to the transaction and the essence of the transaction is the furnishing of judgment, skill, or services; or

(iii) any person who—

(I) acts in only a financial capacity with respect to the sale of a product; or

(II) leases a product under a lease arrangement in which the selection, possession, maintenance, and operation of the product are controlled by a person other than the lessor.

(19) **PUNITIVE DAMAGES.**—The term “punitive damages” means damages awarded against any person not to compensate for actual injury suffered, but to punish or deter such person or others from engaging in similar behavior in the future.

(20) **STATE.**—The term “State” means each of the several States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, and any other territory or possession of the United States.

**SEC. 403. EFFECTIVE DATE.**

This title will apply to—

- (1) any health care liability action brought in a Federal or State court; and
  - (2) any health care liability claim subject to an alternative dispute resolution system,
- that is initiated on or after the date of enactment of this title, except that any health care liability claim or action arising from an injury occurring before the date of enactment of this title shall be governed by the applicable statute of limitations provisions in effect at the time the injury occurred.

## **Subtitle B—Uniform Standards for Health Care Liability Actions**

### **SEC. 411. STATUTE OF LIMITATIONS.**

A health care liability action may not be brought after the expiration of the 2-year period that begins on the date on which the alleged injury that is the subject of the action was discovered or should reasonably have been discovered, but in no case after the expiration of the 5-year period that begins on the date the alleged injury occurred.

### **SEC. 412. CALCULATION AND PAYMENT OF DAMAGES.**

#### **(a) TREATMENT OF NON-ECONOMIC DAMAGES.—**

(1) **LIMITATION ON NON-ECONOMIC DAMAGES.**—The total amount of non-economic damages that may be awarded to a claimant for losses resulting from the injury which is the subject of a health care liability action may not exceed \$250,000, regardless of the number of parties against whom the action is brought or the number of actions brought with respect to the injury. The limitation under this paragraph shall not apply to an action for damages based solely on intentional denial of medical treatment necessary to preserve a patient's life that the patient is otherwise qualified to receive, against the wishes of a patient, or if the patient is incompetent, against the wishes of the patient's guardian, on the basis of the patient's present or predicated age, disability, degree of medical dependency, or quality of life.

(2) **LIMIT.**—If, after the date of the enactment of this Act, a State enacts a law which prescribes the amount of non-economic damages which may be awarded in a health care liability action which is different from the amount prescribed by section 412(a)(1), the State amount shall apply in lieu of the amount prescribed by such section. If, after the date of the enactment of this Act, a State enacts a law which limits the amount of recovery in a health care liability action without delineating between economic and non-economic damages, the State amount shall apply in lieu of the amount prescribed by such section.

(3) **JOINT AND SEVERAL LIABILITY.**—In any health care liability action brought in State or Federal court, a defendant shall be liable only for the amount of non-economic damages attributable to such defendant in direct proportion to such defendant's share of fault or responsibility for the claimant's actual damages, as determined by the trier of fact. In all such cases,

the liability of a defendant for non-economic damages shall be several and not joint and a separate judgment shall be rendered against each defendant for the amount allocated to such defendant.

(b) TREATMENT OF PUNITIVE DAMAGES.—

(1) GENERAL RULE.—Punitive damages may, to the extent permitted by applicable State law, be awarded in any health care liability action for harm in any Federal or State court against a defendant if the claimant establishes by clear and convincing evidence that the harm suffered was the result of conduct—

(A) specifically intended to cause harm; or

(B) conduct manifesting a conscious, flagrant indifference to the rights or safety of others.

(2) APPLICABILITY.—This subsection shall apply to any health care liability action brought in any Federal or State court on any theory where punitive damages are sought. This subsection does not create a cause of action for punitive damages.

(3) LIMITATION ON PUNITIVE DAMAGES.—The total amount of punitive damages that may be awarded to a claimant for losses resulting from the injury which is the subject of a health care liability action may not exceed the greater of—

(A) 2 times the amount of economic damages, or

(B) \$250,000,

regardless of the number of parties against whom the action is brought or the number of actions brought with respect to the injury. This subsection does not preempt or supersede any State or Federal law to the extent that such law would further limit the award of punitive damages.

(4) BIFURCATION.—At the request of any party, the trier of fact shall consider in a separate proceeding whether punitive damages are to be awarded and the amount of such award. If a separate proceeding is requested, evidence relevant only to the claim of punitive damages, as determined by applicable State law, shall be inadmissible in any proceeding to determine whether actual damages are to be awarded.

(4) DRUGS AND DEVICES.—

(A) IN GENERAL.—

(i) PUNITIVE DAMAGES.—Punitive damages shall not be awarded against a manufacturer or product seller of a drug or medical device which caused the claimant's harm where—

(I) such drug or device was subject to premarket approval by the Food and Drug Administration with respect to the safety of the formulation or performance of the aspect of such drug or device which caused the claimant's harm, or the adequacy of the packaging or labeling of such drug or device which caused the harm, and such drug, device, packaging, or labeling was approved by the Food and Drug Administration; or

(II) the drug is generally recognized as safe and effective pursuant to conditions established by the Food and Drug Administration and applicable reg-

ulations, including packaging and labeling regulations.

(ii) APPLICATION.—Clause (i) shall not apply in any case in which the defendant, before or after premarket approval of a drug or device—

(I) intentionally and wrongfully withheld from or misrepresented to the Food and Drug Administration information concerning such drug or device required to be submitted under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or section 351 of the Public Health Service Act (42 U.S.C. 262) that is material and relevant to the harm suffered by the claimant; or

(II) made an illegal payment to an official or employee of the Food and Drug Administration for the purpose of securing or maintaining approval of such drug or device.

(B) PACKAGING.—In a health care liability action for harm which is alleged to relate to the adequacy of the packaging or labeling of a drug which is required to have tamper-resistant packaging under regulations of the Secretary of Health and Human Services (including labeling regulations related to such packaging), the manufacturer or product seller of the drug shall not be held liable for punitive damages unless such packaging or labeling is found by the court by clear and convincing evidence to be substantially out of compliance with such regulations.

(c) PERIODIC PAYMENTS FOR FUTURE LOSSES.—

(1) GENERAL RULE.—In any health care liability action in which the damages awarded for future economic and non-economic loss exceeds \$50,000, a person shall not be required to pay such damages in a single, lump-sum payment, but shall be permitted to make such payments periodically based on when the damages are likely to occur, as such payments are determined by the court.

(2) FINALITY OF JUDGMENT.—The judgment of the court awarding periodic payments under this subsection may not, in the absence of fraud, be reopened at any time to contest, amend, or modify the schedule or amount of the payments.

(3) LUMP-SUM SETTLEMENTS.—This subsection shall not be construed to preclude a settlement providing for a single, lump-sum payment.

(d) TREATMENT OF COLLATERAL SOURCE PAYMENTS.—

(1) INTRODUCTION INTO EVIDENCE.—In any health care liability action, any defendant may introduce evidence of collateral source payments. If any defendant elects to introduce such evidence, the claimant may introduce evidence of any amount paid or contributed or reasonably likely to be paid or contributed in the future by or on behalf of the claimant to secure the right to such collateral source payments.

(2) NO SUBROGATION.—No provider of collateral source payments shall recover any amount against the claimant or receive any lien or credit against the claimant's recovery or be

equitably or legally subrogated to the right of the claimant in a health care liability action.

(3) APPLICATION TO SETTLEMENTS.—This subsection shall apply to an action that is settled as well as an action that is resolved by a fact finder.

**SEC. 413. ALTERNATIVE DISPUTE RESOLUTION.**

Any ADR used to resolve a health care liability action or claim shall contain provisions relating to statute of limitations, non-economic damages, joint and several liability, punitive damages, collateral source rule, and periodic payments which are consistent with the provisions relating to such matters in this title.

**SEC. 414. REPORTING ON FRAUD AND ABUSE ENFORCEMENT ACTIVITIES.**

The General Accounting Office shall—

(1) monitor—

(A) the compliance of the Department of Justice and all United States Attorneys—with the guideline entitled “Guidance on the Use of the False Claims Act in Civil Health Care Matters” issued by the Department on June 3, 1998, including any revisions to that guideline; and

(B) the compliance of the Office of the Inspector General of the Department of Health and Human Services with the protocols and guidelines entitled “National Project Protocols—Best Practice Guidelines” issued by the Inspector General on June 3, 1998, including any revisions to such protocols and guidelines; and

(2) submit a report on such compliance to the Committee on Commerce, the Committee on the Judiciary, and the Committee on Ways and Means of the House of Representatives and the Committee on the Judiciary and the Committee on Finance of the Senate not later than February 1, 2000, and every year thereafter for a period of 4 years ending February 1, 2003.

**2. AN AMENDMENT TO BE OFFERED BY REPRESENTATIVE GOSS OF FLORIDA, OR REPRESENTATIVE COBURN OF OKLAHOMA, OR A DESIGNEE, DEBATABLE FOR 60 MINUTES**

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 “Health Care Quality and Choice Act of 1999”.

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

Sec. 1. Short title; table of contents.

**TITLE I— AMENDMENTS TO THE PUBLIC HEALTH SERVICE ACT**

Sec. 101. Application to group health plans and group health insurance coverage.

Sec. 102. Application to individual health insurance coverage.

Sec. 103. Improving managed care.

**“TITLE XXVIII—IMPROVING MANAGED CARE**

**“Subtitle A—Grievance and Appeals**

“Sec. 2801. Utilization review activities.

“Sec. 2802. Internal appeals procedures.

- “Sec. 2803. External appeals procedures.
- “Sec. 2804. Establishment of a grievance process.

“Subtitle B—Access to Care

- “Sec. 2811. Consumer choice option.
- “Sec. 2812. Choice of health care professional.
- “Sec. 2813. Access to emergency care.
- “Sec. 2814. Access to specialty care.
- “Sec. 2815. Access to obstetrical and gynecological care.
- “Sec. 2816. Access to pediatric care.
- “Sec. 2817. Continuity of care.
- “Sec. 2818. Network adequacy.
- “Sec. 2819. Access to experimental or investigational prescription drugs.
- “Sec. 2820. Coverage for individuals participating in approved cancer clinical trials.

“Subtitle C—Access to Information

- “Sec. 2821. Patient access to information.

“Subtitle D—Protecting the Doctor-Patient Relationship

- “Sec. 2831. Prohibition of interference with certain medical communications.
- “Sec. 2832. Prohibition of discrimination against providers based on licensure.
- “Sec. 2833. Prohibition against improper incentive arrangements.
- “Sec. 2834. Payment of clean claims.

“Subtitle E—Definitions

- “Sec. 2841. Definitions.
- “Sec. 2842. Rule of construction.
- “Sec. 2843. Exclusions.
- “Sec. 2844. Coverage of limited scope plans.
- “Sec. 2845. Regulations.
- “Sec. 2846. Limitation on application of provisions relating to group health plans..

TITLE II—AMENDMENTS TO THE EMPLOYEE RETIREMENT INCOME  
SECURITY ACT OF 1974

- Sec. 201. Application of patient protection standards to group health plans and group health insurance coverage under the Employee Retirement Income Security Act of 1974.
- Sec. 202. Improving managed care.

“PART 8—IMPROVING MANAGED CARE

“SUBPART A—GRIEVANCE AND APPEALS

- “Sec. 801. Utilization review activities.
- “Sec. 802. Internal appeals procedures.
- “Sec. 803. External appeals procedures.
- “Sec. 804. Establishment of a grievance process.

“SUBPART B—ACCESS TO CARE

- “Sec. 812. Choice of health care professional.
- “Sec. 813. Access to emergency care.
- “Sec. 814. Access to specialty care.
- “Sec. 815. Access to obstetrical and gynecological care.
- “Sec. 816. Access to pediatric care.
- “Sec. 817. Continuity of care.
- “Sec. 818. Network adequacy.
- “Sec. 819. Access to experimental or investigational prescription drugs.
- “Sec. 820. Coverage for individuals participating in approved cancer clinical trials.

“SUBPART C—ACCESS TO INFORMATION

- “Sec. 821. Patient access to information.

“SUBPART D—PROTECTING THE DOCTOR-PATIENT RELATIONSHIP

- “Sec. 831. Prohibition of interference with certain medical communications.

- “Sec. 832. Prohibition of discrimination against providers based on licensure.
- “Sec. 833. Prohibition against improper incentive arrangements.
- “Sec. 834. Payment of clean claims.

“SUBPART E—DEFINITIONS

- “Sec. 841. Definitions.
- “Sec. 842. Rule of construction.
- “Sec. 843. Exclusions.
- “Sec. 844. Coverage of limited scope plans.
- “Sec. 845. Regulations.
- Sec. 203. Availability of court remedies.
- Sec. 204. Availability of binding arbitration.

TITLE III— AMENDMENTS TO THE INTERNAL REVENUE CODE OF 1986

- Sec. 301. Application to group health plans under the Internal Revenue Code of 1986.
- Sec. 302. Improving managed care.

“CHAPTER 101—IMPROVING MANAGED CARE

“SUBCHAPTER A—GRIEVANCE AND APPEALS.

- “Sec. 9901. Utilization review activities.
- “Sec. 9902. Internal appeals procedures.
- “Sec. 9903. External appeals procedures.
- “Sec. 9904. Establishment of a grievance process.

“SUBCHAPTER B—ACCESS TO CARE

- “Sec. 9912. Choice of health care professional.
- “Sec. 9913. Access to emergency care.
- “Sec. 9914. Access to specialty care.
- “Sec. 9915. Access to obstetrical and gynecological care.
- “Sec. 9916. Access to pediatric care.
- “Sec. 9917. Continuity of care.
- “Sec. 9918. Network adequacy.
- “Sec. 9919. Access to experimental or investigational prescription drugs.
- “Sec. 9920. Coverage for individuals participating in approved cancer clinical trials.

“SUBCHAPTER C—ACCESS TO INFORMATION

- “Sec. 9921. Patient access to information.

“SUBCHAPTER D—PROTECTING THE DOCTOR-PATIENT RELATIONSHIP

- “Sec. 9931. Prohibition of interference with certain medical communications.
- “Sec. 9932. Prohibition of discrimination against providers based on licensure.
- “Sec. 9933. Prohibition against improper incentive arrangements.
- “Sec. 9934. Payment of clean claims.

“SUBCHAPTER E—DEFINITIONS

- “Sec. 9941. Definitions.
- “Sec. 9942. Exclusions.
- “Sec. 9943. Coverage of limited scope plans.
- “Sec. 9944. Regulations.

TITLE IV—EFFECTIVE DATES; COORDINATION IN IMPLEMENTATION

- Sec. 401. Effective dates.
- Sec. 402. Coordination in implementation.

TITLE V—OTHER PROVISIONS

Subtitle A—Protection of Information

- Sec. 501. Protection for certain information.

Subtitle B—Other Matters

- Sec. 511. Health care paperwork simplification.

## **TITLE I— AMENDMENTS TO THE PUBLIC HEALTH SERVICE ACT**

### **SEC. 101. APPLICATION TO GROUP HEALTH PLANS AND GROUP HEALTH INSURANCE COVERAGE.**

(a) **IN GENERAL.**—Subpart 2 of part A of title XXVII of the Public Health Service Act is amended by adding at the end the following new section:

#### **“SEC. 2707. PATIENT PROTECTION STANDARDS.**

“(a) **IN GENERAL.**—Each group health plan shall comply with patient protection requirements under title XXVIII, and each health insurance issuer shall comply with patient protection requirements under such title with respect to group health insurance coverage it offers, and such requirements shall be deemed to be incorporated into this subsection.

“(b) **NOTICE.**—A group health plan shall comply with the notice requirement under section 711(d) of the Employee Retirement Income Security Act of 1974 (as in effect on the date of the enactment of the Health Care Quality and Choice Act of 1999) with respect to the requirements referred to in subsection (a) and a health insurance issuer shall comply with such notice requirement as if such section applied to such issuer and such issuer were a group health plan.”.

(b) **CONFORMING AMENDMENT.**—Section 2721(b)(2)(A) of such Act (42 U.S.C. 300gg–21(b)(2)(A)) is amended by inserting “(other than section 2707)” after “requirements of such subparts”.

### **SEC. 102. APPLICATION TO INDIVIDUAL HEALTH INSURANCE COVERAGE.**

Part B of title XXVII of the Public Health Service Act is amended by inserting after section 2752 the following new section:

#### **“SEC. 2753. PATIENT PROTECTION STANDARDS.**

“(a) **IN GENERAL.**—Each health insurance issuer shall comply with patient protection requirements under title XXVIII with respect to individual health insurance coverage it offers, and such requirements shall be deemed to be incorporated into this subsection.

“(b) **NOTICE.**—A health insurance issuer under this part shall comply with the notice requirement under section 711(d) of the Employee Retirement Income Security Act of 1974 with respect to the requirements of such title as if such section applied to such issuer and such issuer were a group health plan.”.

### **SEC. 103. IMPROVING MANAGED CARE.**

The Public Health Service Act is amended by adding at the end the following new title:

## **“TITLE XXVIII—IMPROVING MANAGED CARE**

### **“Subtitle A—Grievance and Appeals**

#### **“SEC. 2801. UTILIZATION REVIEW ACTIVITIES.**

##### **“(a) COMPLIANCE WITH REQUIREMENTS.—**

“(1) **IN GENERAL.**—A group health plan, and a health insurance issuer that provides health insurance coverage, shall conduct utilization review activities in connection with the provision of benefits under such plan or coverage only in accordance with a utilization review program that meets the requirements of this section.

“(2) **USE OF OUTSIDE AGENTS.**—Nothing in this section shall be construed as preventing a group health plan or health insurance issuer from arranging through a contract or otherwise for persons or entities to conduct utilization review activities on behalf of the plan or issuer, so long as such activities are conducted in accordance with a utilization review program that meets the requirements of this section.

“(3) **UTILIZATION REVIEW DEFINED.**—For purposes of this section, the terms ‘utilization review’ and ‘utilization review activities’ mean procedures used to monitor or evaluate the use or coverage, clinical necessity, appropriateness, efficacy, or efficiency of health care services, procedures or settings, and includes prospective review, concurrent review, second opinions, case management, discharge planning, or retrospective review.

##### **“(b) WRITTEN POLICIES AND CRITERIA.—**

“(1) **WRITTEN POLICIES.**—A utilization review program shall be conducted consistent with written policies and procedures that govern all aspects of the program.

##### **“(2) USE OF WRITTEN CRITERIA.—**

“(A) **IN GENERAL.**—Such a program shall utilize written clinical review criteria developed with input from a range of appropriate practicing physicians, as determined by the plan, pursuant to the program. Such criteria shall include written clinical review criteria that are based on valid clinical evidence where available and that are directed specifically at meeting the needs of at-risk populations and covered individuals with chronic conditions or severe illnesses, including gender-specific criteria and pediatric-specific criteria where available and appropriate.

“(B) **CONTINUING USE OF STANDARDS IN RETROSPECTIVE REVIEW.**—If a health care service has been specifically preauthorized or approved for an enrollee under such a program, the program shall not, pursuant to retrospective review, revise or modify the specific standards, criteria, or procedures used for the utilization review for procedures, treatment, and services delivered to the enrollee during the same course of treatment.

“(C) **REVIEW OF SAMPLE OF CLAIMS DENIALS.**—Such a program shall provide for periodic evaluation at reasonable

intervals of the clinical appropriateness of a sample of denials of claims for benefits.

“(c) CONDUCT OF PROGRAM ACTIVITIES.—

“(1) ADMINISTRATION BY HEALTH CARE PROFESSIONALS.—A utilization review program shall be administered by appropriate physician specialists who shall be selected by the plan or issuer and who shall oversee review decisions.

“(2) USE OF QUALIFIED, INDEPENDENT PERSONNEL.—

“(A) IN GENERAL.—A utilization review program shall provide for the conduct of utilization review activities only through personnel who are qualified and have received appropriate training in the conduct of such activities under the program.

“(B) PROHIBITION OF CONTINGENT COMPENSATION ARRANGEMENTS.—Such a program shall not, with respect to utilization review activities, permit or provide compensation or anything of value to its employees, agents, or contractors in a manner that encourages denials of claims for benefits. This subparagraph shall not preclude any capitation arrangements between plans and providers.

“(C) PROHIBITION OF CONFLICTS.—Such a program shall not permit a health care professional who is providing health care services to an individual to perform utilization review activities in connection with the health care services being provided to the individual.

“(3) ACCESSIBILITY OF REVIEW.—Such a program shall provide that appropriate personnel performing utilization review activities under the program, including the utilization review administrator, are reasonably accessible by toll-free telephone during normal business hours to discuss patient care and allow response to telephone requests, and that appropriate provision is made to receive and respond promptly to calls received during other hours.

“(4) LIMITS ON FREQUENCY.—Such a program shall not provide for the performance of utilization review activities with respect to a class of services furnished to an individual more frequently than is reasonably required to assess whether the services under review are medically necessary or appropriate.

“(d) DEADLINE FOR DETERMINATIONS.—

“(1) PRIOR AUTHORIZATION SERVICES.—

“(A) IN GENERAL.—Except as provided in paragraph (2), in the case of a utilization review activity involving the prior authorization of health care items and services for an individual, the utilization review program shall make a determination concerning such authorization, and provide notice of the determination to the individual or the individual’s designee and the individual’s health care provider by telephone and in printed or electronic form, no later than the deadline specified in subparagraph (B). The provider involved shall provide timely access to information relevant to the matter of the review decision.

“(B) DEADLINE.—

“(i) IN GENERAL.—Subject to clauses (ii) and (iii), the deadline specified in this subparagraph is 14 days

after the earliest date as of which the request for prior authorization has been received and all necessary information has been provided.

“(ii) EXTENSION PERMITTED WHERE NOTICE OF ADDITIONAL INFORMATION REQUIRED.—If a utilization review program—

“(I) receives a request for a prior authorization,

“(II) determines that additional information is necessary to complete the review and make the determination on the request,

“(III) notifies the requester, not later than 5 business days after the date of receiving the request, of the need for such specified additional information, and

“(IV) requires the requester to submit specified information not later than 2 business days after notification,

the deadline specified in this subparagraph is 14 days after the date the program receives the specified additional information, but in no case later than 28 days after the date of receipt of the request for the prior authorization. This clause shall not apply if the deadline is specified in clause (iii).

“(iii) EXPEDITED CASES.—In the case of a situation described in section 102(c)(1)(A), the deadline specified in this subparagraph is 48 hours after the time of the request for prior authorization.

“(2) ONGOING CARE.—

“(A) CONCURRENT REVIEW.—

“(i) IN GENERAL.—Subject to subparagraph (B), in the case of a concurrent review of ongoing care (including hospitalization), which results in a termination or reduction of such care, the plan must provide by telephone and in printed or electronic form notice of the concurrent review determination to the individual or the individual’s designee and the individual’s health care provider as soon as possible in accordance with the medical exigencies of the case, with sufficient time prior to the termination or reduction to allow for an appeal under section 102(c)(1)(A) to be completed before the termination or reduction takes effect.

“(ii) CONTENTS OF NOTICE.—Such notice shall include, with respect to ongoing health care items and services, the number of ongoing services approved, the new total of approved services, the date of onset of services, and the next review date, if any, as well as a statement of the individual’s rights to further appeal.

“(B) EXCEPTION.—Subparagraph (A) shall not be interpreted as requiring plans or issuers to provide coverage of care that would exceed the coverage limitations for such care.

“(3) PREVIOUSLY PROVIDED SERVICES.—In the case of a utilization review activity involving retrospective review of health care services previously provided for an individual, the utilization review program shall make a determination concerning such services, and provide notice of the determination to the individual or the individual’s designee and the individual’s health care provider by telephone and in printed or electronic form, within 30 days of the date of receipt of information that is reasonably necessary to make such determination, but in no case later than 60 days after the date of receipt of the claim for benefits.

“(4) FAILURE TO MEET DEADLINE.—In a case in which a group health plan or health insurance issuer fails to make a determination on a claim for benefit under paragraph (1), (2)(A), or (3) by the applicable deadline established under the respective paragraph, the failure shall be treated under this subtitle as a denial of the claim as of the date of the deadline.

“(5) REFERENCE TO SPECIAL RULES FOR EMERGENCY SERVICES, MAINTENANCE CARE, POST-STABILIZATION CARE, AND EMERGENCY AMBULANCE SERVICES.—For waiver of prior authorization requirements in certain cases involving emergency services, maintenance care and post-stabilization care, and emergency ambulance services, see subsections (a)(1), (b), and (c)(1) of section 113, respectively.

“(e) NOTICE OF DENIALS OF CLAIMS FOR BENEFITS.—

“(1) IN GENERAL.—Notice of a denial of claims for benefits under a utilization review program shall be provided in printed or electronic form and written in a manner calculated to be understood by the participant, beneficiary, or enrollee and shall include—

“(A) the reasons for the denial (including the clinical rationale);

“(B) instructions on how to initiate an appeal under section 102; and

“(C) notice of the availability, upon request of the individual (or the individual’s designee) of the clinical review criteria relied upon to make such denial.

“(2) SPECIFICATION OF ANY ADDITIONAL INFORMATION.—Such a notice shall also specify what (if any) additional necessary information must be provided to, or obtained by, the person making the denial in order to make a decision on such an appeal.

“(f) CLAIM FOR BENEFITS AND DENIAL OF CLAIM FOR BENEFITS DEFINED.—For purposes of this subtitle:

“(1) CLAIM FOR BENEFITS.—The term ‘claim for benefits’ means any request for coverage (including authorization of coverage), or for payment in whole or in part, for an item or service under a group health plan or health insurance coverage.

“(2) DENIAL OF CLAIM FOR BENEFITS.—The term ‘denial’ means, with respect to a claim for benefits, a denial, or a failure to act on a timely basis upon, in whole or in part, the claim for benefits and includes a failure to provide or pay for benefits (including items and services) required to be provided or paid for under this title.

**“SEC. 2802. INTERNAL APPEALS PROCEDURES.****“(a) RIGHT OF REVIEW.—**

**“(1) IN GENERAL.—**Each group health plan, and each health insurance issuer offering health insurance coverage—

**“(A)** shall provide adequate notice in written or electronic form to any participant or beneficiary under such plan, or enrollee under such coverage, whose claim for benefits under the plan or coverage has been denied “(within the meaning of section 2801(f)(2)), setting forth the specific reasons for such denial of claim for benefits and rights to any further review or appeal, written in layman’s terms to be understood by the participant, beneficiary, or enrollee; and

**“(B)** shall afford such a participant, beneficiary, or enrollee (and any provider or other person acting on behalf of such an individual with the individual’s consent or without such consent if the individual is medically unable to provide such consent) who is dissatisfied with such a denial of claim for benefits a reasonable opportunity of not less than 180 days to request and obtain a full and fair review by a named fiduciary (with respect to such plan) or named appropriate individual (with respect to such coverage) of the decision denying the claim.

**“(2) TREATMENT OF ORAL REQUESTS.—**The request for review under paragraph (1)(B) may be made orally, but, in the case of an oral request, shall be followed by a request in written or electronic form.

**“(b) INTERNAL REVIEW PROCESS.—****“(1) CONDUCT OF REVIEW.—**

**“(A) IN GENERAL.—**A review of a denial of claim under this section shall be made by an individual (who shall be a physician in a case involving medical judgment) who has been selected by the plan or issuer and who did not make the initial denial in the internally appealable decision, except that in the case of limited scope coverage (as defined in subparagraph (B)) an appropriate specialist shall review the decision.

**“(B) LIMITED SCOPE COVERAGE DEFINED.—**For purposes of subparagraph (A), the term ‘limited scope coverage’ means a group health plan or health insurance coverage the only benefits under which are for benefits described in section 2791(c)(2)(A) of the Public Health Service Act (42 U.S.C. 300gg–91(c)(2)).

**“(2) TIME LIMITS FOR INTERNAL REVIEWS.—**

**“(A) IN GENERAL.—**Having received such a request for review of a denial of claim, the plan or issuer shall, in accordance with the medical exigencies of the case but not later than the deadline specified in subparagraph (B), complete the review on the denial and transmit to the participant, beneficiary, enrollee, or other person involved a decision that affirms, reverses, or modifies the denial. If the decision does not reverse the denial, the plan or issuer shall transmit, in printed or electronic form, a notice that sets forth the grounds for such decision and that includes

a description of rights to any further appeal. Such decision shall be treated as the final decision of the plan. Failure to issue such a decision by such deadline shall be treated as a final decision affirming the denial of claim.

“(B) DEADLINE.—

“(i) IN GENERAL.—Subject to clauses (ii) and (iii), the deadline specified in this subparagraph is 14 days after the earliest date as of which the request for prior authorization has been received and all necessary information has been provided. The provider involved shall provide timely access to information relevant to the matter of the review decision.

“(ii) EXTENSION PERMITTED WHERE NOTICE OF ADDITIONAL INFORMATION REQUIRED.—If a group health plan or health insurance issuer—

“(I) receives a request for internal review,

“(II) determines that additional information is necessary to complete the review and make the determination on the request,

“(III) notifies the requester, not later than 5 business days after the date of receiving the request, of the need for such specified additional information, and

“(IV) requires the requester to submit specified information not later than 48 hours after notification,

the deadline specified in this subparagraph is 14 days after the date the plan or issuer receives the specified additional information, but in no case later than 28 days after the date of receipt of the request for the internal review. This clause shall not apply if the deadline is specified in clause (iii).

“(iii) EXPEDITED CASES.—In the case of a situation described in subsection (c)(1)(A), the deadline specified in this subparagraph is 48 hours after the time of request for review

“(c) EXPEDITED REVIEW PROCESS.—

“(1) IN GENERAL.—A group health plan, and a health insurance issuer, shall establish procedures in writing for the expedited consideration of requests for review under subsection (b) in situations—

“(A) in which, as determined by the plan or issuer or as certified in writing by a treating physician, the application of the normal timeframe for making the determination could seriously jeopardize the life or health of the participant, beneficiary, or enrollee or such individual’s ability to regain maximum function; or

“(B) described in section 2801(d)(2) (relating to requests for continuation of ongoing care which would otherwise be reduced or terminated).

“(2) PROCESS.—Under such procedures—

“(A) the request for expedited review may be submitted orally or in writing by an individual or provider who is otherwise entitled to request the review;

“(B) all necessary information, including the plan’s or issuer’s decision, shall be transmitted between the plan or issuer and the requester by telephone, facsimile, or other similarly expeditious available method; and

“(C) the plan or issuer shall expedite the review in the case of any of the situations described in subparagraph (A) or (B) of paragraph (1).

“(3) DEADLINE FOR DECISION.—The decision on the expedited review must be made and communicated to the parties as soon as possible in accordance with the medical exigencies of the case, and in no event later than 48 hours after the time of receipt of the request for expedited review, except that in a case described in paragraph (1)(B), the decision must be made before the end of the approved period of care.

“(d) WAIVER OF PROCESS.—A plan or issuer may waive its rights for an internal review under subsection (b). In such case the participant, beneficiary, or enrollee involved (and any designee or provider involved) shall be relieved of any obligation to complete the review involved and may, at the option of such participant, beneficiary, enrollee, designee, or provider, proceed directly to seek further appeal through any applicable external appeals process.

**“SEC. 2803. EXTERNAL APPEALS PROCEDURES.**

“(a) RIGHT TO EXTERNAL APPEAL.—

“(1) IN GENERAL.—A group health plan, and a health insurance issuer offering health insurance coverage, shall provide for an external appeals process that meets the requirements of this section in the case of an externally appealable decision described in paragraph (2), for which a timely appeal is made (within a reasonable period not to exceed 365 days) either by the plan or issuer or by the participant, beneficiary, or enrollee (and any provider or other person acting on behalf of such an individual with the individual’s consent or without such consent if such an individual is medically unable to provide such consent).

“(2) EXTERNALLY APPEALABLE DECISION DEFINED.—

“(A) IN GENERAL.—For purposes of this section, the term ‘externally appealable decision’ means a denial of claim for benefits (as defined in section 2801(f)(2)), if—

“(i) the item or service involved is covered under the plan or coverage,

“(ii) the amount involved exceeds \$100, increased or decreased, for each calendar year that ends after December 31, 2001, by the same percentage as the percentage by which the medical care expenditure category of the Consumer Price Index for All Urban Consumers (United States city average), published by the Bureau of Labor Statistics, for September of the preceding calendar year has increased or decreased from such index for September 2000, and

“(iii) the requirements of subparagraph (B) are met with respect to such denial.

Such term also includes a failure to meet an applicable deadline for internal review under section 2802 or such standards as are established pursuant to section 2818.

“(B) REQUIREMENTS.—For purposes of subparagraph (A)(iii), the requirements of this subparagraph are met with respect to a denial of a claim for benefits if—

“(i) the denial is based in whole or in part on a decision that the item or service is not medically necessary or appropriate or is investigational or experimental, or

“(ii) in such denial, the decision as to whether an item or service is covered involves a medical judgment.

“(C) EXCLUSIONS.—The term ‘externally appealable decision’ does not include—

“(i) specific exclusions or express limitations on the amount, duration, or scope of coverage; or

“(ii) a decision regarding eligibility for any benefits.

“(3) EXHAUSTION OF INTERNAL REVIEW PROCESS.—Except as provided under section 2802(d), a plan or issuer may condition the use of an external appeal process in the case of an externally appealable decision upon a final decision in an internal review under section 2802, but only if the decision is made in a timely basis consistent with the deadlines provided under this subtitle.

“(4) FILING FEE REQUIREMENT.—

“(A) IN GENERAL.—A plan or issuer may condition the use of an external appeal process upon payment in advance to the plan or issuer of a \$25 filing fee.

“(B) REFUNDING FEE IN CASE OF SUCCESSFUL APPEALS.—The plan or issuer shall refund payment of the filing fee under this paragraph if the recommendation of the external appeal entity is to reverse the denial of a claim for benefits which is the subject of the appeal.

“(b) GENERAL ELEMENTS OF EXTERNAL APPEALS PROCESS.—

“(1) USE OF QUALIFIED EXTERNAL APPEAL ENTITY.—

“(A) IN GENERAL.—The external appeal process under this section of a plan or issuer shall be conducted between the plan or issuer and one or more qualified external appeal entities (as defined in subsection (c)). Nothing in this subsection shall be construed as requiring that such procedures provide for the selection for any plan of more than one such entity.

“(B) LIMITATION ON PLAN OR ISSUER SELECTION.—The Secretary shall implement procedures to assure that the selection process among qualified external appeal entities will not create any incentives for external appeal entities to make a decision in a biased manner.

“(C) OTHER TERMS AND CONDITIONS.—The terms and conditions of this paragraph shall be consistent with the standards the Secretary shall establish to assure there is no real or apparent conflict of interest in the conduct of external appeal activities. All costs of the process (except those incurred by the participant, beneficiary, enrollee, or treating professional in support of the appeal) shall be paid by the plan or issuer, and not by the participant, beneficiary, or enrollee. The previous sentence shall not be construed as applying to the imposition of a filing fee under subsection (a)(4).

“(2) ELEMENTS OF PROCESS.—An external appeal process shall be conducted consistent with standards established by the Secretary that include at least the following:

“(A) FAIR AND DE NOVO DETERMINATION.—The process shall provide for a fair, de novo determination described in subparagraph (B) based on evidence described in subparagraphs (C) and (D).

“(B) STANDARD OF REVIEW.—An external appeal entity shall determine whether the plan’s or issuer’s decision is appropriate for the medical condition of the patient involved (as determined by the entity) taking into account as of the time of the entity’s determination the patient’s medical condition and any relevant and reliable evidence the entity obtains under subparagraphs (C) and (D). If the entity determines the decision is appropriate for such condition, the entity shall affirm the decision and to the extent that the entity determines the decision is not appropriate for such condition, the entity shall reverse the decision. Nothing in this subparagraph shall be construed as providing for coverage of items or services not provided or covered by the plan or issuer.

“(C) REQUIRED CONSIDERATION OF CERTAIN MATTERS.—In making such determination, the external appeal entity shall consider, but not be bound by—

“(i) any language in the plan or coverage document relating to the definitions of the terms medical necessity, medically necessary or appropriate, or experimental, investigational, or related terms;

“(ii) the decision made by the plan or issuer upon internal review under section 2802 and any guidelines or standards used by the plan or issuer in reaching such decision; and

“(iii) the opinion of the individual’s treating physician or health care professional.

The entity also shall consider any personal health and medical information supplied with respect to the individual whose denial of claim for benefits has been appealed. The entity also shall consider the results of studies that meet professionally recognized standards of validity and replicability or that have been published in peer-reviewed journals.

“(D) ADDITIONAL EVIDENCE.—Such entity may also take into consideration but not be limited to the following evidence (to the extent available):

“(i) The results of professional consensus conferences.

“(ii) Practice and treatment policies.

“(iii) Community standard of care.

“(iv) Generally accepted principles of professional medical practice consistent with the best practice of medicine.

“(v) To the extent that the entity determines it to be free of any conflict of interest, the opinions of individuals who are qualified as experts in one or more fields

of health care which are directly related to the matters under appeal.

“(vi) To the extent that the entity determines it to be free of any conflict of interest, the results of peer reviews conducted by the plan or issuer involved.

“(E) DETERMINATION CONCERNING EXTERNALLY APPEALABLE DECISIONS.—

“(i) IN GENERAL.—A qualified external appeal entity shall determine—

“(I) whether a denial of claim for benefits is an externally appealable decision (within the meaning of subsection (a)(2));

“(II) whether an externally appealable decision involves an expedited appeal;

“(III) for purposes of initiating an external review, whether the internal review process has been completed; and

“(IV) whether the item or services is covered under the plan or coverage.

“(ii) CONSTRUCTION.—Nothing in a determination by a qualified external appeal entity under this section shall be construed as authorizing, or providing for, coverage of items and services for which benefits are not provided under the plan or coverage.

“(F) OPPORTUNITY TO SUBMIT EVIDENCE.—Each party to an externally appealable decision may submit evidence related to the issues in dispute.

“(G) PROVISION OF INFORMATION.—The plan or issuer involved shall provide to the external appeal entity timely access to information and to provisions of the plan or health insurance coverage relating to the matter of the externally appealable decision, as determined by the entity. The provider involved shall provide to the external appeal entity timely access to information relevant to the matter of the externally appealable decision, as determined by the entity.

“(H) TIMELY DECISIONS.—A determination by the external appeal entity on the decision shall—

“(i) be made orally or in written or electronic form and, if it is made orally, shall be supplied to the parties in written or electronic form as soon as possible;

“(ii) be made in accordance with the medical exigencies of the case involved, but in no event later than 21 days after the date (or, in the case of an expedited appeal, 48 hours after the time) of requesting an external appeal of the decision;

“(iii) state, in layperson’s language, the scientific rationale for such determination as well as the basis for such determination, including, if relevant, any basis in the terms or conditions of the plan or coverage; and

“(iv) inform the participant, beneficiary, or enrollee of the individual’s rights (including any limitation on such rights) to seek binding arbitration or further re-

view by the courts (or other process) of the external appeal determination.

“(I) COMPLIANCE WITH DETERMINATION.—If the external appeal entity determines that a denial of a claim for benefits was not reasonable and reverses the denial, the plan or issuer—

“(i) shall (upon the receipt of the determination) authorize the provision or payment for benefits in accordance with such determination;

“(ii) shall take such actions as may be necessary to provide or pay for benefits (including items or services) in a timely manner consistent with such determination; and

“(iii) shall submit information to the entity documenting compliance with the entity’s determination and this subparagraph.

“(J) CONSTRUCTION.—Nothing in this paragraph shall be construed as providing for coverage of items and services for which benefits are not provided under the plan or coverage.

“(c) QUALIFICATIONS OF EXTERNAL APPEAL ENTITIES.—

“(1) IN GENERAL.—For purposes of this section, the term ‘qualified external appeal entity’ means, in relation to a plan or issuer, an entity that is certified under paragraph (2) as meeting the following requirements:

“(A) The entity meets the independence requirements of paragraph (3).

“(B) The entity conducts external appeal activities through at least three clinical peers who are practicing physicians.

“(C) The entity has sufficient medical, legal, and other expertise and sufficient staffing to conduct external appeal activities for the plan or issuer on a timely basis consistent with subsection (b)(2)(G).

“(2) INITIAL CERTIFICATION OF EXTERNAL APPEAL ENTITIES.—

“(A) IN GENERAL.—In order to be treated as a qualified external appeal entity with respect to a group health plan or health insurance issuer operating in a State, the entity must be certified (and, in accordance with subparagraph (B), periodically recertified) as meeting such requirements—

“(i) by the applicable State authority (or under a process recognized or approved by such authority); or

“(ii) if the State has not established a certification and recertification process for such entities, by the Secretary, under a process recognized or approved by the Secretary, or to the extent provided in subparagraph (C)(ii), by a qualified private standard-setting organization (certified under such subparagraph), if elected by the entity.

“(B) RECERTIFICATION PROCESS.—The Secretary shall develop standards for the recertification of external appeal entities. Such standards shall include a review of—

“(i) the number of cases reviewed;

“(ii) a summary of the disposition of those cases;

“(iii) the length of time in making determinations on those cases;

“(iv) updated information of what was required to be submitted as a condition of certification for the entity’s performance of external appeal activities; and

“(v) information necessary to assure that the entity meets the independence requirements (described in paragraph (3)) with respect to plans and issuers for which it conducts external review activities.

“(C) CERTIFICATION OF QUALIFIED PRIVATE STANDARD-SETTING ORGANIZATIONS.—For purposes of subparagraph (A)(ii), the Secretary may provide for a process for certification (and periodic recertification) of qualified private standard-setting organizations which provide for certification of external appeal entities. Such an organization shall only be certified if the organization does not certify an external appeal entity unless it meets standards as least as stringent as the standards required for certification of such an entity by the Secretary under subparagraph (A)(ii).

“(3) INDEPENDENCE REQUIREMENTS.—

“(A) IN GENERAL.—A clinical peer or other entity meets the independence requirements of this paragraph if—

“(i) the peer or entity is not affiliated with any related party;

“(ii) any compensation received by such peer or entity in connection with the external review is reasonable and not contingent on any decision rendered by the peer or entity;

“(iii) the plan and the issuer (if any) have no recourse against the peer or entity in connection with the external review; and

“(iv) the peer or entity does not otherwise have a conflict of interest with a related party.

“(B) RELATED PARTY.—For purposes of this paragraph, the term ‘related party’ means—

“(i) with respect to—

“(I) a group health plan or health insurance coverage offered in connection with such a plan, the plan or the health insurance issuer offering such coverage, or

“(II) individual health insurance coverage, the health insurance issuer offering such coverage, or any plan sponsor, fiduciary, officer, director, or management employee of such plan or issuer;

“(ii) the health care professional that provided the health care involved in the coverage decision;

“(iii) the institution at which the health care involved in the coverage decision is provided; or

“(iv) the manufacturer of any drug or other item that was included in the health care involved in the coverage decision.

“(C) AFFILIATED.—For purposes of this paragraph, the term ‘affiliated’ means, in connection with any peer or entity, having a familial, financial, or fiduciary relationship with such peer or entity.

“(4) LIMITATION ON LIABILITY OF REVIEWERS.—No qualified external appeal entity having a contract with a plan or issuer under this part and no person who is employed by any such entity or who furnishes professional services to such entity, shall be held by reason of the performance of any duty, function, or activity required or authorized pursuant to this section, to have violated any criminal law, or to be civilly liable under any law of the United States or of any State (or political subdivision thereof) if due care was exercised in the performance of such duty, function, or activity and there was no actual malice or gross misconduct in the performance of such duty, function, or activity.

“(d) EXTERNAL APPEAL DETERMINATION BINDING ON PLAN.—

“(1) IN GENERAL.—The determination by an external appeal entity shall be binding on the plan (and issuer, if any) involved in the determination.

“(2) PROTECTION OF LEGAL RIGHTS.—Nothing in this subtitle shall be construed as removing any legal rights of participants, beneficiaries, enrollees, and others under State or Federal law, including the right to file judicial actions to enforce rights.

“(e) PENALTIES AGAINST AUTHORIZED OFFICIALS FOR REFUSING TO AUTHORIZE THE DETERMINATION OF AN EXTERNAL APPEAL ENTITY.—

“(1) MONETARY PENALTIES.—In any case in which the determination of an external appeal entity is not followed in a timely fashion by a group health plan, or by a health insurance issuer offering health insurance coverage, any named fiduciary who, acting in the capacity of authorizing the benefit, causes such refusal may, in the discretion in a court of competent jurisdiction, be liable to an aggrieved participant, beneficiary, or enrollee for a civil penalty in an amount of up to \$1,000 a day from the date on which the determination was transmitted to the plan or issuer by the external appeal entity until the date the refusal to provide the benefit is corrected.

“(2) CEASE AND DESIST ORDER AND ORDER OF ATTORNEY’S FEES.—In any action described in paragraph (1) brought by a participant, beneficiary, or enrollee with respect to a group health plan, or a health insurance issuer offering health insurance coverage, in which a plaintiff alleges that a person referred to in such paragraph has taken an action resulting in a refusal of a benefit determined by an external appeal entity in violation of such terms of the plan, coverage, or this subtitle, or has failed to take an action for which such person is responsible under the plan, coverage, or this title and which is necessary under the plan or coverage for authorizing a benefit, the court shall cause to be served on the defendant an order requiring the defendant—

“(A) to cease and desist from the alleged action or failure to act; and

“(B) to pay to the plaintiff a reasonable attorney’s fee and other reasonable costs relating to the prosecution of the action on the charges on which the plaintiff prevails.

“(f) PROTECTION OF LEGAL RIGHTS.—Nothing in this subtitle shall be construed as removing or limiting any legal rights of participants, beneficiaries, enrollees, and others under State or Federal law (including section 502 of the Employee Retirement Income Security Act of 1974), including the right to file judicial actions to enforce rights.

**“SEC. 2804. ESTABLISHMENT OF A GRIEVANCE PROCESS.**

“(a) ESTABLISHMENT OF GRIEVANCE SYSTEM.—

“(1) IN GENERAL.—A group health plan, and a health insurance issuer in connection with the provision of health insurance coverage, shall establish and maintain a system to provide for the presentation and resolution of oral and written grievances brought by individuals who are participants, beneficiaries, or enrollees, or health care providers or other individuals acting on behalf of an individual and with the individual’s consent or without such consent if the individual is medically unable to provide such consent, regarding any aspect of the plan’s or issuer’s services.

“(2) GRIEVANCE DEFINED.—In this section, the term ‘grievance’ means any question, complaint, or concern brought by a participant, beneficiary, or enrollee that is not a claim for benefits.

“(b) GRIEVANCE SYSTEM.—Such system shall include the following components with respect to individuals who are participants, beneficiaries, or enrollees:

“(1) Written notification to all such individuals and providers of the telephone numbers and business addresses of the plan or issuer personnel responsible for resolution of grievances and appeals.

“(2) A system to record and document, over a period of at least 3 previous years beginning two months after the date of the enactment of this Act, all grievances and appeals made and their status.

“(3) A process providing processing and resolution of grievances within 60 days.

“(4) Procedures for follow-up action, including the methods to inform the person making the grievance of the resolution of the grievance.

Grievances are not subject to appeal under the previous provisions of this subtitle.

## **“Subtitle B—Access to Care**

**“SEC. 2811. CONSUMER CHOICE OPTION.**

“(a) IN GENERAL.—If a health insurance issuer offers to enrollees health insurance coverage in connection with a group health plan which provides for coverage of services only if such services are furnished through health care professionals and providers who are members of a network of health care professionals and providers who have entered into a contract with the issuer to provide such

services, the issuer shall also offer to such enrollees (at the time of enrollment and during an annual open season as provided under subsection (c)) the option of health insurance coverage which provides for coverage of such services which are not furnished through health care professionals and providers who are members of such a network unless enrollees are offered such non-network coverage through another health insurance issuer.

“(b) **ADDITIONAL COSTS.**—The amount of any additional premium charged by the health insurance issuer for the additional cost of the creation and maintenance of the option described in subsection (a) and the amount of any additional cost sharing imposed under such option shall be borne by the enrollee unless it is paid by the health plan sponsor through agreement with the health insurance issuer.

“(c) **OPEN SEASON.**—An enrollee may change to the offering provided under this section only during a time period determined by the health insurance issuer. Such time period shall occur at least annually.

**“SEC. 2812. CHOICE OF HEALTH CARE PROFESSIONAL.**

“(a) **PRIMARY CARE.**—If a group health plan, or a health insurance issuer that offers health insurance coverage, requires or provides for designation by a participant, beneficiary, or enrollee of a participating primary care provider, then the plan or issuer shall permit each participant, beneficiary, and enrollee to designate any participating primary care provider who is available to accept such individual.

“(b) **SPECIALISTS.**—A group health plan and a health insurance issuer that offers health insurance coverage shall permit each participant, beneficiary, or enrollee to receive medically necessary or appropriate specialty care, pursuant to appropriate referral procedures, from any qualified participating health care professional who is available to accept such individual for such care.

**“SEC. 2813. ACCESS TO EMERGENCY CARE.**

“(a) **COVERAGE OF EMERGENCY SERVICES.**—

“(1) **IN GENERAL.**—If a group health plan, or health insurance coverage offered by a health insurance issuer, provides or covers any benefits with respect to services in an emergency department of a hospital, the plan or issuer shall cover emergency services (as defined in paragraph (2)(B))—

“(A) without the need for any prior authorization determination;

“(B) whether the health care provider furnishing such services is a participating provider with respect to such services;

“(C) in a manner so that, if such services are provided to a participant, beneficiary, or enrollee—

“(i) by a nonparticipating health care provider with or without prior authorization, or

“(ii) by a participating health care provider without prior authorization,

the participant, beneficiary, or enrollee is not liable for amounts that exceed the amounts of liability that would be

incurred if the services were provided by a participating health care provider with prior authorization; and

“(D) without regard to any other term or condition of such coverage (other than exclusion or coordination of benefits, or an affiliation or waiting period, permitted under section 2701 of the Public Health Service Act, section 701 of the Employee Retirement Income Security Act of 1974, or section 9801 of the Internal Revenue Code of 1986, and other than applicable cost-sharing).

“(2) DEFINITIONS.—In this section:

“(A) EMERGENCY MEDICAL CONDITION.—The term ‘emergency medical condition’ means—

“(i) a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act; and

“(ii) a medical condition manifesting itself in a neonate by acute symptoms of sufficient severity (including severe pain) such that a prudent health care professional could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act.

“(B) EMERGENCY SERVICES.—The term ‘emergency services’ means—

“(i) with respect to an emergency medical condition described in subparagraph (A)(i)—

“(I) a medical screening examination (as required under section 1867 of the Social Security Act) that is within the capability of the emergency department of a hospital, including ancillary services routinely available to the emergency department to evaluate such emergency medical condition, and

“(II) within the capabilities of the staff and facilities available at the hospital, such further medical examination and treatment as are required under section 1867 of such Act to stabilize the patient; or

“(ii) with respect to an emergency medical condition described in subparagraph (A)(ii), medical treatment for such condition rendered by a health care provider in a hospital to a neonate, including available hospital ancillary services in response to an urgent request of a health care professional and to the extent necessary to stabilize the neonate.

“(C) STABILIZE.—The term ‘to stabilize’ means, with respect to an emergency medical condition, to provide such medical treatment of the condition as may be necessary to assure, within reasonable medical probability, that no ma-

terial deterioration of the condition is likely to result from or occur during the transfer of the individual from a facility.

“(b) REIMBURSEMENT FOR MAINTENANCE CARE AND POST-STABILIZATION CARE.—If benefits are available under a group health plan, or under health insurance coverage offered by a health insurance issuer, with respect to maintenance care or post-stabilization care covered under the guidelines established under section 1852(d)(2) of the Social Security Act, the plan or issuer shall provide for reimbursement with respect to such services provided to a participant, beneficiary, or enrollee other than through a participating health care provider in a manner consistent with subsection (a)(1)(C) (and shall otherwise comply with such guidelines).

“(c) COVERAGE OF EMERGENCY AMBULANCE SERVICES.—

“(1) IN GENERAL.—If a group health plan, or health insurance coverage provided by a health insurance issuer, provides any benefits with respect to ambulance services and emergency services, the plan or issuer shall cover emergency ambulance services (as defined in paragraph (2)) furnished under the plan or coverage under the same terms and conditions under subparagraphs (A) through (D) of subsection (a)(1) under which coverage is provided for emergency services.

“(2) EMERGENCY AMBULANCE SERVICES.—For purposes of this subsection, the term ‘emergency ambulance services’ means ambulance services (as defined for purposes of section 1861(s)(7) of the Social Security Act) furnished to transport an individual who has an emergency medical condition (as defined in subsection (a)(2)(A)) to a hospital for the receipt of emergency services (as defined in subsection (a)(2)(B)) in a case in which the emergency services are covered under the plan or coverage pursuant to subsection (a)(1) and a prudent layperson, with an average knowledge of health and medicine, could reasonably expect that the absence of such transport would result in placing the health of the individual in serious jeopardy, serious impairment of bodily function, or serious dysfunction of any bodily organ or part.

**“SEC. 2814. ACCESS TO SPECIALTY CARE.**

“(a) SPECIALTY CARE FOR COVERED SERVICES.—

“(1) IN GENERAL.—If—

“(A) an individual is a participant or beneficiary under a group health plan or an enrollee who is covered under health insurance coverage offered by a health insurance issuer,

“(B) the individual has a condition or disease of sufficient seriousness and complexity to require treatment by a specialist or the individual requires physician pathology services, and

“(C) benefits for such treatment or services are provided under the plan or coverage,

the plan or issuer shall make or provide for a referral to a specialist who is available and accessible (consistent with standards developed under section 2818) to provide the treatment for such condition or disease or to provide such services.

“(2) SPECIALIST DEFINED.—For purposes of this subsection, the term ‘specialist’ means, with respect to a condition or services, a health care practitioner, facility, or center or physician pathologist that has adequate expertise through appropriate training and experience (including, in the case of a child, appropriate pediatric expertise and in the case of a pregnant woman, appropriate obstetrical expertise) to provide high quality care in treating the condition or to provide physician pathology services.

“(3) CARE UNDER REFERRAL.—A group health plan or health insurance issuer may require that the care provided to an individual pursuant to such referral under paragraph (1) with respect to treatment be—

“(A) pursuant to a treatment plan, only if the treatment plan is developed by the specialist and approved by the plan or issuer, in consultation with the designated primary care provider or specialist and the individual (or the individual’s designee), and

“(B) in accordance with applicable quality assurance and utilization review standards of the plan or issuer.

Nothing in this subsection shall be construed as preventing such a treatment plan for an individual from requiring a specialist to provide the primary care provider with regular updates on the specialty care provided, as well as all necessary medical information.

“(4) REFERRALS TO PARTICIPATING PROVIDERS.—A group health plan or health insurance issuer is not required under paragraph (1) to provide for a referral to a specialist that is not a participating provider, unless the plan or issuer does not have a specialist that is available and accessible to treat the individual’s condition or provide physician pathology services and that is a participating provider with respect to such treatment or services.

“(5) REFERRALS TO NONPARTICIPATING PROVIDERS.—In a case in which a referral of an individual to a nonparticipating specialist is required under paragraph (1), the group health plan or health insurance issuer shall provide the individual the option of at least three nonparticipating specialists.

“(6) TREATMENT OF NONPARTICIPATING PROVIDERS.—If a plan or issuer refers an individual to a nonparticipating specialist pursuant to paragraph (1), services provided pursuant to the approved treatment plan (if any) shall be provided at no additional cost to the individual beyond what the individual would otherwise pay for services received by such a specialist that is a participating provider.

“(b) SPECIALISTS AS GATEKEEPER FOR TREATMENT OF ONGOING SPECIAL CONDITIONS.—

“(1) IN GENERAL.—A group health plan, or a health insurance issuer, in connection with the provision of health insurance coverage, shall have a procedure by which an individual who is a participant, beneficiary, or enrollee and who has an ongoing special condition (as defined in paragraph (3)) may request and receive a referral to a specialist for such condition who shall be responsible for and capable of providing and coordi-

nating the individual's care with respect to the condition. Under such procedures if such an individual's care would most appropriately be coordinated by such a specialist, such plan or issuer shall refer the individual to such specialist.

“(2) TREATMENT FOR RELATED REFERRALS.—Such specialists shall be permitted to treat the individual without a referral from the individual's primary care provider and may authorize such referrals, procedures, tests, and other medical services as the individual's primary care provider would otherwise be permitted to provide or authorize, subject to the terms of the treatment (referred to in subsection (a)(3)(A)) with respect to the ongoing special condition.

“(3) ONGOING SPECIAL CONDITION DEFINED.—In this subsection, the term ‘ongoing special condition’ means a condition or disease that—

“(A) is life-threatening, degenerative, or disabling, and

“(B) requires specialized medical care over a prolonged period of time.

“(4) TERMS OF REFERRAL.—The provisions of paragraphs (3) through (5) of subsection (a) apply with respect to referrals under paragraph (1) of this subsection in the same manner as they apply to referrals under subsection (a)(1).

“(5) CONSTRUCTION.—Nothing in this subsection shall be construed as preventing an individual who is a participant, beneficiary, or enrollee and who has an ongoing special condition from having the individual's primary care physician assume the responsibilities for providing and coordinating care described in paragraph (1).

“(c) STANDING REFERRALS.—

“(1) IN GENERAL.—A group health plan, and a health insurance issuer in connection with the provision of health insurance coverage, shall have a procedure by which an individual who is a participant, beneficiary, or enrollee and who has a condition that requires ongoing care from a specialist may receive a standing referral to such specialist for treatment of such condition. If the plan or issuer, or if the primary care provider in consultation with the medical director of the plan or issuer and the specialist (if any), determines that such a standing referral is appropriate, the plan or issuer shall make such a referral to such a specialist if the individual so desires.

“(2) TERMS OF REFERRAL.—The provisions of paragraphs (3) through (5) of subsection (a) apply with respect to referrals under paragraph (1) of this subsection in the same manner as they apply to referrals under subsection (a)(1).

**“SEC. 2815. ACCESS TO OBSTETRICAL AND GYNECOLOGICAL CARE.**

“(a) IN GENERAL.—If a group health plan, or a health insurance issuer in connection with the provision of health insurance coverage, requires or provides for a participant, beneficiary, or enrollee to designate a participating primary care health care professional, the plan or issuer—

“(1) may not require authorization or a referral by the individual's primary care health care professional or otherwise for covered gynecological care (including preventive women's health examinations) or for covered pregnancy-related services

provided by a participating physician (including a family practice physician) who specializes or is trained and experienced in gynecology or obstetrics, respectively, to the extent such care is otherwise covered; and

“(2) shall treat the ordering of other gynecological or obstetrical care by such a participating physician as the authorization of the primary care health care professional with respect to such care under the plan or coverage.

“(b) CONSTRUCTION.—Nothing in subsection (a) shall be construed to—

“(1) waive any exclusions of coverage under the terms of the plan with respect to coverage of gynecological or obstetrical care;

“(2) preclude the group health plan or health insurance issuer involved from requiring that the gynecologist or obstetrician notify the primary care health care professional or the plan of treatment decisions; or

“(3) prevent a plan or issuer from offering, in addition to physicians described in subsection (a)(1), non-physician health care professionals who are trained and experienced in gynecology or obstetrics.

**“SEC. 2816. ACCESS TO PEDIATRIC CARE.**

“(a) PEDIATRIC CARE.—If a group health plan, or a health insurance issuer in connection with the provision of health insurance coverage, requires or provides for an enrollee to designate a participating primary care provider for a child of such enrollee, the plan or issuer shall permit the enrollee to designate a physician (including a family practice physician) who specializes or is trained and experienced in pediatrics as the child’s primary care provider.

“(b) CONSTRUCTION.—Nothing in subsection (a) shall be construed to waive any exclusions of coverage under the terms of the plan with respect to coverage of pediatric care.

**“SEC. 2817. CONTINUITY OF CARE.**

“(a) IN GENERAL.—

“(1) TERMINATION OF PROVIDER.—If a contract between a group health plan, or a health insurance issuer in connection with the provision of health insurance coverage, and a health care provider is terminated (as defined in paragraph (3)(B)), or benefits or coverage provided by a health care provider are terminated because of a change in the terms of provider participation in a group health plan, and an individual who is a participant, beneficiary, or enrollee in the plan or coverage is undergoing treatment from the provider for an ongoing special condition (as defined in paragraph (3)(A)) at the time of such termination, the plan or issuer shall—

“(A) notify the individual on a timely basis of such termination and of the right to elect continuation of coverage of treatment by the provider under this section; and

“(B) subject to subsection (c), permit the individual to elect to continue to be covered with respect to treatment by the provider of such condition during a transitional period (provided under subsection (b)).

“(2) TREATMENT OF TERMINATION OF CONTRACT WITH HEALTH INSURANCE ISSUER.—If a contract for the provision of health insurance coverage between a group health plan and a health insurance issuer is terminated and, as a result of such termination, coverage of services of a health care provider is terminated with respect to an individual, the provisions of paragraph (1) (and the succeeding provisions of this section) shall apply under the plan in the same manner as if there had been a contract between the plan and the provider that had been terminated, but only with respect to benefits that are covered under the plan after the contract termination.

“(3) DEFINITIONS.—For purposes of this section:

“(A) ONGOING SPECIAL CONDITION.—The term ‘ongoing special condition’ has the meaning given such term in section 2814(b)(3), and also includes pregnancy.

“(B) TERMINATION.—The term ‘terminated’ includes, with respect to a contract, the expiration or nonrenewal of the contract, but does not include a termination of the contract by the plan or issuer for failure to meet applicable quality standards or for fraud.

“(b) TRANSITIONAL PERIOD.—

“(1) IN GENERAL.—Except as provided in paragraphs (2) through (4), the transitional period under this subsection shall extend up to 90 days (as determined by the treating health care professional) after the date of the notice described in subsection (a)(1)(A) of the provider’s termination.

“(2) SCHEDULED SURGERY AND ORGAN TRANSPLANTATION.—If surgery or organ transplantation was scheduled for an individual before the date of the announcement of the termination of the provider status under subsection (a)(1)(A) or if the individual on such date was on an established waiting list or otherwise scheduled to have such surgery or transplantation, the transitional period under this subsection with respect to the surgery or transplantation shall extend beyond the period under paragraph (1) and until the date of discharge of the individual after completion of the surgery or transplantation.

“(3) PREGNANCY.—If—

“(A) a participant, beneficiary, or enrollee was determined to be pregnant at the time of a provider’s termination of participation, and

“(B) the provider was treating the pregnancy before date of the termination,

the transitional period under this subsection with respect to provider’s treatment of the pregnancy shall extend through the provision of post-partum care directly related to the delivery.

“(4) TERMINAL ILLNESS.—If—

“(A) a participant, beneficiary, or enrollee was determined to be terminally ill (as determined under section 1861(dd)(3)(A) of the Social Security Act) at the time of a provider’s termination of participation, and

“(B) the provider was treating the terminal illness before the date of termination,

the transitional period under this subsection shall extend for the remainder of the individual’s life for care directly related

to the treatment of the terminal illness or its medical manifestations.

“(c) PERMISSIBLE TERMS AND CONDITIONS.—A group health plan or health insurance issuer may condition coverage of continued treatment by a provider under subsection (a)(1)(B) upon the individual notifying the plan of the election of continued coverage and upon the provider agreeing to the following terms and conditions:

“(1) The provider agrees to accept reimbursement from the plan or issuer and individual involved (with respect to cost-sharing) at the rates applicable prior to the start of the transitional period as payment in full (or, in the case described in subsection (a)(2), at the rates applicable under the replacement plan or issuer after the date of the termination of the contract with the health insurance issuer) and not to impose cost-sharing with respect to the individual in an amount that would exceed the cost-sharing that could have been imposed if the contract referred to in subsection (a)(1) had not been terminated.

“(2) The provider agrees to adhere to the quality assurance standards of the plan or issuer responsible for payment under paragraph (1) and to provide to such plan or issuer necessary medical information related to the care provided.

“(3) The provider agrees otherwise to adhere to such plan’s or issuer’s policies and procedures, including procedures regarding referrals and obtaining prior authorization and providing services pursuant to a treatment plan (if any) approved by the plan or issuer.

“(d) CONSTRUCTION.—Nothing in this section shall be construed to require the coverage of benefits which would not have been covered if the provider involved remained a participating provider.

**“SEC. 2818. NETWORK ADEQUACY.**

“(a) REQUIREMENT.—A group health plan, and a health insurance issuer providing health insurance coverage, shall meet such standards for network adequacy as are established by law pursuant to this section.

“(b) DEVELOPMENT OF STANDARDS.—

“(1) ESTABLISHMENT OF PANEL.—There is established a panel to be known as the Health Care Panel to Establish Network Adequacy Standards (in this section referred to as the ‘Panel’).

“(2) DUTIES OF PANEL.—The Panel shall devise standards for group health plans and health insurance issuers that offer health insurance coverage to ensure that—

“(A) participants, beneficiaries, and enrollees have access to a sufficient number, mix, and distribution of health care professionals and providers; and

“(B) covered items and services are available and accessible to each participant, beneficiary, and enrollee—

“(i) in the service area of the plan or issuer;

“(ii) at a variety of sites of service;

“(iii) with reasonable promptness (including reasonable hours of operation and after hours services);

“(iv) with reasonable proximity to the residences or workplaces of enrollees; and

“(v) in a manner that takes into account the diverse needs of enrollees and reasonably assures continuity of care.

“(c) MEMBERSHIP.—

“(1) SIZE AND COMPOSITION.—The Panel shall be composed of 15 members. The Secretary of Health and Human Services, the Majority Leader of the Senate, and the Speaker of House of Representatives shall each appoint 1 member from representatives of private insurance organizations, consumer groups, State insurance commissioners, State medical societies, and State medical specialty societies.

“(2) TERMS OF APPOINTMENT.—The members of the Panel shall serve for the life of the Panel.

“(3) VACANCIES.—A vacancy in the Panel shall not affect the power of the remaining members to execute the duties of the Panel, but any such vacancy shall be filled in the same manner in which the original appointment was made.

“(d) PROCEDURES.—

“(1) MEETINGS.—The Panel shall meet at the call of a majority of its members.

“(2) FIRST MEETING.—The Panel shall convene not later than 60 days after the date of the enactment of the Health Care Quality and Choice Act of 1999.

“(3) QUORUM.—A quorum shall consist of a majority of the members of the Panel.

“(4) HEARINGS.—For the purpose of carrying out its duties, the Panel may hold such hearings and undertake such other activities as the Panel determines to be necessary to carry out its duties.

“(e) ADMINISTRATION.—

“(1) COMPENSATION.—Except as provided in paragraph (1), members of the Panel shall receive no additional pay, allowances, or benefits by reason of their service on the Panel.

“(2) TRAVEL EXPENSES AND PER DIEM.—Each member of the Panel who is not an officer or employee of the Federal Government shall receive travel expenses and per diem in lieu of subsistence in accordance with sections 5702 and 5703 of title 5, United States Code.

“(3) CONTRACT AUTHORITY.—The Panel may contract with and compensate government and private agencies or persons for items and services, without regard to section 3709 of the Revised Statutes (41 U.S.C. 5).

“(4) USE OF MAILS.—The Panel may use the United States mails in the same manner and under the same conditions as Federal agencies and shall, for purposes of the frank, be considered a commission of Congress as described in section 3215 of title 39, United States Code.

“(5) ADMINISTRATIVE SUPPORT SERVICES.—Upon the request of the Panel, the Secretary of Health and Human Services shall provide to the Panel on a reimbursable basis such administrative support services as the Panel may request.

“(f) REPORT AND ESTABLISHMENT OF STANDARDS.—Not later than 2 years after the first meeting, the Panel shall submit a report to Congress and the Secretary of Health and Human Services detail-

ing the standards devised under subsection (b) and recommendations regarding the implementation of such standards. Such standards shall take effect to the extent provided by Federal law enacted after the date of the submission of such report.

“(g) TERMINATION.—The Panel shall terminate on the day after submitting its report to the Secretary of Health and Human Services under subsection (f).

**“SEC. 2819. ACCESS TO EXPERIMENTAL OR INVESTIGATIONAL PRESCRIPTION DRUGS.**

“No use of a prescription drug or medical device shall be considered experimental or investigational under a group health plan or under health insurance coverage provided by a health insurance issuer if such use is included in the labeling authorized by the U.S. Food and Drug Administration under section 505, 513 or 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or under section 351 of the Public Health Service Act (42 U.S.C. 262), unless such use is demonstrated to be unsafe or ineffective.

**“SEC. 2820. COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CANCER CLINICAL TRIALS.**

“(a) COVERAGE.—

“(1) IN GENERAL.—If a group health plan (or a health insurance issuer offering health insurance coverage) provides coverage to a qualified individual (as defined in subsection (b)), the plan or issuer—

“(A) may not deny the individual participation in the clinical trial referred to in subsection (b)(2);

“(B) subject to subsections (b), (c), and (d), may not deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and services furnished in connection with participation in the trial; and

“(C) may not discriminate against the individual on the basis of the individual’s participation in such trial.

“(2) EXCLUSION OF CERTAIN COSTS.—For purposes of paragraph (1)(B), routine patient costs do not include the cost of the tests or measurements conducted primarily for the purpose of the clinical trial involved.

“(3) USE OF IN-NETWORK PROVIDERS.—If one or more participating providers is participating in a clinical trial, nothing in paragraph (1) shall be construed as preventing a plan or issuer from requiring that a qualified individual participate in the trial through such a participating provider if the provider will accept the individual as a participant in the trial.

“(b) QUALIFIED INDIVIDUAL DEFINED.—For purposes of subsection (a), the term ‘qualified individual’ means an individual who is a participant or beneficiary in a group health plan or an enrollee in health insurance coverage and who meets the following conditions:

“(1)(A) The individual has been diagnosed with cancer.

“(B) The individual is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of such illness.

“(C) The individual’s participation in the trial offers meaningful potential for significant clinical benefit for the individual.

“(2) Either—

“(A) the referring physician is a participating health care professional and has concluded that the individual’s participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1); or

“(B) the individual provides medical and scientific information establishing that the individual’s participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1).

“(c) PAYMENT.—

“(1) IN GENERAL.—Under this section a group health plan (or health insurance issuer offering health insurance) shall provide for payment for routine patient costs described in subsection (a)(2) but is not required to pay for costs of items and services that are reasonably expected to be paid for by the sponsors of an approved clinical trial.

“(2) ROUTINE PATIENT CARE COSTS.—For purposes of this section—

“(A) IN GENERAL.—The term ‘routine patient care costs’ includes the costs associated with the provision of items and services that—

“(i) would otherwise be covered under the group health plan or health insurance coverage if such items and services were not provided in connection with an approved clinical trial program; and

“(ii) are furnished according to the protocol of an approved clinical trial program.

“(B) EXCLUSION.—Such term does include the costs associated with the provision of—

“(i) an investigational drug or device, unless the Secretary has authorized the manufacturer of such drug or device to charge for such drug or device; or

“(ii) any item or service supplied without charge by the sponsor of the approved clinical trial program.

“(3) PAYMENT RATE.—In the case of covered items and services provided by—

“(A) a participating provider, the payment rate shall be at the agreed upon rate, or

“(B) a nonparticipating provider, the payment rate shall be at the rate the plan or issuer would normally pay for comparable items or services under subparagraph (A).

“(d) APPROVED CLINICAL TRIAL DEFINED.—In this section, the term ‘approved clinical trial’ means a cancer clinical research study or cancer clinical investigation approved by an Institutional Review Board.

“(e) CONSTRUCTION.—Nothing in this section shall be construed to limit a plan’s or issuer’s coverage with respect to clinical trials.

“(f) PLAN SATISFACTION OF CERTAIN REQUIREMENTS; RESPONSIBILITIES OF FIDUCIARIES.—

“(1) IN GENERAL.—For purposes of this section, insofar as a group health plan provides benefits in the form of health insurance coverage through a health insurance issuer, the plan shall be treated as meeting the requirements of this section with respect to such benefits and not be considered as failing to meet

such requirements because of a failure of the issuer to meet such requirements so long as the plan sponsor or its representatives did not cause such failure by the issuer.

“(2) CONSTRUCTION.—Nothing in this section shall be construed to affect or modify the responsibilities of the fiduciaries of a group health plan under part 4 of subtitle B of the Employee Retirement Income Security Act of 1974.

“(g) STUDY AND REPORT.—

“(1) STUDY.—The Secretary of Health and Human Services, in consultation with the Secretary and the Secretary of the Treasury, shall analyze cancer clinical research and its cost implications for managed care, including differentiation in—

“(A) the cost of patient care in trials versus standard care;

“(B) the cost effectiveness achieved in different sites of service;

“(C) research outcomes;

“(D) volume of research subjects available in different sites of service;

“(E) access to research sites and clinical trials by cancer patients;

“(F) patient cost sharing or copayment costs realized in different sites of service;

“(G) health outcomes experienced in different sites of service;

“(H) long term health care services and costs experienced in different sites of service;

“(I) morbidity and mortality experienced in different sites of service; and

“(J) patient satisfaction and preference of sites of service.

“(2) REPORT TO CONGRESS.—Not later than January 1, 2005, the Secretary of Health and Human Services shall submit a report to Congress that contains—

“(A) an assessment of any incremental cost to group health plans and health insurance issuers resulting from the provisions of this section;

“(B) a projection of expenditures to such plans and issuers resulting from this section;

“(C) an assessment of any impact on premiums resulting from this section; and

“(D) recommendations regarding action on other diseases.

## “Subtitle C—Access to Information

### “SEC. 2821. PATIENT ACCESS TO INFORMATION.

“(a) DISCLOSURE REQUIREMENT.—

“(1) GROUP HEALTH PLANS.—A group health plan shall—

“(A) provide to participants and beneficiaries at the time of initial coverage under the plan (or the effective date of this section, in the case of individuals who are participants

or beneficiaries as of such date), and at least annually thereafter, the information described in subsection (b);

“(B) provide to participants and beneficiaries, within a reasonable period (as specified by the Secretary) before or after the date of significant changes in the information described in subsection (b), information on such significant changes; and

“(C) upon request, make available to participants and beneficiaries, the Secretary, and prospective participants and beneficiaries, the information described in subsection (b) or (c).

The plan may charge a reasonable fee for provision in printed form of any of the information described in subsection (b) or (c) more than once during any plan year.

“(2) HEALTH INSURANCE ISSUERS.—A health insurance issuer in connection with the provision of health insurance coverage shall—

“(A) provide to individuals enrolled under such coverage at the time of enrollment, and at least annually thereafter, the information described in subsection (b);

“(B) provide to enrollees, within a reasonable period (as specified by the Secretary) before or after the date of significant changes in the information described in subsection (b), information in printed form on such significant changes; and

“(C) upon request, make available to the Secretary, to individuals who are prospective enrollees, and to the public the information described in subsection (b) or (c).

“(b) INFORMATION PROVIDED.—The information described in this subsection with respect to a group health plan or health insurance coverage offered by a health insurance issuer shall be provided to a participant, beneficiary, or enrollee free of charge at least once a year and includes the following:

“(1) SERVICE AREA.—The service area of the plan or issuer.

“(2) BENEFITS.—Benefits offered under the plan or coverage, including—

“(A) those that are covered benefits “(all of which shall be referred to by such relevant CPT and DRG codes as are available), limits and conditions on such benefits, and those benefits that are explicitly excluded from coverage (all of which shall be referred to by such relevant CPT and DRG codes as are available);

“(B) cost sharing, such as deductibles, coinsurance, and copayment amounts, including any liability for balance billing, any maximum limitations on out of pocket expenses, and the maximum out of pocket costs for services that are provided by nonparticipating providers or that are furnished without meeting the applicable utilization review requirements;

“(C) the extent to which benefits may be obtained from nonparticipating providers;

“(D) the extent to which a participant, beneficiary, or enrollee may select from among participating providers and

- the types of providers participating in the plan or issuer network;
- “(E) process for determining experimental coverage; and
  - “(F) use of a prescription drug formulary.
- “(3) ACCESS.—A description of the following:
- “(A) The number, mix, and distribution of providers under the plan or coverage.
  - “(B) Out-of-network coverage (if any) provided by the plan or coverage.
  - “(C) Any point-of-service option (including any supplemental premium or cost-sharing for such option).
  - “(D) The procedures for participants, beneficiaries, and enrollees to select, access, and change participating primary and specialty providers.
  - “(E) The rights and procedures for obtaining referrals (including standing referrals) to participating and non-participating providers.
  - “(F) The name, address, and telephone number of participating health care providers and an indication of whether each such provider is available to accept new patients.
  - “(G) Any limitations imposed on the selection of qualifying participating health care providers, including any limitations imposed under section 2812(b)(2).
- “(4) OUT-OF-AREA COVERAGE.—Out-of-area coverage provided by the plan or issuer.
- “(5) EMERGENCY COVERAGE.—Coverage of emergency services, including—
- “(A) the appropriate use of emergency services, including use of the 911 telephone system or its local equivalent in emergency situations and an explanation of what constitutes an emergency situation;
  - “(B) the process and procedures of the plan or issuer for obtaining emergency services; and
  - “(C) the locations of (i) emergency departments, and (ii) other settings, in which plan physicians and hospitals provide emergency services and post-stabilization care.
- “(6) PRIOR AUTHORIZATION RULES.—Rules regarding prior authorization or other review requirements that could result in noncoverage or nonpayment.
- “(7) GRIEVANCE AND APPEALS PROCEDURES.—All appeal or grievance rights and procedures under the plan or coverage, including the method for filing grievances and the time frames and circumstances for acting on grievances and appeals, who is the applicable authority with respect to the plan or issuer.
- “(8) ACCOUNTABILITY.—A description of the legal recourse options available for participants and beneficiaries under the plan including—
- “(A) the preemption that applies under section 514 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1144) to certain actions arising out of the provision of health benefits; and

“(B) the extent to which coverage decisions made by the plan are subject to internal review or any external review and the proper time frames under

“(9) QUALITY ASSURANCE.—Any information made public by an accrediting organization in the process of accreditation of the plan or issuer or any additional quality indicators the plan or issuer makes available.

“(10) INFORMATION ON ISSUER.—Notice of appropriate mailing addresses and telephone numbers to be used by participants, beneficiaries, and enrollees in seeking information or authorization for treatment.

“(11) AVAILABILITY OF INFORMATION ON REQUEST.—Notice that the information described in subsection (c) is available upon request.

“(c) INFORMATION MADE AVAILABLE UPON REQUEST.—The information described in this subsection is the following:

“(1) UTILIZATION REVIEW ACTIVITIES.—A description of procedures used and requirements (including circumstances, time frames, and appeal rights) under any utilization review program under section 2801.

“(2) GRIEVANCE AND APPEALS INFORMATION.—Information on the number of grievances and appeals and on the disposition in the aggregate of such matters.

“(3) FORMULARY RESTRICTIONS.—A description of the nature of any drug formula restrictions.

“(4) PARTICIPATING PROVIDER LIST.—A list of current participating health care providers.

“(d) CONSTRUCTION.—Nothing in this section shall be construed as requiring public disclosure of individual contracts or financial arrangements between a group health plan or health insurance issuer and any provider.

## **“Subtitle D—Protecting the Doctor-Patient Relationship**

### **“SEC. 2831. PROHIBITION OF INTERFERENCE WITH CERTAIN MEDICAL COMMUNICATIONS.**

“(a) GENERAL RULE.—The provisions of any contract or agreement, or the operation of any contract or agreement, between a group health plan or health insurance issuer in relation to health insurance coverage (including any partnership, association, or other organization that enters into or administers such a contract or agreement) and a health care provider (or group of health care providers) shall not prohibit or otherwise restrict a health care professional from advising such a participant, beneficiary, or enrollee who is a patient of the professional about the health status of the individual or medical care or treatment for the individual’s condition or disease, regardless of whether benefits for such care or treatment are provided under the plan or coverage, if the professional is acting within the lawful scope of practice.

“(b) NULLIFICATION.—Any contract provision or agreement that restricts or prohibits medical communications in violation of subsection (a) shall be null and void.

**“SEC. 2832. PROHIBITION OF DISCRIMINATION AGAINST PROVIDERS BASED ON LICENSURE.**

“(a) IN GENERAL.—A group health plan and a health insurance issuer offering health insurance coverage shall not discriminate with respect to participation or indemnification as to any provider who is acting within the scope of the provider’s license or certification under applicable State law, solely on the basis of such license or certification.

“(b) CONSTRUCTION.—Subsection (a) shall not be construed—

“(1) as requiring the coverage under a group health plan or health insurance coverage of particular benefits or services or to prohibit a plan or issuer from including providers only to the extent necessary to meet the needs of the plan’s or issuer’s participants, beneficiaries, or enrollees or from establishing any measure designed to maintain quality and control costs consistent with the responsibilities of the plan or issuer;

“(2) to override any State licensure or scope-of-practice law;

“(3) as requiring a plan or issuer that offers network coverage to include for participation every willing provider who meets the terms and conditions of the plan or issuer; or

“(4) as prohibiting a family practice physician with appropriate expertise from providing pediatric or obstetrical or gynecological care.

**“SEC. 2833. PROHIBITION AGAINST IMPROPER INCENTIVE ARRANGEMENTS.**

“(a) IN GENERAL.—A group health plan and a health insurance issuer offering health insurance coverage may not operate any physician incentive plan (as defined in subparagraph (B) of section 1876(i)(8) of the Social Security Act) unless the requirements described in clauses (i), (ii)(I), and (iii) of subparagraph (A) of such section are met with respect to such a plan.

“(b) APPLICATION.—For purposes of carrying out paragraph (1), any reference in section 1876(i)(8) of the Social Security Act to the Secretary, an eligible organization, or an individual enrolled with the organization shall be treated as a reference to the applicable authority, a group health plan or health insurance issuer, respectively, and a participant, beneficiary, or enrollee with the plan or organization, respectively.

“(c) CONSTRUCTION.—Nothing in this section shall be construed as prohibiting all capitation and similar arrangements or all provider discount arrangements.

**“SEC. 2834. PAYMENT OF CLEAN CLAIMS.**

“A group health plan, and a health insurance issuer offering group health insurance coverage, shall provide for prompt payment of claims submitted for health care services or supplies furnished to a participant, beneficiary, or enrollee with respect to benefits covered by the plan or issuer, in a manner consistent with the provisions of sections 1816(c)(2) and 1842(c)(2) of the Social Security Act (42 U.S.C. 1395h(c)(2) and 42 U.S.C. 1395u(c)(2)), except that for purposes of this section, subparagraph (C) of section 1816(c)(2) of the Social Security Act shall be treated as applying to claims received from a participant, beneficiary, or enrollee as well as claims referred to in such subparagraph.

## “Subtitle E—Definitions

**“SEC. 2841. DEFINITIONS.**

“(a) INCORPORATION OF GENERAL DEFINITIONS.—Except as otherwise provided, the provisions of section 2791 shall apply for purposes of this title in the same manner as they apply for purposes of title XXVII.

“(b) ADDITIONAL DEFINITIONS.—For purposes of this title:

“(1) APPLICABLE AUTHORITY.—The term ‘applicable authority’ means—

“(A) in the case of a group health plan, the Secretary of Health and Human Services; and

“(B) in the case of a health insurance issuer with respect to a specific provision of this title, the applicable State authority (as defined in section 2791(d) of the Public Health Service Act), or the Secretary of Health and Human Services, if such Secretary is enforcing such provision under section 2722(a)(2) or 2761(a)(2) of the Public Health Service Act.

“(2) CLINICAL PEER.—The term ‘clinical peer’ means, with respect to a review or appeal, a practicing physician or other health care professional who holds a nonrestricted license and who is—

“(A) appropriately certified by a nationally recognized, peer reviewed accrediting body in the same or similar specialty as typically manages the medical condition, procedure, or treatment under review or appeal, or

“(B) is trained and experienced in managing such condition, procedure, or treatment,

and includes a pediatric specialist where appropriate; except that only a physician may be a clinical peer with respect to the review or appeal of treatment recommended or rendered by a physician.

“(3) ENROLLEE.—The term ‘enrollee’ means, with respect to health insurance coverage offered by a health insurance issuer, an individual enrolled with the issuer to receive such coverage.

“(4) HEALTH CARE PROFESSIONAL.—The term ‘health care professional’ means an individual who is licensed, accredited, or certified under State law to provide specified health care services and who is operating within the scope of such licensure, accreditation, or certification.

“(5) HEALTH CARE PROVIDER.—The term ‘health care provider’ includes a physician or other health care professional, as well as an institutional or other facility or agency that provides health care services and that is licensed, accredited, or certified to provide health care items and services under applicable State law.

“(6) NETWORK.—The term ‘network’ means, with respect to a group health plan or health insurance issuer offering health insurance coverage, the participating health care professionals and providers through whom the plan or issuer provides health care items and services to participants, beneficiaries, or enrollees.

“(7) NONPARTICIPATING.—The term ‘nonparticipating’ means, with respect to a health care provider that provides health care items and services to a participant, beneficiary, or enrollee under group health plan or health insurance coverage, a health care provider that is not a participating health care provider with respect to such items and services.

“(8) PARTICIPATING.—The term ‘participating’ means, with respect to a health care provider that provides health care items and services to a participant, beneficiary, or enrollee under group health plan or health insurance coverage offered by a health insurance issuer, a health care provider that furnishes such items and services under a contract or other arrangement with the plan or issuer.

“(9) PHYSICIAN.—The term ‘physician’ means an allopathic or osteopathic physician.

“(10) PRACTICING PHYSICIAN.—The term ‘practicing physician’ means a physician who is licensed in the State in which the physician furnishes professional services and who provides professional services to individual patients on average at least two full days per week.

“(11) PRIOR AUTHORIZATION.—The term ‘prior authorization’ means the process of obtaining prior approval from a health insurance issuer or group health plan for the provision or coverage of medical services.

**“SEC. 2842. RULE OF CONSTRUCTION.**

“(a) CONTINUED APPLICABILITY OF STATE LAW WITH RESPECT TO HEALTH INSURANCE ISSUERS.—

“(1) IN GENERAL.—Subject to paragraph (2), this title shall not be construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers except to the extent that such standard or requirement prevents the application of a requirement of this title.

“(2) CONTINUED PREEMPTION WITH RESPECT TO GROUP HEALTH PLANS.—Nothing in this title shall be construed to affect or modify the provisions of section 514 of the Employee Retirement Income Security Act of 1974.

“(b) DEFINITIONS.—For purposes of this section:

“(1) STATE LAW.—The term ‘State law’ includes all laws, decisions, rules, regulations, or other State action having the effect of law, of any State. A law of the United States applicable only to the District of Columbia shall be treated as a State law rather than a law of the United States.

“(2) STATE.—The term ‘State’ includes a State, the District of Columbia, the Northern Mariana Islands, any political subdivisions of a State or such Islands, or any agency or instrumentality of either.

**“SEC. 2843. EXCLUSIONS.**

“(a) NO BENEFIT REQUIREMENTS.—Nothing in this title shall be construed to require a group health plan or a health insurance issuer offering health insurance coverage to provide specific benefits under the terms of such plan or coverage, other than those provided under the terms of such plan or coverage.

“(b) **EXCLUSION FOR FEE-FOR-SERVICE COVERAGE.**—

“(1) **IN GENERAL.**—

“(A) **GROUP HEALTH PLANS.**—The provisions of sections 2811 through 2821 shall not apply to a group health plan if the only coverage offered under the plan is fee-for-service coverage (as defined in paragraph (2)).

“(B) **HEALTH INSURANCE COVERAGE.**—The provisions of sections 2801 through 2821 shall not apply to health insurance coverage if the only coverage offered under the coverage is fee-for-service coverage (as defined in paragraph (2)).

“(2) **FEE-FOR-SERVICE COVERAGE DEFINED.**—For purposes of this subsection, the term ‘fee-for-service coverage’ means coverage under a group health plan or health insurance coverage that—

“(A) reimburses hospitals, health professionals, and other providers on a fee-for-service basis without placing the provider at financial risk;

“(B) does not vary reimbursement for such a provider based on an agreement to contract terms and conditions or the utilization of health care items or services relating to such provider;

“(C) allows access to any provider that is lawfully authorized to provide the covered services and agree to accept the terms and conditions of payment established under the plan or by the issuer; and

“(D) for which the plan or issuer does not require prior authorization before providing for any health care services.

“**SEC. 2844. COVERAGE OF LIMITED SCOPE PLANS.**

“Only for purposes of applying the requirements of this title under sections 2707 and 2753, section 2791(c)(2)(A) shall be deemed not to apply.

“**SEC. 2845. REGULATIONS.**

“The Secretary of Health and Human Services shall issue such regulations as may be necessary or appropriate to carry out this title under sections 2707 and 2753. The Secretary may promulgate such regulations in the form of interim final rules as may be necessary to carry out this title in a timely manner.

“**SEC. 2846. LIMITATION ON APPLICATION OF PROVISIONS RELATING TO GROUP HEALTH PLANS.**

“The requirements of this title shall apply with respect to group health plans only—

“(1) in the case of a plan that is a non-Federal governmental plan (as defined in section 2791(d)(8)(C)), and

“(2) with respect to health insurance coverage offered in connection with a group health plan (including such a plan that is a church plan or a governmental plan), except that subtitle A shall apply with respect to such coverage only to the extent it is offered in connection with a non-Federal governmental plan or a church plan.”.

## **TITLE II—AMENDMENTS TO THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974**

### **SEC. 201. APPLICATION OF PATIENT PROTECTION STANDARDS TO GROUP HEALTH PLANS AND GROUP HEALTH INSURANCE COVERAGE UNDER THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974.**

(a) **IN GENERAL.**—Subpart B of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 is amended by adding at the end the following new section:

#### **“SEC. 714. PATIENT PROTECTION STANDARDS.**

“A group health plan (and a health insurance issuer offering group health insurance coverage in connection with such a plan) shall comply with the requirements of part 8 and such requirements shall be deemed to be incorporated into this section.”.

(b) **SATISFACTION OF ERISA CLAIMS PROCEDURE REQUIREMENT.**—Section 503 of such Act (29 U.S.C. 1133) is amended by inserting “(a)” after “SEC. 503.” and by adding at the end the following new subsection:

“(b) In the case of a group health plan (as defined in section 733) compliance with the requirements of subpart A of part 8 in the case of a claims denial shall be deemed compliance with subsection (a) with respect to such claims denial. For purposes of applying the previous sentence, the exceptions provided under section 732 shall be deemed to apply.”.

(c) **CONFORMING AMENDMENTS.**—(1) Section 732(a) of such Act (29 U.S.C. 1185(a)) is amended by striking “section 711” and inserting “sections 711 and 714”.

(2) The table of contents in section 1 of such Act is amended by inserting after the item relating to section 713 the following new item:

“Sec. 714. Patient protection standards.”.

### **SEC. 202. IMPROVING MANAGED CARE.**

(a) **IN GENERAL.**—Subtitle B of title I of the Employee Retirement Income Security Act of 1974 is amended by adding at the end the following new part:

“PART 8—IMPROVING MANAGED CARE

“SUBPART A—GRIEVANCE AND APPEALS

#### **“SEC. 801. UTILIZATION REVIEW ACTIVITIES.**

“(a) **COMPLIANCE WITH REQUIREMENTS.**—

“(1) **IN GENERAL.**—A group health plan, and a health insurance issuer that provides health insurance coverage in connection with such a plan, shall conduct utilization review activities in connection with the provision of benefits under such plan or coverage only in accordance with a utilization review program that meets the requirements of this section.

“(2) **USE OF OUTSIDE AGENTS.**—Nothing in this section shall be construed as preventing a group health plan or health insurance issuer from arranging through a contract or otherwise

for persons or entities to conduct utilization review activities on behalf of the plan or issuer, so long as such activities are conducted in accordance with a utilization review program that meets the requirements of this section.

“(3) UTILIZATION REVIEW DEFINED.—For purposes of this section, the terms ‘utilization review’ and ‘utilization review activities’ mean procedures used to monitor or evaluate the use or coverage, clinical necessity, appropriateness, efficacy, or efficiency of health care services, procedures or settings, and includes prospective review, concurrent review, second opinions, case management, discharge planning, or retrospective review.

“(b) WRITTEN POLICIES AND CRITERIA.—

“(1) WRITTEN POLICIES.—A utilization review program shall be conducted consistent with written policies and procedures that govern all aspects of the program.

“(2) USE OF WRITTEN CRITERIA.—

“(A) IN GENERAL.—Such a program shall utilize written clinical review criteria developed with input from a range of appropriate practicing physicians, as determined by the plan, pursuant to the program. Such criteria shall include written clinical review criteria that are based on valid clinical evidence where available and that are directed specifically at meeting the needs of at-risk populations and covered individuals with chronic conditions or severe illnesses, including gender-specific criteria and pediatric-specific criteria where available and appropriate.

“(B) CONTINUING USE OF STANDARDS IN RETROSPECTIVE REVIEW.—If a health care service has been specifically pre-authorized or approved for a participant or beneficiary under such a program, the program shall not, pursuant to retrospective review, revise or modify the specific standards, criteria, or procedures used for the utilization review for procedures, treatment, and services delivered to the individual during the same course of treatment.

“(C) REVIEW OF SAMPLE OF CLAIMS DENIALS.—Such a program shall provide for periodic evaluation at reasonable intervals of the clinical appropriateness of a sample of denials of claims for benefits.

“(c) CONDUCT OF PROGRAM ACTIVITIES.—

“(1) ADMINISTRATION BY HEALTH CARE PROFESSIONALS.—A utilization review program shall be administered by appropriate physician specialists who shall be selected by the plan or issuer and who shall oversee review decisions.

“(2) USE OF QUALIFIED, INDEPENDENT PERSONNEL.—

“(A) IN GENERAL.—A utilization review program shall provide for the conduct of utilization review activities only through personnel who are qualified and have received appropriate training in the conduct of such activities under the program.

“(B) PROHIBITION OF CONTINGENT COMPENSATION ARRANGEMENTS.—Such a program shall not, with respect to utilization review activities, permit or provide compensation or anything of value to its employees, agents, or contractors in a manner that encourages denials of claims for

benefits. This subparagraph shall not preclude any capitation arrangements between plans and providers.

“(C) PROHIBITION OF CONFLICTS.—Such a program shall not permit a health care professional who is providing health care services to an individual to perform utilization review activities in connection with the health care services being provided to the individual.

“(3) ACCESSIBILITY OF REVIEW.—Such a program shall provide that appropriate personnel performing utilization review activities under the program, including the utilization review administrator, are reasonably accessible by toll-free telephone during normal business hours to discuss patient care and allow response to telephone requests, and that appropriate provision is made to receive and respond promptly to calls received during other hours.

“(4) LIMITS ON FREQUENCY.—Such a program shall not provide for the performance of utilization review activities with respect to a class of services furnished to an individual more frequently than is reasonably required to assess whether the services under review are medically necessary or appropriate.

“(d) DEADLINE FOR DETERMINATIONS.—

“(1) PRIOR AUTHORIZATION SERVICES.—

“(A) IN GENERAL.—Except as provided in paragraph (2), in the case of a utilization review activity involving the prior authorization of health care items and services for an individual, the utilization review program shall make a determination concerning such authorization, and provide notice of the determination to the individual or the individual’s designee and the individual’s health care provider by telephone and in printed or electronic form, no later than the deadline specified in subparagraph (B). The provider involved shall provide timely access to information relevant to the matter of the review decision.

“(B) DEADLINE.—

“(i) IN GENERAL.—Subject to clauses (ii) and (iii), the deadline specified in this subparagraph is 14 days after the earliest date as of which the request for prior authorization has been received and all necessary information has been provided.

“(ii) EXTENSION PERMITTED WHERE NOTICE OF ADDITIONAL INFORMATION REQUIRED.—If a utilization review program—

“(I) receives a request for a prior authorization,

“(II) determines that additional information is necessary to complete the review and make the determination on the request,

“(III) notifies the requester, not later than 5 business days after the date of receiving the request, of the need for such specified additional information, and

“(IV) requires the requester to submit specified information not later than 2 business days after notification,

the deadline specified in this subparagraph is 14 days after the date the program receives the specified additional information, but in no case later than 28 days after the date of receipt of the request for the prior authorization. This clause shall not apply if the deadline is specified in clause (iii).

“(iii) EXPEDITED CASES.—In the case of a situation described in section 802(c)(1)(A), the deadline specified in this subparagraph is 48 hours after the time of the request for prior authorization.

“(2) ONGOING CARE.—

“(A) CONCURRENT REVIEW.—

“(i) IN GENERAL.—Subject to subparagraph (B), in the case of a concurrent review of ongoing care (including hospitalization), which results in a termination or reduction of such care, the plan must provide by telephone and in printed or electronic form notice of the concurrent review determination to the individual or the individual’s designee and the individual’s health care provider as soon as possible in accordance with the medical exigencies of the case, with sufficient time prior to the termination or reduction to allow for an appeal under section 802(c)(1)(A) to be completed before the termination or reduction takes effect.

“(ii) CONTENTS OF NOTICE.—Such notice shall include, with respect to ongoing health care items and services, the number of ongoing services approved, the new total of approved services, the date of onset of services, and the next review date, if any, as well as a statement of the individual’s rights to further appeal.

“(B) EXCEPTION.—Subparagraph (A) shall not be interpreted as requiring plans or issuers to provide coverage of care that would exceed the coverage limitations for such care.

“(3) PREVIOUSLY PROVIDED SERVICES.—In the case of a utilization review activity involving retrospective review of health care services previously provided for an individual, the utilization review program shall make a determination concerning such services, and provide notice of the determination to the individual or the individual’s designee and the individual’s health care provider by telephone and in printed or electronic form, within 30 days of the date of receipt of information that is reasonably necessary to make such determination, but in no case later than 60 days after the date of receipt of the claim for benefits.

“(4) FAILURE TO MEET DEADLINE.—In a case in which a group health plan or health insurance issuer fails to make a determination on a claim for benefit under paragraph (1), (2)(A), or (3) by the applicable deadline established under the respective paragraph, the failure shall be treated under this subpart as a denial of the claim as of the date of the deadline.

“(5) REFERENCE TO SPECIAL RULES FOR EMERGENCY SERVICES, MAINTENANCE CARE, POST-STABILIZATION CARE, AND EMERGENCY AMBULANCE SERVICES.—For waiver of prior authorization requirements in certain cases involving emergency services, maintenance care and post-stabilization care, and emergency ambulance services, see subsections (a)(1), (b), and (c)(1) of section 813, respectively.

“(e) NOTICE OF DENIALS OF CLAIMS FOR BENEFITS.—

“(1) IN GENERAL.—Notice of a denial of claims for benefits under a utilization review program shall be provided in printed or electronic form and written in a manner calculated to be understood by the participant or beneficiary and shall include—

“(A) the reasons for the denial (including the clinical rationale);

“(B) instructions on how to initiate an appeal under section 802; and

“(C) notice of the availability, upon request of the individual (or the individual’s designee) of the clinical review criteria relied upon to make such denial.

“(2) SPECIFICATION OF ANY ADDITIONAL INFORMATION.—Such a notice shall also specify what (if any) additional necessary information must be provided to, or obtained by, the person making the denial in order to make a decision on such an appeal.

“(f) CLAIM FOR BENEFITS AND DENIAL OF CLAIM FOR BENEFITS DEFINED.—For purposes of this subpart:

“(1) CLAIM FOR BENEFITS.—The term ‘claim for benefits’ means any request for coverage (including authorization of coverage), or for payment in whole or in part, for an item or service under a group health plan or health insurance coverage offered in connection with such a plan.

“(2) DENIAL OF CLAIM FOR BENEFITS.—The term ‘denial’ means, with respect to a claim for benefits, a denial, or a failure to act on a timely basis upon, in whole or in part, the claim for benefits and includes a failure to provide or pay for benefits (including items and services) required to be provided or paid for under this part.

**“SEC. 802. INTERNAL APPEALS PROCEDURES.**

“(a) RIGHT OF REVIEW.—

“(1) IN GENERAL.—Each group health plan, and each health insurance issuer offering health insurance coverage in connection with such a plan—

“(A) shall provide adequate notice in written or electronic form to any participant or beneficiary under such plan whose claim for benefits under the plan or coverage has been denied (within the meaning of section 801(f)(2)), setting forth the specific reasons for such denial of claim for benefits and rights to any further review or appeal, written in layman’s terms to be understood by the participant or beneficiary; and

“(B) shall afford such a participant or beneficiary (and any provider or other person acting on behalf of such an individual with the individual’s consent or without such consent if the individual is medically unable to provide such consent) who is dissatisfied with such a denial of

claim for benefits a reasonable opportunity of not less than 180 days to request and obtain a full and fair review by a named fiduciary (with respect to such plan) or named appropriate individual (with respect to such coverage) of the decision denying the claim.

“(2) TREATMENT OF ORAL REQUESTS.—The request for review under paragraph (1)(B) may be made orally, but, in the case of an oral request, shall be followed by a request in written or electronic form.

“(b) INTERNAL REVIEW PROCESS.—

“(1) CONDUCT OF REVIEW.—

“(A) IN GENERAL.—A review of a denial of claim under this section shall be made by an individual (who shall be a physician in a case involving medical judgment) who has been selected by the plan or issuer and who did not make the initial denial in the internally appealable decision, except that in the case of limited scope coverage (as defined in subparagraph (B)) an appropriate specialist shall review the decision.

“(B) LIMITED SCOPE COVERAGE DEFINED.—For purposes of subparagraph (A), the term ‘limited scope coverage’ means a group health plan or health insurance coverage the only benefits under which are for benefits described in section 2791(c)(2)(A) of the Public Health Service Act (42 U.S.C. 300gg–91(c)(2)).

“(2) TIME LIMITS FOR INTERNAL REVIEWS.—

“(A) IN GENERAL.—Having received such a request for review of a denial of claim, the plan or issuer shall, in accordance with the medical exigencies of the case but not later than the deadline specified in subparagraph (B), complete the review on the denial and transmit to the participant, beneficiary, or other person involved a decision that affirms, reverses, or modifies the denial. If the decision does not reverse the denial, the plan or issuer shall transmit, in printed or electronic form, a notice that sets forth the grounds for such decision and that includes a description of rights to any further appeal. Such decision shall be treated as the final decision of the plan. Failure to issue such a decision by such deadline shall be treated as a final decision affirming the denial of claim.

“(B) DEADLINE.—

“(i) IN GENERAL.—Subject to clauses (ii) and (iii), the deadline specified in this subparagraph is 14 days after the earliest date as of which the request for prior authorization has been received and all necessary information has been provided. The provider involved shall provide timely access to information relevant to the matter of the review decision.

“(ii) EXTENSION PERMITTED WHERE NOTICE OF ADDITIONAL INFORMATION REQUIRED.—If a group health plan or health insurance issuer—

“(I) receives a request for internal review,

“(II) determines that additional information is necessary to complete the review and make the determination on the request,

“(III) notifies the requester, not later than 5 business days after the date of receiving the request, of the need for such specified additional information, and

“(IV) requires the requester to submit specified information not later than 48 hours after notification,

the deadline specified in this subparagraph is 14 days after the date the plan or issuer receives the specified additional information, but in no case later than 28 days after the date of receipt of the request for the internal review. This clause shall not apply if the deadline is specified in clause (iii).

“(iii) EXPEDITED CASES.—In the case of a situation described in subsection (c)(1)(A), the deadline specified in this subparagraph is 48 hours after the time of request for review.

“(c) EXPEDITED REVIEW PROCESS.—

“(1) IN GENERAL.—A group health plan, and a health insurance issuer, shall establish procedures in writing for the expedited consideration of requests for review under subsection (b) in situations—

“(A) in which, as determined by the plan or issuer or as certified in writing by a treating physician, the application of the normal timeframe for making the determination could seriously jeopardize the life or health of the participant or beneficiary or such individual’s ability to regain maximum function; or

“(B) described in section 801(d)(2) (relating to requests for continuation of ongoing care which would otherwise be reduced or terminated).

“(2) PROCESS.—Under such procedures—

“(A) the request for expedited review may be submitted orally or in writing by an individual or provider who is otherwise entitled to request the review;

“(B) all necessary information, including the plan’s or issuer’s decision, shall be transmitted between the plan or issuer and the requester by telephone, facsimile, or other similarly expeditious available method; and

“(C) the plan or issuer shall expedite the review in the case of any of the situations described in subparagraph (A) or (B) of paragraph (1).

“(3) DEADLINE FOR DECISION.—The decision on the expedited review must be made and communicated to the parties as soon as possible in accordance with the medical exigencies of the case, and in no event later than 48 hours after the time of receipt of the request for expedited review, except that in a case described in paragraph (1)(B), the decision must be made before the end of the approved period of care.

“(d) WAIVER OF PROCESS.—A plan or issuer may waive its rights for an internal review under subsection (b). In such case the partic-

ipant or beneficiary involved (and any designee or provider involved) shall be relieved of any obligation to complete the review involved and may, at the option of such participant, beneficiary, designee, or provider, proceed directly to seek further appeal through any applicable external appeals process.

**“SEC. 803. EXTERNAL APPEALS PROCEDURES.**

**“(a) RIGHT TO EXTERNAL APPEAL.—**

**“(1) IN GENERAL.—**A group health plan, and a health insurance issuer offering health insurance coverage in connection with such a plan, shall provide for an external appeals process that meets the requirements of this section in the case of an externally appealable decision described in paragraph (2), for which a timely appeal is made (within a reasonable period not to exceed 365 days) either by the plan or issuer or by the participant or beneficiary (and any provider or other person acting on behalf of such an individual with the individual’s consent or without such consent if such an individual is medically unable to provide such consent).

**“(2) EXTERNALLY APPEALABLE DECISION DEFINED.—**

**“(A) IN GENERAL.—**For purposes of this section, the term ‘externally appealable decision’ means a denial of claim for benefits (as defined in section 801(f)(2)), if—

“(i) the item or service involved is covered under the plan or coverage,

“(ii) the amount involved exceeds \$100, increased or decreased, for each calendar year that ends after December 31, 2001, by the same percentage as the percentage by which the medical care expenditure category of the Consumer Price Index for All Urban Consumers (United States city average), published by the Bureau of Labor Statistics, for September of the preceding calendar year has increased or decreased from such index for September 2000, and

“(iii) the requirements of subparagraph (B) are met with respect to such denial.

Such term also includes a failure to meet an applicable deadline for internal review under section 802 or such standards as are established pursuant to section 818.

**“(B) REQUIREMENTS.—**For purposes of subparagraph (A)(iii), the requirements of this subparagraph are met with respect to a denial of a claim for benefits if—

“(i) the denial is based in whole or in part on a decision that the item or service is not medically necessary or appropriate or is investigational or experimental, or

“(ii) in such denial, the decision as to whether an item or service is covered involves a medical judgment.

**“(C) EXCLUSIONS.—**The term ‘externally appealable decision’ does not include—

“(i) specific exclusions or express limitations on the amount, duration, or scope of coverage; or

“(ii) a decision regarding eligibility for any benefits.

**“(3) EXHAUSTION OF INTERNAL REVIEW PROCESS.—**Except as provided under section 802(d), a plan or issuer may condition the use of an external appeal process in the case of an exter-

nally appealable decision upon a final decision in an internal review under section 802, but only if the decision is made in a timely basis consistent with the deadlines provided under this subpart.

“(4) FILING FEE REQUIREMENT.—

“(A) IN GENERAL.—A plan or issuer may condition the use of an external appeal process upon payment in advance to the plan or issuer of a \$25 filing fee.

“(B) REFUNDING FEE IN CASE OF SUCCESSFUL APPEALS.—The plan or issuer shall refund payment of the filing fee under this paragraph if the recommendation of the external appeal entity is to reverse the denial of a claim for benefits which is the subject of the appeal.

“(b) GENERAL ELEMENTS OF EXTERNAL APPEALS PROCESS.—

“(1) USE OF QUALIFIED EXTERNAL APPEAL ENTITY.—

“(A) IN GENERAL.—The external appeal process under this section of a plan or issuer shall be conducted between the plan or issuer and one or more qualified external appeal entities (as defined in subsection (c)). Nothing in this subsection shall be construed as requiring that such procedures provide for the selection for any plan of more than one such entity.

“(B) LIMITATION ON PLAN OR ISSUER SELECTION.—The Secretary shall implement procedures to assure that the selection process among qualified external appeal entities will not create any incentives for external appeal entities to make a decision in a biased manner.

“(C) OTHER TERMS AND CONDITIONS.—The terms and conditions of this paragraph shall be consistent with the standards the Secretary shall establish to assure there is no real or apparent conflict of interest in the conduct of external appeal activities. All costs of the process (except those incurred by the participant, beneficiary, or treating professional in support of the appeal) shall be paid by the plan or issuer, and not by the participant or beneficiary. The previous sentence shall not be construed as applying to the imposition of a filing fee under subsection (a)(4).

“(2) ELEMENTS OF PROCESS.—An external appeal process shall be conducted consistent with standards established by the Secretary that include at least the following:

“(A) FAIR AND DE NOVO DETERMINATION.—The process shall provide for a fair, de novo determination described in subparagraph (B) based on evidence described in subparagraphs (C) and (D).

“(B) STANDARD OF REVIEW.—An external appeal entity shall determine whether the plan’s or issuer’s decision is appropriate for the medical condition of the patient involved (as determined by the entity) taking into account as of the time of the entity’s determination the patient’s medical condition and any relevant and reliable evidence the entity obtains under subparagraphs (C) and (D). If the entity determines the decision is appropriate for such condition, the entity shall affirm the decision and to the extent that the entity determines the decision is not appropriate

for such condition, the entity shall reverse the decision. Nothing in this subparagraph shall be construed as providing for coverage of items or services not provided or covered by the plan or issuer.

“(C) REQUIRED CONSIDERATION OF CERTAIN MATTERS.—In making such determination, the external appeal entity shall consider, but not be bound by—

“(i) any language in the plan or coverage document relating to the definitions of the terms medical necessity, medically necessary or appropriate, or experimental, investigational, or related terms;

“(ii) the decision made by the plan or issuer upon internal review under section 802 and any guidelines or standards used by the plan or issuer in reaching such decision; and

“(iii) the opinion of the individual’s treating physician or health care professional.

The entity also shall consider any personal health and medical information supplied with respect to the individual whose denial of claim for benefits has been appealed. The entity also shall consider the results of studies that meet professionally recognized standards of validity and replicability or that have been published in peer-reviewed journals.

“(D) ADDITIONAL EVIDENCE.—Such entity may also take into consideration but not be limited to the following evidence (to the extent available):

“(i) The results of professional consensus conferences.

“(ii) Practice and treatment policies.

“(iii) Community standard of care.

“(iv) Generally accepted principles of professional medical practice consistent with the best practice of medicine.

“(v) To the extent that the entity determines it to be free of any conflict of interest, the opinions of individuals who are qualified as experts in one or more fields of health care which are directly related to the matters under appeal.

“(vi) To the extent that the entity determines it to be free of any conflict of interest, the results of peer reviews conducted by the plan or issuer involved.

“(E) DETERMINATION CONCERNING EXTERNALLY APPEALABLE DECISIONS.—

“(i) IN GENERAL.—A qualified external appeal entity shall determine—

“(I) whether a denial of claim for benefits is an externally appealable decision (within the meaning of subsection (a)(2));

“(II) whether an externally appealable decision involves an expedited appeal;

“(III) for purposes of initiating an external review, whether the internal review process has been completed; and

“(IV) whether the item or services is covered under the plan or coverage.

“(ii) CONSTRUCTION.—Nothing in a determination by a qualified external appeal entity under this section shall be construed as authorizing, or providing for, coverage of items and services for which benefits are not provided under the plan or coverage.

“(F) OPPORTUNITY TO SUBMIT EVIDENCE.—Each party to an externally appealable decision may submit evidence related to the issues in dispute.

“(G) PROVISION OF INFORMATION.—The plan or issuer involved shall provide to the external appeal entity timely access to information and to provisions of the plan or health insurance coverage relating to the matter of the externally appealable decision, as determined by the entity. The provider involved shall provide to the external appeal entity timely access to information relevant to the matter of the externally appealable decision, as determined by the entity.

“(H) TIMELY DECISIONS.—A determination by the external appeal entity on the decision shall—

“(i) be made orally or in written or electronic form and, if it is made orally, shall be supplied to the parties in written or electronic form as soon as possible;

“(ii) be made in accordance with the medical exigencies of the case involved, but in no event later than 21 days after the date (or, in the case of an expedited appeal, 48 hours after the time) of requesting an external appeal of the decision;

“(iii) state, in layperson’s language, the scientific rationale for such determination as well as the basis for such determination, including, if relevant, any basis in the terms or conditions of the plan or coverage; and

“(iv) inform the participant or beneficiary of the individual’s rights (including any limitation on such rights) to seek binding arbitration or further review by the courts (or other process) of the external appeal determination.

“(I) COMPLIANCE WITH DETERMINATION.—If the external appeal entity determines that a denial of a claim for benefits was not reasonable and reverses the denial, the plan or issuer—

“(i) shall (upon the receipt of the determination) authorize benefits in accordance with such determination;

“(ii) shall take such actions as may be necessary to provide benefits (including items or services) in a timely manner consistent with such determination; and

“(iii) shall submit information to the entity documenting compliance with the entity’s determination and this subparagraph.

“(J) CONSTRUCTION.—Nothing in this paragraph shall be construed as providing for coverage of items and services

for which benefits are not provided under the plan or coverage.

“(c) QUALIFICATIONS OF EXTERNAL APPEAL ENTITIES.—

“(1) IN GENERAL.—For purposes of this section, the term ‘qualified external appeal entity’ means, in relation to a plan or issuer, an entity that is certified under paragraph (2) as meeting the following requirements:

“(A) The entity meets the independence requirements of paragraph (3).

“(B) The entity conducts external appeal activities through at least three clinical peers who are practicing physicians.

“(C) The entity has sufficient medical, legal, and other expertise and sufficient staffing to conduct external appeal activities for the plan or issuer on a timely basis consistent with subsection (b)(2)(G).

“(2) INITIAL CERTIFICATION OF EXTERNAL APPEAL ENTITIES.—

“(A) IN GENERAL.—In order to be treated as a qualified external appeal entity with respect to a group health plan or a health insurance issuer in connection with a group health plan, the entity must be certified (and, in accordance with subparagraph (B), periodically recertified), under such standards as may be prescribed by the Secretary, as meeting the requirements of paragraph (1)—

“(i) by the Secretary;

“(ii) under a process recognized or approved by the Secretary; or

“(iii) to the extent provided in subparagraph (C)(i), by a qualified private standard-setting organization (certified under such subparagraph), if elected by the entity.

“(B) RECERTIFICATION PROCESS.—The Secretary shall develop standards for the recertification of external appeal entities. Such standards shall include a review of—

“(i) the number of cases reviewed;

“(ii) a summary of the disposition of those cases;

“(iii) the length of time in making determinations on those cases;

“(iv) updated information of what was required to be submitted as a condition of certification for the entity’s performance of external appeal activities; and

“(v) information necessary to assure that the entity meets the independence requirements (described in paragraph (3)) with respect to plans and issuers for which it conducts external review activities.

“(C) CERTIFICATION OF QUALIFIED PRIVATE STANDARD-SETTING ORGANIZATIONS.—For purposes of subparagraph (A)(iii), the Secretary shall provide for a process for certification (and periodic recertification) of qualified private standard-setting organizations which provide for certification of external appeal entities. Such an organization shall only be certified if the organization does not certify an external appeal entity unless it meets standards at least as stringent as the standards required for certifi-

cation of such an entity by the Secretary under subparagraph (A)(i).

“(D) CONSTRUCTION.—Nothing in subparagraph (A) shall be construed as permitting the Secretary to delegate certification or regulatory authority under clause (i) of such subparagraph to any person outside the Department of Labor.

“(3) INDEPENDENCE REQUIREMENTS.—

“(A) IN GENERAL.—A clinical peer or other entity meets the independence requirements of this paragraph if—

“(i) the peer or entity is not affiliated with any related party;

“(ii) any compensation received by such peer or entity in connection with the external review is reasonable and not contingent on any decision rendered by the peer or entity;

“(iii) the plan and the issuer (if any) have no recourse against the peer or entity in connection with the external review; and

“(iv) the peer or entity does not otherwise have a conflict of interest with a related party.

“(B) RELATED PARTY.—For purposes of this paragraph, the term ‘related party’ means—

“(i) a group health plan or health insurance coverage offered in connection with such a plan, the plan or the health insurance issuer offering such coverage, or any plan sponsor, fiduciary, officer, director, or management employee of such plan or issuer;

“(ii) the health care professional that provided the health care involved in the coverage decision;

“(iii) the institution at which the health care involved in the coverage decision is provided; or

“(iv) the manufacturer of any drug or other item that was included in the health care involved in the coverage decision.

“(C) AFFILIATED.—For purposes of this paragraph, the term ‘affiliated’ means, in connection with any peer or entity, having a familial, financial, or fiduciary relationship with such peer or entity.

“(4) LIMITATION ON LIABILITY OF REVIEWERS.—No qualified external appeal entity having a contract with a plan or issuer under this part and no person who is employed by any such entity or who furnishes professional services to such entity, shall be held by reason of the performance of any duty, function, or activity required or authorized pursuant to this section, to have violated any criminal law, or to be civilly liable under any law of the United States or of any State (or political subdivision thereof) if due care was exercised in the performance of such duty, function, or activity and there was no actual malice or gross misconduct in the performance of such duty, function, or activity.

“(d) EXTERNAL APPEAL DETERMINATION BINDING ON PLAN.—

“(1) IN GENERAL.—The determination by an external appeal entity shall be binding on the plan (and issuer, if any) involved in the determination.

“(2) PROTECTION OF LEGAL RIGHTS.—Nothing in this subpart shall be construed as removing any legal rights of participants, beneficiaries, and others under State or Federal law, including the right to file judicial actions to enforce rights.

“(e) PENALTIES AGAINST AUTHORIZED OFFICIALS FOR REFUSING TO AUTHORIZE THE DETERMINATION OF AN EXTERNAL APPEAL ENTITY.—

“(1) MONETARY PENALTIES.—In any case in which the determination of an external appeal entity is not followed in a timely fashion by a group health plan, or by a health insurance issuer offering health insurance coverage in connection with such a plan, any named fiduciary who, acting in the capacity of authorizing the benefit, causes such refusal may, in the discretion in a court of competent jurisdiction, be liable to an aggrieved participant or beneficiary for a civil penalty in an amount of up to \$1,000 a day from the date on which the determination was transmitted to the plan or issuer by the external appeal entity until the date the refusal to provide the benefit is corrected.

“(2) CEASE AND DESIST ORDER AND ORDER OF ATTORNEY’S FEES.—In any action described in paragraph (1) brought by a participant or beneficiary with respect to a group health plan, or a health insurance issuer offering health insurance coverage in connection with such a plan, in which a plaintiff alleges that a person referred to in such paragraph has taken an action resulting in a refusal of a benefit determined by an external appeal entity in violation of such terms of the plan, coverage, or this subpart, or has failed to take an action for which such person is responsible under the plan, coverage, or this part and which is necessary under the plan or coverage for authorizing a benefit, the court shall cause to be served on the defendant an order requiring the defendant—

“(A) to cease and desist from the alleged action or failure to act; and

“(B) to pay to the plaintiff a reasonable attorney’s fee and other reasonable costs relating to the prosecution of the action on the charges on which the plaintiff prevails.

“(f) PROTECTION OF LEGAL RIGHTS.—Nothing in this subpart shall be construed as removing or limiting any legal rights of participants, beneficiaries, and others under State or Federal law (including section 502), including the right to file judicial actions to enforce rights.

**“SEC. 804. ESTABLISHMENT OF A GRIEVANCE PROCESS.**

“(a) ESTABLISHMENT OF GRIEVANCE SYSTEM.—

“(1) IN GENERAL.—A group health plan, and a health insurance issuer in connection with the provision of health insurance coverage in connection with such a plan, shall establish and maintain a system to provide for the presentation and resolution of oral and written grievances brought by individuals who are participants or beneficiaries or health care providers or other individuals acting on behalf of an individual and with

the individual's consent or without such consent if the individual is medically unable to provide such consent, regarding any aspect of the plan's or issuer's services.

“(2) GRIEVANCE DEFINED.—In this section, the term ‘grievance’ means any question, complaint, or concern brought by a participant or beneficiary that is not a claim for benefits.

“(b) GRIEVANCE SYSTEM.—Such system shall include the following components with respect to individuals who are participants or beneficiaries:

“(1) Written notification to all such individuals and providers of the telephone numbers and business addresses of the plan or issuer personnel responsible for resolution of grievances and appeals.

“(2) A system to record and document, over a period of at least 3 previous years beginning two months after the date of the enactment of this Act, all grievances and appeals made and their status.

“(3) A process providing processing and resolution of grievances within 60 days.

“(4) Procedures for follow-up action, including the methods to inform the person making the grievance of the resolution of the grievance.

Grievances are not subject to appeal under the previous provisions of this subpart.

#### “SUBPART B—ACCESS TO CARE

##### “SEC. 812. CHOICE OF HEALTH CARE PROFESSIONAL.

“(a) PRIMARY CARE.—If a group health plan, or a health insurance issuer that offers health insurance coverage in connection with such a plan, requires or provides for designation by a participant or beneficiary of a participating primary care provider, then the plan or issuer shall permit each participant and beneficiary to designate any participating primary care provider who is available to accept such individual.

“(b) SPECIALISTS.—A group health plan and a health insurance issuer that offers health insurance coverage in connection with such a plan shall permit each participant or beneficiary to receive medically necessary or appropriate specialty care, pursuant to appropriate referral procedures, from any qualified participating health care professional who is available to accept such individual for such care.

##### “SEC. 813. ACCESS TO EMERGENCY CARE.

“(a) COVERAGE OF EMERGENCY SERVICES.—

“(1) IN GENERAL.—If a group health plan, or health insurance coverage offered by a health insurance issuer in connection with such a plan, provides or covers any benefits with respect to services in an emergency department of a hospital, the plan or issuer shall cover emergency services (as defined in paragraph (2)(B))—

“(A) without the need for any prior authorization determination;

“(B) whether the health care provider furnishing such services is a participating provider with respect to such services;

“(C) in a manner so that, if such services are provided to a participant or beneficiary—

“(i) by a nonparticipating health care provider with or without prior authorization, or

“(ii) by a participating health care provider without prior authorization,

the participant or beneficiary is not liable for amounts that exceed the amounts of liability that would be incurred if the services were provided by a participating health care provider with prior authorization; and

“(D) without regard to any other term or condition of such coverage (other than exclusion or coordination of benefits, or an affiliation or waiting period, permitted under section 2701 of the Public Health Service Act, section 701, or section 9801 of the Internal Revenue Code of 1986, and other than applicable cost-sharing).

“(2) DEFINITIONS.—In this section:

“(A) EMERGENCY MEDICAL CONDITION.—The term ‘emergency medical condition’ means—

“(i) a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act; and

“(ii) a medical condition manifesting itself in a neonate by acute symptoms of sufficient severity (including severe pain) such that a prudent health care professional could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act.

“(B) EMERGENCY SERVICES.—The term ‘emergency services’ means—

“(i) with respect to an emergency medical condition described in subparagraph (A)(i)—

“(I) a medical screening examination (as required under section 1867 of the Social Security Act) that is within the capability of the emergency department of a hospital, including ancillary services routinely available to the emergency department to evaluate such emergency medical condition, and

“(II) within the capabilities of the staff and facilities available at the hospital, such further medical examination and treatment as are required under section 1867 of such Act to stabilize the patient; or

“(ii) with respect to an emergency medical condition described in subparagraph (A)(ii), medical treatment for such condition rendered by a health care provider in a hospital to a neonate, including available hospital ancillary services in response to an urgent request of a health care professional and to the extent necessary to stabilize the neonate.

“(C) STABILIZE.—The term ‘to stabilize’ means, with respect to an emergency medical condition, to provide such medical treatment of the condition as may be necessary to assure, within reasonable medical probability, that no material deterioration of the condition is likely to result from or occur during the transfer of the individual from a facility.

“(b) REIMBURSEMENT FOR MAINTENANCE CARE AND POST-STABILIZATION CARE.—If benefits are available under a group health plan, or under health insurance coverage offered by a health insurance issuer in connection with such a plan, with respect to maintenance care or post-stabilization care covered under the guidelines established under section 1852(d)(2) of the Social Security Act, the plan or issuer shall provide for reimbursement with respect to such services provided to a participant or beneficiary other than through a participating health care provider in a manner consistent with subsection (a)(1)(C) (and shall otherwise comply with such guidelines).

“(c) COVERAGE OF EMERGENCY AMBULANCE SERVICES.—

“(1) IN GENERAL.—If a group health plan, or health insurance coverage provided by a health insurance issuer in connection with such a plan, provides any benefits with respect to ambulance services and emergency services, the plan or issuer shall cover emergency ambulance services (as defined in paragraph (2)) furnished under the plan or coverage under the same terms and conditions under subparagraphs (A) through (D) of subsection (a)(1) under which coverage is provided for emergency services.

“(2) EMERGENCY AMBULANCE SERVICES.—For purposes of this subsection, the term ‘emergency ambulance services’ means ambulance services (as defined for purposes of section 1861(s)(7) of the Social Security Act) furnished to transport an individual who has an emergency medical condition (as defined in subsection (a)(2)(A)) to a hospital for the receipt of emergency services (as defined in subsection (a)(2)(B)) in a case in which the emergency services are covered under the plan or coverage pursuant to subsection (a)(1) and a prudent layperson, with an average knowledge of health and medicine, could reasonably expect that the absence of such transport would result in placing the health of the individual in serious jeopardy, serious impairment of bodily function, or serious dysfunction of any bodily organ or part.

**“SEC. 814. ACCESS TO SPECIALTY CARE.**

“(a) SPECIALTY CARE FOR COVERED SERVICES.—

“(1) IN GENERAL.—If—

“(A) an individual is a participant or beneficiary under a group health plan or is covered under health insurance

coverage offered by a health insurance issuer in connection with such a plan,

“(B) the individual has a condition or disease of sufficient seriousness and complexity to require treatment by a specialist or the individual requires physician pathology services, and

“(C) benefits for such treatment or services are provided under the plan or coverage,

the plan or issuer shall make or provide for a referral to a specialist who is available and accessible (consistent with standards developed under section 818) to provide the treatment for such condition or disease or to provide such services.

“(2) SPECIALIST DEFINED.—For purposes of this subsection, the term ‘specialist’ means, with respect to a condition or services, a health care practitioner, facility, or center or physician pathologist that has adequate expertise through appropriate training and experience (including, in the case of a child, appropriate pediatric expertise and in the case of a pregnant woman, appropriate obstetrical expertise) to provide high quality care in treating the condition or to provide physician pathology services.

“(3) CARE UNDER REFERRAL.—A group health plan or health insurance issuer may require that the care provided to an individual pursuant to such referral under paragraph (1) with respect to treatment be—

“(A) pursuant to a treatment plan, only if the treatment plan is developed by the specialist and approved by the plan or issuer, in consultation with the designated primary care provider or specialist and the individual (or the individual’s designee), and

“(B) in accordance with applicable quality assurance and utilization review standards of the plan or issuer.

Nothing in this subsection shall be construed as preventing such a treatment plan for an individual from requiring a specialist to provide the primary care provider with regular updates on the specialty care provided, as well as all necessary medical information.

“(4) REFERRALS TO PARTICIPATING PROVIDERS.—A group health plan or health insurance issuer is not required under paragraph (1) to provide for a referral to a specialist that is not a participating provider, unless the plan or issuer does not have a specialist that is available and accessible to treat the individual’s condition or provide physician pathology services and that is a participating provider with respect to such treatment or services.

“(5) REFERRALS TO NONPARTICIPATING PROVIDERS.—In a case in which a referral of an individual to a nonparticipating specialist is required under paragraph (1), the group health plan or health insurance issuer shall provide the individual the option of at least three nonparticipating specialists.

“(6) TREATMENT OF NONPARTICIPATING PROVIDERS.—If a plan or issuer refers an individual to a nonparticipating specialist pursuant to paragraph (1), services provided pursuant to the approved treatment plan (if any) shall be provided at no addi-

tional cost to the individual beyond what the individual would otherwise pay for services received by such a specialist that is a participating provider.

“(b) SPECIALISTS AS GATEKEEPER FOR TREATMENT OF ONGOING SPECIAL CONDITIONS.—

“(1) IN GENERAL.—A group health plan, or a health insurance issuer, in connection with the provision of health insurance coverage in connection with such a plan, shall have a procedure by which an individual who is a participant or beneficiary and who has an ongoing special condition (as defined in paragraph (3)) may request and receive a referral to a specialist for such condition who shall be responsible for and capable of providing and coordinating the individual’s care with respect to the condition. Under such procedures if such an individual’s care would most appropriately be coordinated by such a specialist, such plan or issuer shall refer the individual to such specialist.

“(2) TREATMENT FOR RELATED REFERRALS.—Such specialists shall be permitted to treat the individual without a referral from the individual’s primary care provider and may authorize such referrals, procedures, tests, and other medical services as the individual’s primary care provider would otherwise be permitted to provide or authorize, subject to the terms of the treatment (referred to in subsection (a)(3)(A)) with respect to the ongoing special condition.

“(3) ONGOING SPECIAL CONDITION DEFINED.—In this subsection, the term ‘ongoing special condition’ means a condition or disease that—

“(A) is life-threatening, degenerative, or disabling, and

“(B) requires specialized medical care over a prolonged period of time.

“(4) TERMS OF REFERRAL.—The provisions of paragraphs (3) through (5) of subsection (a) apply with respect to referrals under paragraph (1) of this subsection in the same manner as they apply to referrals under subsection (a)(1).

“(5) CONSTRUCTION.—Nothing in this subsection shall be construed as preventing an individual who is a participant or beneficiary and who has an ongoing special condition from having the individual’s primary care physician assume the responsibilities for providing and coordinating care described in paragraph (1).

“(c) STANDING REFERRALS.—

“(1) IN GENERAL.—A group health plan, and a health insurance issuer in connection with the provision of health insurance coverage in connection with such a plan, shall have a procedure by which an individual who is a participant or beneficiary and who has a condition that requires ongoing care from a specialist may receive a standing referral to such specialist for treatment of such condition. If the plan or issuer, or if the primary care provider in consultation with the medical director of the plan or issuer and the specialist (if any), determines that such a standing referral is appropriate, the plan or issuer shall make such a referral to such a specialist if the individual so desires.

“(2) TERMS OF REFERRAL.—The provisions of paragraphs (3) through (5) of subsection (a) apply with respect to referrals under paragraph (1) of this subsection in the same manner as they apply to referrals under subsection (a)(1).

**“SEC. 815. ACCESS TO OBSTETRICAL AND GYNECOLOGICAL CARE.**

“(a) IN GENERAL.—If a group health plan, or a health insurance issuer in connection with the provision of health insurance coverage in connection with such a plan, requires or provides for a participant or beneficiary to designate a participating primary care health care professional, the plan or issuer—

“(1) may not require authorization or a referral by the individual’s primary care health care professional or otherwise for covered gynecological care (including preventive women’s health examinations) or for covered pregnancy-related services provided by a participating physician (including a family practice physician) who specializes or is trained and experienced in gynecology or obstetrics, respectively, to the extent such care is otherwise covered; and

“(2) shall treat the ordering of other gynecological or obstetrical care by such a participating physician as the authorization of the primary care health care professional with respect to such care under the plan or coverage.

“(b) CONSTRUCTION.—Nothing in subsection (a) shall be construed to—

“(1) waive any exclusions of coverage under the terms of the plan with respect to coverage of gynecological or obstetrical care;

“(2) preclude the group health plan or health insurance issuer involved from requiring that the gynecologist or obstetrician notify the primary care health care professional or the plan of treatment decisions; or

“(3) prevent a plan or issuer from offering, in addition to physicians described in subsection (a)(1), non-physician health care professionals who are trained and experienced in gynecology or obstetrics.

**“SEC. 816. ACCESS TO PEDIATRIC CARE.**

“(a) PEDIATRIC CARE.—If a group health plan, or a health insurance issuer in connection with the provision of health insurance coverage in connection with such a plan, requires or provides for a participant or beneficiary to designate a participating primary care provider for a child of such individual, the plan or issuer shall permit the participant or beneficiary to designate a physician (including a family practice physician) who specializes or is trained and experienced in pediatrics as the child’s primary care provider.

“(b) CONSTRUCTION.—Nothing in subsection (a) shall be construed to waive any exclusions of coverage under the terms of the plan with respect to coverage of pediatric care.

**“SEC. 817. CONTINUITY OF CARE.**

“(a) IN GENERAL.—

“(1) TERMINATION OF PROVIDER.—If a contract between a group health plan, or a health insurance issuer in connection with the provision of health insurance coverage in connection with such a plan, and a health care provider is terminated (as

defined in paragraph (3)(B)), or benefits or coverage provided by a health care provider are terminated because of a change in the terms of provider participation in a group health plan, and an individual who is a participant or beneficiary in the plan or coverage is undergoing treatment from the provider for an ongoing special condition (as defined in paragraph (3)(A)) at the time of such termination, the plan or issuer shall—

“(A) notify the individual on a timely basis of such termination and of the right to elect continuation of coverage of treatment by the provider under this section; and

“(B) subject to subsection (c), permit the individual to elect to continue to be covered with respect to treatment by the provider of such condition during a transitional period (provided under subsection (b)).

“(2) TREATMENT OF TERMINATION OF CONTRACT WITH HEALTH INSURANCE ISSUER.—If a contract for the provision of health insurance coverage between a group health plan and a health insurance issuer is terminated and, as a result of such termination, coverage of services of a health care provider is terminated with respect to an individual, the provisions of paragraph (1) (and the succeeding provisions of this section) shall apply under the plan in the same manner as if there had been a contract between the plan and the provider that had been terminated, but only with respect to benefits that are covered under the plan after the contract termination.

“(3) DEFINITIONS.—For purposes of this section:

“(A) ONGOING SPECIAL CONDITION.—The term ‘ongoing special condition’ has the meaning given such term in section 814(b)(3), and also includes pregnancy.

“(B) TERMINATION.—The term ‘terminated’ includes, with respect to a contract, the expiration or nonrenewal of the contract, but does not include a termination of the contract by the plan or issuer for failure to meet applicable quality standards or for fraud.

“(b) TRANSITIONAL PERIOD.—

“(1) IN GENERAL.—Except as provided in paragraphs (2) through (4), the transitional period under this subsection shall extend up to 90 days (as determined by the treating health care professional) after the date of the notice described in subsection (a)(1)(A) of the provider’s termination.

“(2) SCHEDULED SURGERY AND ORGAN TRANSPLANTATION.—If surgery or organ transplantation was scheduled for an individual before the date of the announcement of the termination of the provider status under subsection (a)(1)(A) or if the individual on such date was on an established waiting list or otherwise scheduled to have such surgery or transplantation, the transitional period under this subsection with respect to the surgery or transplantation shall extend beyond the period under paragraph (1) and until the date of discharge of the individual after completion of the surgery or transplantation.

“(3) PREGNANCY.—If—

“(A) a participant or beneficiary was determined to be pregnant at the time of a provider’s termination of participation, and

“(B) the provider was treating the pregnancy before date of the termination,  
the transitional period under this subsection with respect to provider’s treatment of the pregnancy shall extend through the provision of post-partum care directly related to the delivery.

“(4) TERMINAL ILLNESS.—If—

“(A) a participant or beneficiary was determined to be terminally ill (as determined under section 1861(dd)(3)(A) of the Social Security Act) at the time of a provider’s termination of participation, and

“(B) the provider was treating the terminal illness before the date of termination,  
the transitional period under this subsection shall extend for the remainder of the individual’s life for care directly related to the treatment of the terminal illness or its medical manifestations.

“(c) PERMISSIBLE TERMS AND CONDITIONS.—A group health plan or health insurance issuer may condition coverage of continued treatment by a provider under subsection (a)(1)(B) upon the individual notifying the plan of the election of continued coverage and upon the provider agreeing to the following terms and conditions:

“(1) The provider agrees to accept reimbursement from the plan or issuer and individual involved (with respect to cost-sharing) at the rates applicable prior to the start of the transitional period as payment in full (or, in the case described in subsection (a)(2), at the rates applicable under the replacement plan or issuer after the date of the termination of the contract with the health insurance issuer) and not to impose cost-sharing with respect to the individual in an amount that would exceed the cost-sharing that could have been imposed if the contract referred to in subsection (a)(1) had not been terminated.

“(2) The provider agrees to adhere to the quality assurance standards of the plan or issuer responsible for payment under paragraph (1) and to provide to such plan or issuer necessary medical information related to the care provided.

“(3) The provider agrees otherwise to adhere to such plan’s or issuer’s policies and procedures, including procedures regarding referrals and obtaining prior authorization and providing services pursuant to a treatment plan (if any) approved by the plan or issuer.

“(d) CONSTRUCTION.—Nothing in this section shall be construed to require the coverage of benefits which would not have been covered if the provider involved remained a participating provider.

**“SEC. 818. NETWORK ADEQUACY.**

“(a) REQUIREMENT.—A group health plan, and a health insurance issuer providing health insurance coverage in connection with such a plan, shall meet such standards for network adequacy as are established by law pursuant to this section.

“(b) DEVELOPMENT OF STANDARDS.—

“(1) ESTABLISHMENT OF PANEL.—There is established a panel to be known as the Health Care Panel to Establish Network Adequacy Standards (in this section referred to as the ‘Panel’).

“(2) DUTIES OF PANEL.—The Panel shall devise standards for group health plans and health insurance issuers that offer

health insurance coverage in connection with such a plan to ensure that—

“(A) participants and beneficiaries have access to a sufficient number, mix, and distribution of health care professionals and providers; and

“(B) covered items and services are available and accessible to each participant and beneficiary—

“(i) in the service area of the plan or issuer;

“(ii) at a variety of sites of service;

“(iii) with reasonable promptness (including reasonable hours of operation and after hours services);

“(iv) with reasonable proximity to the residences or workplaces of participants and beneficiaries; and

“(v) in a manner that takes into account the diverse needs of such individuals and reasonably assures continuity of care.

“(c) MEMBERSHIP.—

“(1) SIZE AND COMPOSITION.—The Panel shall be composed of 15 members. The Secretary of Health and Human Services, the Majority Leader of the Senate, and the Speaker of House of Representatives shall each appoint 1 member from representatives of private insurance organizations, consumer groups, State insurance commissioners, State medical societies, and State medical specialty societies.

“(2) TERMS OF APPOINTMENT.—The members of the Panel shall serve for the life of the Panel.

“(3) VACANCIES.—A vacancy in the Panel shall not affect the power of the remaining members to execute the duties of the Panel, but any such vacancy shall be filled in the same manner in which the original appointment was made.

“(d) PROCEDURES.—

“(1) MEETINGS.—The Panel shall meet at the call of a majority of its members.

“(2) FIRST MEETING.—The Panel shall convene not later than 60 days after the date of the enactment of the Health Care Quality and Choice Act of 1999.

“(3) QUORUM.—A quorum shall consist of a majority of the members of the Panel.

“(4) HEARINGS.—For the purpose of carrying out its duties, the Panel may hold such hearings and undertake such other activities as the Panel determines to be necessary to carry out its duties.

“(e) ADMINISTRATION.—

“(1) COMPENSATION.—Except as provided in paragraph (1), members of the Panel shall receive no additional pay, allowances, or benefits by reason of their service on the Panel.

“(2) TRAVEL EXPENSES AND PER DIEM.—Each member of the Panel who is not an officer or employee of the Federal Government shall receive travel expenses and per diem in lieu of subsistence in accordance with sections 5702 and 5703 of title 5, United States Code.

“(3) CONTRACT AUTHORITY.—The Panel may contract with and compensate government and private agencies or persons

for items and services, without regard to section 3709 of the Revised Statutes (41 U.S.C. 5).

“(4) USE OF MAILS.—The Panel may use the United States mails in the same manner and under the same conditions as Federal agencies and shall, for purposes of the frank, be considered a commission of Congress as described in section 3215 of title 39, United States Code.

“(5) ADMINISTRATIVE SUPPORT SERVICES.—Upon the request of the Panel, the Secretary of Health and Human Services shall provide to the Panel on a reimbursable basis such administrative support services as the Panel may request.

“(f) REPORT AND ESTABLISHMENT OF STANDARDS.—Not later than 2 years after the first meeting, the Panel shall submit a report to Congress and the Secretary of Health and Human Services detailing the standards devised under subsection (b) and recommendations regarding the implementation of such standards. Such standards shall take effect to the extent provided by Federal law enacted after the date of the submission of such report.

“(g) TERMINATION.—The Panel shall terminate on the day after submitting its report to the Secretary of Health and Human Services under subsection (f).

**“SEC. 819. ACCESS TO EXPERIMENTAL OR INVESTIGATIONAL PRESCRIPTION DRUGS.**

“No use of a prescription drug or medical device shall be considered experimental or investigational under a group health plan or under health insurance coverage provided by a health insurance issuer in connection with such a plan if such use is included in the labeling authorized by the U.S. Food and Drug Administration under section 505, 513 or 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or under section 351 of the Public Health Service Act (42 U.S.C. 262), unless such use is demonstrated to be unsafe or ineffective.

**“SEC. 820. COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CANCER CLINICAL TRIALS.**

“(a) COVERAGE.—

“(1) IN GENERAL.—If a group health plan (or a health insurance issuer offering health insurance coverage in connection with such a plan) provides coverage to a qualified individual (as defined in subsection (b)), the plan or issuer—

“(A) may not deny the individual participation in the clinical trial referred to in subsection (b)(2);

“(B) subject to subsections (b), (c), and (d), may not deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and services furnished in connection with participation in the trial; and

“(C) may not discriminate against the individual on the basis of the individual’s participation in such trial.

“(2) EXCLUSION OF CERTAIN COSTS.—For purposes of paragraph (1)(B), routine patient costs do not include the cost of the tests or measurements conducted primarily for the purpose of the clinical trial involved.

“(3) USE OF IN-NETWORK PROVIDERS.—If one or more participating providers is participating in a clinical trial, nothing in paragraph (1) shall be construed as preventing a plan or issuer

from requiring that a qualified individual participate in the trial through such a participating provider if the provider will accept the individual as a participant in the trial.

“(b) QUALIFIED INDIVIDUAL DEFINED.—For purposes of subsection (a), the term ‘qualified individual’ means an individual who is a participant or beneficiary in a group health plan who meets the following conditions:

“(1)(A) The individual has been diagnosed with cancer.

“(B) The individual is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of such illness.

“(C) The individual’s participation in the trial offers meaningful potential for significant clinical benefit for the individual.

“(2) Either—

“(A) the referring physician is a participating health care professional and has concluded that the individual’s participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1); or

“(B) the individual provides medical and scientific information establishing that the individual’s participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1).

“(c) PAYMENT.—

“(1) IN GENERAL.—Under this section a group health plan (or health insurance issuer offering health insurance) shall provide for payment for routine patient costs described in subsection (a)(2) but is not required to pay for costs of items and services that are reasonably expected to be paid for by the sponsors of an approved clinical trial.

“(2) ROUTINE PATIENT CARE COSTS.—For purposes of this section—

“(A) IN GENERAL.—The term ‘routine patient care costs’ includes the costs associated with the provision of items and services that—

“(i) would otherwise be covered under the group health plan if such items and services were not provided in connection with an approved clinical trial program; and

“(ii) are furnished according to the protocol of an approved clinical trial program.

“(B) EXCLUSION.—Such term does include the costs associated with the provision of—

“(i) an investigational drug or device, unless the Secretary has authorized the manufacturer of such drug or device to charge for such drug or device; or

“(ii) any item or service supplied without charge by the sponsor of the approved clinical trial program.

“(3) PAYMENT RATE.—In the case of covered items and services provided by—

“(A) a participating provider, the payment rate shall be at the agreed upon rate, or

“(B) a nonparticipating provider, the payment rate shall be at the rate the plan or issuer would normally pay for comparable items or services under subparagraph (A).

“(d) APPROVED CLINICAL TRIAL DEFINED.—In this section, the term ‘approved clinical trial’ means a cancer clinical research study or cancer clinical investigation approved by an Institutional Review Board.

“(e) CONSTRUCTION.—Nothing in this section shall be construed to limit a plan’s or issuer’s coverage with respect to clinical trials.

“(f) PLAN SATISFACTION OF CERTAIN REQUIREMENTS; RESPONSIBILITIES OF FIDUCIARIES.—

“(1) IN GENERAL.—For purposes of this section, insofar as a group health plan provides benefits in the form of health insurance coverage through a health insurance issuer, the plan shall be treated as meeting the requirements of this section with respect to such benefits and not be considered as failing to meet such requirements because of a failure of the issuer to meet such requirements so long as the plan sponsor or its representatives did not cause such failure by the issuer.

“(2) CONSTRUCTION.—Nothing in this section shall be construed to affect or modify the responsibilities of the fiduciaries of a group health plan under part 4 of subtitle B.

#### “SUBPART C—ACCESS TO INFORMATION

#### “SEC. 821. PATIENT ACCESS TO INFORMATION.

“(a) DISCLOSURE REQUIREMENT.—

“(1) GROUP HEALTH PLANS.—A group health plan shall—

“(A) provide to participants and beneficiaries at the time of initial coverage under the plan (or the effective date of this section, in the case of individuals who are participants or beneficiaries as of such date), and at least annually thereafter, the information described in subsection (b);

“(B) provide to participants and beneficiaries, within a reasonable period (as specified by the Secretary) before or after the date of significant changes in the information described in subsection (b), information on such significant changes; and

“(C) upon request, make available to participants and beneficiaries, the Secretary, and prospective participants and beneficiaries, the information described in subsection (b) or (c).

The plan may charge a reasonable fee for provision in printed form of any of the information described in subsection (b) or (c) more than once during any plan year.

“(2) HEALTH INSURANCE ISSUERS.—A health insurance issuer in connection with the provision of health insurance coverage in connection with a group health plan shall—

“(A) provide to participants and beneficiaries enrolled under such coverage at the time of enrollment, and at least annually thereafter, the information described in subsection (b);

“(B) provide to such participants and beneficiaries, within a reasonable period (as specified by the Secretary) before or after the date of significant changes in the informa-

tion described in subsection (b), information in printed form on such significant changes; and

“(C) upon request, make available to the Secretary, to individuals who are prospective participants and beneficiaries, and to the public the information described in subsection (b) or (c).

“(3) EMPLOYERS.—Effective 5 years after the date this part first becomes effective, each employer (other than an employer described in paragraph (1) of subsection (d)) shall provide to each employee at least annually information (consistent with such subsection) on the amount that the employer contributes on behalf of the employee (and any dependents of the employee) for health benefits coverage.

“(b) INFORMATION PROVIDED.—The information described in this subsection with respect to a group health plan or health insurance coverage offered by a health insurance issuer shall be provided to a participant or beneficiary free of charge at least once a year and includes the following:

“(1) SERVICE AREA.—The service area of the plan or issuer.

“(2) BENEFITS.—Benefits offered under the plan or coverage, including—

“(A) those that are covered benefits “(all of which shall be referred to by such relevant CPT and DRG codes as are available), limits and conditions on such benefits, and those benefits that are explicitly excluded from coverage (all of which shall be referred to by such relevant CPT and DRG codes as are available);

“(B) cost sharing, such as deductibles, coinsurance, and copayment amounts, including any liability for balance billing, any maximum limitations on out of pocket expenses, and the maximum out of pocket costs for services that are provided by nonparticipating providers or that are furnished without meeting the applicable utilization review requirements;

“(C) the extent to which benefits may be obtained from nonparticipating providers;

“(D) the extent to which a participant or beneficiary may select from among participating providers and the types of providers participating in the plan or issuer network;

“(E) process for determining experimental coverage; and

“(F) use of a prescription drug formulary.

“(3) ACCESS.—A description of the following:

“(A) The number, mix, and distribution of providers under the plan or coverage.

“(B) Out-of-network coverage (if any) provided by the plan or coverage.

“(C) Any point-of-service option (including any supplemental premium or cost-sharing for such option).

“(D) The procedures for participants and beneficiaries to select, access, and change participating primary and specialty providers.

“(E) The rights and procedures for obtaining referrals (including standing referrals) to participating and nonparticipating providers.

- “(F) The name, address, and telephone number of participating health care providers and an indication of whether each such provider is available to accept new patients.
- “(G) Any limitations imposed on the selection of qualifying participating health care providers, including any limitations imposed under section 812(b)(2).
- “(4) OUT-OF-AREA COVERAGE.—Out-of-area coverage provided by the plan or issuer.
- “(5) EMERGENCY COVERAGE.—Coverage of emergency services, including—
- “(A) the appropriate use of emergency services, including use of the 911 telephone system or its local equivalent in emergency situations and an explanation of what constitutes an emergency situation;
  - “(B) the process and procedures of the plan or issuer for obtaining emergency services; and
  - “(C) the locations of (i) emergency departments, and (ii) other settings, in which plan physicians and hospitals provide emergency services and post-stabilization care.
- “(6) PRIOR AUTHORIZATION RULES.—Rules regarding prior authorization or other review requirements that could result in noncoverage or nonpayment.
- “(7) GRIEVANCE AND APPEALS PROCEDURES.—All appeal or grievance rights and procedures under the plan or coverage, including the method for filing grievances and the time frames and circumstances for acting on grievances and appeals, who is the applicable authority with respect to the plan or issuer.
- “(8) ACCOUNTABILITY.—A description of the legal recourse options available for participants and beneficiaries under the plan including—
- “(A) the preemption that applies under section 514 to certain actions arising out of the provision of health benefits; and
  - “(B) the extent to which coverage decisions made by the plan are subject to internal review or any external review and the proper time frames under
- “(9) QUALITY ASSURANCE.—Any information made public by an accrediting organization in the process of accreditation of the plan or issuer or any additional quality indicators the plan or issuer makes available.
- “(10) INFORMATION ON ISSUER.—Notice of appropriate mailing addresses and telephone numbers to be used by participants and beneficiaries in seeking information or authorization for treatment.
- “(11) AVAILABILITY OF INFORMATION ON REQUEST.—Notice that the information described in subsection (c) is available upon request.
- “(c) INFORMATION MADE AVAILABLE UPON REQUEST.—The information described in this subsection is the following:
- “(1) UTILIZATION REVIEW ACTIVITIES.—A description of procedures used and requirements (including circumstances, time frames, and appeal rights) under any utilization review program under section 801.

“(2) GRIEVANCE AND APPEALS INFORMATION.—Information on the number of grievances and appeals and on the disposition in the aggregate of such matters.

“(3) FORMULARY RESTRICTIONS.—A description of the nature of any drug formula restrictions.

“(4) PARTICIPATING PROVIDER LIST.—A list of current participating health care providers.

“(d) EMPLOYER INFORMATION.—

“(1) SMALL EMPLOYER EXEMPTION.—Subsection (a)(3) shall not apply to an employer that is a small employer (as defined in section 712(c)(1)(B)) or would be such an employer if ‘100’ were substituted for ‘50’ in such section.

“(2) COMPUTATION.—The amount described in subsection (a)(3) may be computed on an average, per employee basis, and may be based on rules similar to the rules applied in computing the applicable premium under section 604.

“(3) FORM OF DISCLOSURE.—The information under subsection (a)(3) may be provided in any reasonable form, including as part of the summary plan description, a letter, or information accompanying a W-2 form.

“(e) CONSTRUCTION.—Nothing in this section shall be construed as requiring public disclosure of individual contracts or financial arrangements between a group health plan or health insurance issuer and any provider.

“SUBPART D—PROTECTING THE DOCTOR-PATIENT RELATIONSHIP

“SEC. 831. PROHIBITION OF INTERFERENCE WITH CERTAIN MEDICAL COMMUNICATIONS.

“(a) GENERAL RULE.—The provisions of any contract or agreement, or the operation of any contract or agreement, between a group health plan or health insurance issuer in relation to health insurance coverage offered in connection with such a plan (including any partnership, association, or other organization that enters into or administers such a contract or agreement) and a health care provider (or group of health care providers) shall not prohibit or otherwise restrict a health care professional from advising such a participant or beneficiary who is a patient of the professional about the health status of the individual or medical care or treatment for the individual’s condition or disease, regardless of whether benefits for such care or treatment are provided under the plan or coverage, if the professional is acting within the lawful scope of practice.

“(b) NULLIFICATION.—Any contract provision or agreement that restricts or prohibits medical communications in violation of subsection (a) shall be null and void.

“SEC. 832. PROHIBITION OF DISCRIMINATION AGAINST PROVIDERS BASED ON LICENSURE.

“(a) IN GENERAL.—A group health plan and a health insurance issuer offering health insurance coverage in connection with such a plan shall not discriminate with respect to participation or indemnification as to any provider who is acting within the scope of the provider’s license or certification under applicable State law, solely on the basis of such license or certification.

“(b) CONSTRUCTION.—Subsection (a) shall not be construed—

“(1) as requiring the coverage under a group health plan or health insurance coverage of particular benefits or services or to prohibit a plan or issuer from including providers only to the extent necessary to meet the needs of the plan’s or issuer’s participants or beneficiaries or from establishing any measure designed to maintain quality and control costs consistent with the responsibilities of the plan or issuer;

“(2) to override any State licensure or scope-of-practice law;

“(3) as requiring a plan or issuer that offers network coverage to include for participation every willing provider who meets the terms and conditions of the plan or issuer; or

“(4) as prohibiting a family practice physician with appropriate expertise from providing pediatric or obstetrical or gynecological care.

**“SEC. 833. PROHIBITION AGAINST IMPROPER INCENTIVE ARRANGEMENTS.**

“(a) IN GENERAL.—A group health plan and a health insurance issuer offering health insurance coverage in connection with such a plan may not operate any physician incentive plan (as defined in subparagraph (B) of section 1876(i)(8) of the Social Security Act) unless the requirements described in clauses (i), (ii)(I), and (iii) of subparagraph (A) of such section are met with respect to such a plan.

“(b) APPLICATION.—For purposes of carrying out paragraph (1), any reference in section 1876(i)(8) of the Social Security Act to the Secretary, an eligible organization, or an individual enrolled with the organization shall be treated as a reference to the applicable authority, a group health plan or health insurance issuer, respectively, and a participant or beneficiary with the plan or organization, respectively.

“(c) CONSTRUCTION.—Nothing in this section shall be construed as prohibiting all capitation and similar arrangements or all provider discount arrangements.

**“SEC. 834. PAYMENT OF CLEAN CLAIMS.**

“A group health plan, and a health insurance issuer offering group health insurance coverage, shall provide for prompt payment of claims submitted for health care services or supplies furnished to a participant or beneficiary with respect to benefits covered by the plan or issuer, in a manner consistent with the provisions of sections 1816(c)(2) and 1842(c)(2) of the Social Security Act (42 U.S.C. 1395h(c)(2) and 42 U.S.C. 1395u(c)(2)), except that for purposes of this section, subparagraph (C) of section 1816(c)(2) of the Social Security Act shall be treated as applying to claims received from a participant or beneficiary as well as claims referred to in such subparagraph.

**“SUBPART E—DEFINITIONS**

**“SEC. 841. DEFINITIONS.**

“(a) INCORPORATION OF GENERAL DEFINITIONS.—Except as otherwise provided, the provisions of section 733 shall apply for purposes of this part in the same manner as they apply for purposes of part 7.

“(b) ADDITIONAL DEFINITIONS.—For purposes of this part:

“(1) APPLICABLE AUTHORITY.—The term ‘applicable authority’ means—

“(A) in the case of a group health plan, the Secretary of Labor; and

“(B) in the case of a health insurance issuer with respect to a specific provision of this part, the applicable State authority (as defined in section 2791(d) of the Public Health Service Act), or the Secretary of Health and Human Services, if such Secretary is enforcing such provision under section 2722(a)(2) or 2761(a)(2) of the Public Health Service Act.

“(2) CLINICAL PEER.—The term ‘clinical peer’ means, with respect to a review or appeal, a practicing physician or other health care professional who holds a nonrestricted license and who is—

“(A) appropriately certified by a nationally recognized, peer reviewed accrediting body in the same or similar specialty as typically manages the medical condition, procedure, or treatment under review or appeal, or

“(B) is trained and experienced in managing such condition, procedure, or treatment, and includes a pediatric specialist where appropriate; except that only a physician may be a clinical peer with respect to the review or appeal of treatment recommended or rendered by a physician.

“(3) HEALTH CARE PROFESSIONAL.—The term ‘health care professional’ means an individual who is licensed, accredited, or certified under State law to provide specified health care services and who is operating within the scope of such licensure, accreditation, or certification.

“(4) HEALTH CARE PROVIDER.—The term ‘health care provider’ includes a physician or other health care professional, as well as an institutional or other facility or agency that provides health care services and that is licensed, accredited, or certified to provide health care items and services under applicable State law.

“(5) NETWORK.—The term ‘network’ means, with respect to a group health plan or health insurance issuer offering health insurance coverage, the participating health care professionals and providers through whom the plan or issuer provides health care items and services to participants or beneficiaries.

“(6) NONPARTICIPATING.—The term ‘nonparticipating’ means, with respect to a health care provider that provides health care items and services to a participant or beneficiary under group health plan or health insurance coverage, a health care provider that is not a participating health care provider with respect to such items and services.

“(7) PARTICIPATING.—The term ‘participating’ means, with respect to a health care provider that provides health care items and services to a participant or beneficiary under group health plan or health insurance coverage offered by a health insurance issuer in connection with such a plan, a health care provider that furnishes such items and services under a contract or other arrangement with the plan or issuer.

“(8) PHYSICIAN.—The term ‘physician’ means an allopathic or osteopathic physician.

“(9) PRACTICING PHYSICIAN.—The term ‘practicing physician’ means a physician who is licensed in the State in which the physician furnishes professional services and who provides professional services to individual patients on average at least two full days per week.

“(10) PRIOR AUTHORIZATION.—The term ‘prior authorization’ means the process of obtaining prior approval from a health insurance issuer or group health plan for the provision or coverage of medical services.

**“SEC. 842. RULE OF CONSTRUCTION.**

“Nothing in this part or section 714 shall be construed to affect or modify the provisions of section 514.

**“SEC. 843. EXCLUSIONS.**

“(a) NO BENEFIT REQUIREMENTS.—Nothing in this part shall be construed to require a group health plan or a health insurance issuer offering health insurance coverage in connection with such a plan to provide specific benefits under the terms of such plan or coverage, other than those provided under the terms of such plan or coverage.

“(b) EXCLUSION FOR FEE-FOR-SERVICE COVERAGE.—

“(1) IN GENERAL.—

“(A) GROUP HEALTH PLANS.—The provisions of sections 811 through 821 shall not apply to a group health plan if the only coverage offered under the plan is fee-for-service coverage (as defined in paragraph (2)).

“(B) HEALTH INSURANCE COVERAGE.—The provisions of sections 801 through 821 shall not apply to health insurance coverage if the only coverage offered under the coverage is fee-for-service coverage (as defined in paragraph (2)).

“(2) FEE-FOR-SERVICE COVERAGE DEFINED.—For purposes of this subsection, the term ‘fee-for-service coverage’ means coverage under a group health plan or health insurance coverage that—

“(A) reimburses hospitals, health professionals, and other providers on a fee-for-service basis without placing the provider at financial risk;

“(B) does not vary reimbursement for such a provider based on an agreement to contract terms and conditions or the utilization of health care items or services relating to such provider;

“(C) allows access to any provider that is lawfully authorized to provide the covered services and agree to accept the terms and conditions of payment established under the plan or by the issuer; and

“(D) for which the plan or issuer does not require prior authorization before providing for any health care services.

**“SEC. 844. COVERAGE OF LIMITED SCOPE PLANS.**

“Only for purposes of applying the requirements of this part under section 714, section 733(c)(2)(A) shall be deemed not to apply.

**“SEC. 845. REGULATIONS.**

“(a) REGULATIONS.—The Secretary of Labor shall issue such regulations as may be necessary or appropriate to carry out this part under section 714. The Secretary may promulgate such regulations in the form of interim final rules as may be necessary to carry out this part in a timely manner.”.

(b) CLERICAL AMENDMENT.—The table of contents in section 1 of the Employee Retirement Income Security Act of 1974 is amended by inserting after the item relating to section 734 the following new items:

“PART 8—IMPROVING MANAGED CARE

“SUBPART A—GRIEVANCE AND APPEALS

- “Sec. 801. Utilization review activities.
- “Sec. 802. Internal appeals procedures.
- “Sec. 803. External appeals procedures.
- “Sec. 804. Establishment of a grievance process.

“SUBPART B—ACCESS TO CARE

- “Sec. 812. Choice of health care professional.
- “Sec. 813. Access to emergency care.
- “Sec. 814. Access to specialty care.
- “Sec. 815. Access to obstetrical and gynecological care.
- “Sec. 816. Access to pediatric care.
- “Sec. 817. Continuity of care.
- “Sec. 818. Network adequacy.
- “Sec. 819. Access to experimental or investigational prescription drugs.
- “Sec. 820. Coverage for individuals participating in approved cancer clinical trials.

“SUBPART C—ACCESS TO INFORMATION

- “Sec. 821. Patient access to information.

“SUBPART D—PROTECTING THE DOCTOR-PATIENT RELATIONSHIP

- “Sec. 831. Prohibition of interference with certain medical communications.
- “Sec. 832. Prohibition of discrimination against providers based on licensure.
- “Sec. 833. Prohibition against improper incentive arrangements.
- “Sec. 834. Payment of clean claims.

“SUBPART E—DEFINITIONS

- “Sec. 841. Definitions.
- “Sec. 842. Preemption; State flexibility; construction.
- “Sec. 843. Exclusions.
- “Sec. 844. Coverage of limited scope plans.
- “Sec. 845. Regulations.

**SEC. 203. AVAILABILITY OF COURT REMEDIES.**

(a) IN GENERAL.—Section 502 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1132) is amended by adding at the end the following new subsection:

“(n) CAUSE OF ACTION RELATING TO PROVISION OF HEALTH BENEFITS.—

“(1) IN GENERAL.—In any case in which—

“(A) a person who is a fiduciary of a group health plan, a health insurance issuer offering health insurance coverage in connection with the plan, or an agent of the plan or plan sponsor (not including a participating physician, other than a physician who participated in making the final decision under section 802 pursuant to section 802(b)(1)(A)) and who, under the plan, has authority to make final decisions under 802—

“(i) fails to exercise ordinary care in making an incorrect determination in the case of a participant or beneficiary that an item or service is excluded from coverage under the terms of the plan based on the fact that the item or service—

“(I) does not meet the requirements for medical appropriateness or necessity,

“(II) would constitute experimental treatment or technology (as defined under the plan), or

“(III) is not a covered benefit, or

“(ii) fails to exercise ordinary care to ensure that—

“(I) any denial of claim for benefits (within the meaning of section 801(f)), or

“(II) any decision by the plan on a request, made by a participant or beneficiary under section 802 or 803, for a reversal of an earlier decision of the plan,

is made and issued to the participant or beneficiary (in such form and manner as may be prescribed in regulations of the Secretary) before the end of the applicable period specified in section 801, 802, or 803, and

“(B) such failure is the proximate cause of substantial harm to, or wrongful death of, the participant or beneficiary,

such person shall be liable to the participant or beneficiary (or the estate of such participant or beneficiary) for economic and noneconomic damages in connection with such failure and such injury or death (subject to paragraph (10)). For purposes of this subsection, the term ‘final decision’ means, with respect to a group health plan, the sole final decision of the plan under section 802.

“(2) ORDINARY CARE.—For purposes of this subsection, the term ‘ordinary care’ means the care, skill, prudence, and diligence under the circumstances then prevailing that a prudent individual acting in a like capacity and familiar with such matters would use in the conduct of an enterprise of a like character and with like aims.

“(3) SUBSTANTIAL HARM.—The term ‘substantial harm’ means loss of life, loss or significant impairment of limb or bodily function, significant disfigurement, or severe and chronic physical pain.

“(4) EXCEPTION FOR EMPLOYERS AND OTHER PLAN SPONSORS.—

“(A) IN GENERAL.—Subject to subparagraph (B), paragraph (1) does not authorize—

“(i) any cause of action against an employer or other plan sponsor maintaining the group health plan (or against an employee of such an employer or sponsor acting within the scope of employment),

“(ii) a right of recovery or indemnity by a person against an employer or other plan sponsor (or such an employee) for damages assessed against the person pursuant to a cause of action under paragraph (1), or

“(iii) any cause of action in connection with the provision of excepted benefits described in section 733(c), other than those described in section 733(c)(2).

“(B) SPECIAL RULE.—Subparagraph (A) shall not preclude any cause of action described in paragraph (1) commenced against an employer or other plan sponsor (or against an employee of such an employer or sponsor acting within the scope of employment), but only if—

“(i) such action is based on the direct participation of the employer or other plan sponsor (or employee of the employer or plan sponsor) in the final decision of the plan with respect to a specific participant or beneficiary on a claim for benefits covered under the plan or health insurance coverage in the case at issue; and

“(ii) the decision on the claim resulted in substantial harm to, or the wrongful death of, such participant or beneficiary.

“(C) DIRECT PARTICIPATION.—For purposes of this subsection, the term ‘direct participation’ means, in connection with a final decision under section 802, the actual making of such final decision as a plan fiduciary or the actual exercise of final controlling authority in the approval of such final decision. In determining whether an employer or other plan sponsor (or employee of an employer or other plan sponsor) is engaged in direct participation in the final decision of the plan on a claim, the employer or plan sponsor (or employee) shall not be construed to be engaged in such direct participation (and to be liable for any damages whatsoever) because of any form of decisionmaking or other conduct, whether or not fiduciary in nature, that does not involve a final decision with respect to a specific claim for benefits by a specific participant or beneficiary, including (but not limited to)—

“(i) any participation by the employer or other plan sponsor (or employee) in the selection of the group health plan or health insurance coverage involved or the third party administrator or other agent;

“(ii) any engagement by the employer or other plan sponsor (or employee) in any cost-benefit analysis undertaken in connection with the selection of, or continued maintenance of, the plan or coverage involved;

“(iii) any participation by the employer or other plan sponsor (or employee) in the creation, continuation, modification, or termination of the plan or of any coverage, benefit, or item or service covered by the plan;

“(iv) any participation by the employer or other plan sponsor (or employee) in the design of any coverage, benefit, or item or service covered by the plan, including the amount of copayment and limits connected with such coverage, and the specification of any protocol, procedure, or policy for determining whether any such coverage, benefit, or item or service is medically necessary and appropriate or is experimental or investigational;

“(v) any action by an agent of the employer or plan sponsor in making such a final decision on behalf of such employer or plan sponsor;

“(vi) any decision by an employer or plan sponsor (or employee) or agent acting on behalf of an employer or plan sponsor either to authorize coverage for, or to intercede or not to intercede as an advocate for or on behalf of, any specific participant or beneficiary (or group of participants or beneficiaries) under the plan;

“(vii) the approval of, or participation in the approval of, the plan provisions defining medical necessity or of policies or procedures that have a direct bearing on the outcome of the final decision; or

“(viii) any other form of decisionmaking or other conduct performed by the employer or other plan sponsor (or employee) in connection with the plan or coverage involved unless it involves the making of a final decision of the plan consisting of a failure described in clause (i) or (ii) of paragraph (1)(A) as to specific participants or beneficiaries who suffer substantial harm or wrongful death as a proximate cause of such decision.

“(5) REQUIRED DEMONSTRATION OF DIRECT PARTICIPATION.—An action against an employer or plan sponsor (or employee thereof) under this subsection shall be immediately dismissed—

“(A) in the absence of an allegation in the complaint of direct participation by the employer or plan sponsor in the final decision of the plan with respect to a specific participant or beneficiary who suffers substantial harm or wrongful death, or

“(B) upon a demonstration to the court that such employer or plan sponsor (or employee) did not directly participate in the final decision of the plan.

“(6) TREATMENT OF THIRD-PARTY PROVIDERS OF NONDISCRETIONARY ADMINISTRATIVE SERVICES.—Paragraph (1) does not authorize any action against any person providing nondiscretionary administrative services to employers or other plan sponsors.

“(7) REQUIREMENT OF EXHAUSTION OF ADMINISTRATIVE REMEDIES.—

“(A) IN GENERAL.—Paragraph (1) applies in the case of any cause of action only if all remedies under section 503 (including remedies under sections 802 and 803, made applicable under section 714) with respect to such cause of action have been exhausted.

“(B) EXTERNAL REVIEW REQUIRED.—For purposes of subparagraph (A), administrative remedies under section 503 shall not be deemed exhausted until available remedies under section 803 have been elected and are exhausted by issuance of a final determination by an external appeal entity under such section.

“(C) CONSIDERATION OF ADMINISTRATIVE DETERMINATIONS.—Any determinations made under section 802 or

803 made while an action under this paragraph is pending shall be given due consideration by the court in such action.

“(8) USE OF EXTERNAL APPEAL ENTITY IN ESTABLISHING ABSENCE OF SUBSTANTIAL HARM OR CAUSATION IN LITIGATION.—

“(A) IN GENERAL.—In any action under this subsection by an individual in which damages are sought on the basis of substantial harm to the individual, the defendant may obtain (at its own expense), under procedures similar to procedures applicable under section 803, a determination by a qualified external appeal entity (as defined in section 803(c)(1)) that has not been involved in any stage of the grievance or appeals process which resulted in such action as to—

“(i) whether such substantial harm has been sustained, and

“(ii) whether the proximate cause of such injury was the result of the failure of the defendant to exercise ordinary care, as described in paragraph (1)(A).

“(B) EFFECT OF FINDING IN FAVOR OF DEFENDANT.—If the external appeal entity determines that such an injury has not been sustained or was not proximately caused by such a failure, such a finding shall be an affirmative defense, and the action shall be dismissed forthwith unless such finding is overcome upon a showing of clear and convincing evidence to the contrary. Notwithstanding subsection (g), in any case in which the plaintiff fails in any attempt to make such a showing to the contrary, the court shall award to the defendant reasonable attorney’s fees and the costs of the action incurred in connection with such failed showing.

“(9) REBUTTABLE PRESUMPTION.—In the case of any action commenced pursuant to paragraph (1), there shall be a rebuttable presumption in favor of the decision of the external appeal entity rendered upon completion of any review elected under section 803 and such presumption may be overcome only upon a showing of clear and convincing evidence to the contrary.

“(10) MAXIMUM NONECONOMIC DAMAGES.—Total liability for noneconomic loss under this subsection in connection with any failure with respect to any participant or beneficiary may not exceed the lesser of—

“(A) \$500,000, or

“(B) 2 times the amount of economic loss.

The dollar amount under subparagraph (A), shall be increased or decreased, for each calendar year that ends after December 31, 2001, by the same percentage as the percentage by which the medical care expenditure category of the Consumer Price Index for All Urban Consumers (United States city average), published by the Bureau of Labor Statistics, for September of the preceding calendar year has increased or decreased from such index for September 2000

“(11) PROHIBITION OF AWARD OF PUNITIVE DAMAGES.—

“(A) GENERAL RULE.—Except as provided in this paragraph, nothing in this subsection shall be construed as authorizing a cause of action for punitive, exemplary, or similar damages.

“(B) EXCEPTION.—Punitive damages are authorized in any case described in paragraph (1)(A)(ii)(II) in which the plaintiff establishes by clear and convincing evidence that conduct carried out by the defendant with a conscious, flagrant indifference to the rights or safety of others was the proximate cause of the harm that is the subject of the action and that such conduct was contrary to the recommendations of an external appeal entity issued in the determination in such case rendered pursuant to section 803.

“(C) LIMITATION ON AMOUNT.—

“(i) IN GENERAL.—The amount of punitive damages that may be awarded in an action described in subparagraph (B) may not exceed the greater of—

“(I) 2 times the sum of the amount awarded to the claimant for economic loss; or

“(II) \$250,000.

“(ii) SPECIAL RULE.—Notwithstanding clause (i), in any action described in subparagraph (B) against an individual whose net worth does not exceed \$500,000 or against an owner of an unincorporated business, or any partnership, corporation, association, unit of local government, or organization which has fewer than 25 employees, the punitive damages shall not exceed the lesser of—

“(I) 2 times the amount awarded to the claimant for economic loss; or

“(II) \$250,000.

“(iii) CONTROLLED GROUPS.—

“(I) IN GENERAL.—For the purpose of determining the applicability of clause (ii) to any employer, in determining the number of employees of an employer who is a member of a controlled group, the employees of any person in such group shall be deemed to be employees of the employer.

“(II) CONTROLLED GROUP.—For purposes of subclause (I), the term ‘controlled group’ means any group treated as a single employer under subsection (b), (c), (m), or (o) of section 414 of the Internal Revenue Code of 1986.

“(D) EXCEPTION FOR INSUFFICIENT AWARD IN CASES OF EGREGIOUS CONDUCT.—

“(i) DETERMINATION BY COURT.—If the court makes a determination, based on clear and convincing evidence and after considering each of the factors in subparagraph (E), that the application of subparagraph (C) would result in an award of punitive damages that is insufficient to punish the egregious conduct of the defendant against whom the punitive damages are to be awarded or to deter such conduct in the future, the

court shall determine the additional amount of punitive damages (referred to in this subparagraph as the 'additional amount') in excess of the amount determined in accordance with subparagraph (C) to be awarded against the defendant in a separate proceeding in accordance with this subparagraph.

"(ii) ABSOLUTE LIMIT ON PUNITIVES.—Nothing in this subtitle shall be construed to authorize the court to award an additional amount greater than an amount equal to the maximum amount applicable under subparagraph (C).

"(iii) REQUIREMENTS FOR AWARDED ADDITIONAL AMOUNT.—If the court awards an additional amount pursuant to this subparagraph, the court shall state its reasons for setting the amount of the additional amount in findings of fact and conclusions of law.

"(E) FACTORS FOR CONSIDERATION IN CASES OF EGREGIOUS CONDUCT.—In any proceeding under subparagraph (D), the matters to be considered by the court shall include (but are not limited to)—

"(i) the extent to which the defendant acted with actual malice;

"(ii) the likelihood that serious harm would arise from the conduct of the defendant;

"(iii) the degree of the awareness of the defendant of that likelihood;

"(iv) the profitability of the misconduct to the defendant;

"(v) the duration of the misconduct and any concurrent or subsequent concealment of the conduct by the defendant;

"(vi) the attitude and conduct of the defendant upon the discovery of the misconduct and whether the misconduct has terminated;

"(vii) the financial condition of the defendant; and

"(viii) the cumulative deterrent effect of other losses, damages, and punishment suffered by the defendant as a result of the misconduct, reducing the amount of punitive damages on the basis of the economic impact and severity of all measures to which the defendant has been or may be subjected, including—

"(I) compensatory and punitive damage awards to similarly situated claimants;

"(II) the adverse economic effect of stigma or loss of reputation;

"(III) civil fines and criminal and administrative penalties; and

"(IV) stop sale, cease and desist, and other remedial or enforcement orders.

"(F) APPLICATION BY COURT.—This paragraph shall be applied by the court and, in the case of a trial by jury, application of this paragraph shall not be disclosed to the jury.

“(G) LIMITATION ON PUNITIVE DAMAGES.—No person shall be liable for punitive, exemplary, or similar damages in an action under this subsection based on any failure described in paragraph (1) if such failure was in compliance with the recommendations of an external appeal entity issued in a determination under section 803.

“(H) BIFURCATION AT REQUEST OF ANY PARTY.—

“(i) IN GENERAL.—At the request of any party the trier of fact in any action that is subject to this paragraph shall consider in a separate proceeding, held subsequent to the determination of the amount of compensatory damages, whether punitive damages are to be awarded for the harm that is the subject of the action and the amount of the award.

“(ii) INADMISSIBILITY OF EVIDENCE RELATIVE ONLY TO A CLAIM OF PUNITIVE DAMAGES IN A PROCEEDING CONCERNING COMPENSATORY DAMAGES.—If any party requests a separate proceeding under clause (i), in a proceeding to determine whether the claimant may be awarded compensatory damages, any evidence, argument, or contention that is relevant only to the claim of punitive damages, as determined by applicable State law, shall be inadmissible.

“(12) LIMITATION OF ACTION.—Paragraph (1) shall not apply in connection with any action commenced after the later of—

“(A) 1 year after (i) the date of the last action which constituted a part of the failure, or (ii) in the case of an omission, the latest date on which the fiduciary could have cured the failure, or

“(B) 1 year after the earliest date on which the plaintiff first knew, or reasonably should have known, of the substantial harm resulting from the failure.

“(13) COORDINATION WITH FIDUCIARY REQUIREMENTS.—A fiduciary shall not be treated as failing to meet any requirement of part 4 solely by reason of any action taken by a fiduciary which consists of full compliance with the reversal under section 803 of a denial of claim for benefits (within the meaning of section 801(f)).

“(14) CONSTRUCTION.—Nothing in this subsection shall be construed as authorizing a cause of action for the failure to provide an item or service which is not covered under the group health plan involved.

“(15) PROTECTION OF MEDICAL MALPRACTICE AND SIMILAR ACTIONS UNDER STATE LAW.—This subsection shall not be construed to preclude any action under State law (as defined in section 514(c)(1)) not otherwise preempted under this title with respect to the duty (if any) under such State law imposed on any person to exercise a specified standard of care when making a health care treatment decision in any case in which medical services are provided by such person or in any case in which such decision affects the quality of care or treatment provided or received.

“(16) COEXISTING ACTIONS IN FEDERAL AND STATE COURTS DISALLOWED.—

“(A) PRECEDENCE OF FEDERAL ACTION.—An action may be commenced under this subsection only if no action for damages has been commenced by the plaintiff under State law (as defined in section 514(c)(1)) based on the same substantial harm.

“(B) ACTIONS UNDER STATE LAW SUPERSEDED.—Upon the commencement of any action under this subsection, this subsection supersedes any action authorized under State law (as so defined) against any person based on the same substantial harm during the pendency of the action commenced under this subsection.

“(C) DOUBLE RECOVERY OF DAMAGES PRECLUDED.—This subsection supersedes any action under State law (as so defined) for damages based on any substantial harm to the extent that damages for such substantial harm have been recovered in an action under this subsection.

“(17) LIMITATION ON RELIEF WHERE DEFENDANT’S POSITION PREVIOUSLY SUPPORTED UPON EXTERNAL REVIEW.—In any case in which the court finds the defendant to be liable in an action under this subsection, to the extent that such liability is based on a finding by the court of a particular failure described in paragraph (1) and such finding is contrary to a determination by an external review entity in a decision previously rendered under section 803 with respect to such defendant, no relief shall be available under this subsection in addition to the relief otherwise available under subsection (a)(1)(B).”

(b) CONFORMING AMENDMENT.—Section 502(a)(1)(A) of such Act (29 U.S.C. 1132(a)(1)(A)) is amended by inserting “or (n)” after “subsection (c)”.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to acts and omissions (from which a cause of action arises) occurring on or after the date of the enactment of this Act.

**SEC. 204. AVAILABILITY OF BINDING ARBITRATION.**

(a) IN GENERAL.—Section 503 of the Employee Retirement Income Security Act of 1974 (as amended by the preceding provisions of this Act) is amended further—

(1) in subsection (a), by inserting “IN GENERAL.—” after “(a)”;

(2) in subsection (b), by striking “(b) In the case” and inserting the following:

“(b) GROUP HEALTH PLANS.—

“(1) IN GENERAL.—In the case”; and

(3) by adding at the end of subsection (b) the following:

“(2) BINDING ARBITRATION PERMITTED AS ALTERNATIVE MEANS OF DISPUTE RESOLUTION.—

“(A) IN GENERAL.—A group health plan shall not be treated as failing to meet the requirements of the preceding provisions of this section relating to review of any adverse coverage decision rendered by or under the plan, if—

“(i) in lieu of the procedures otherwise provided under the plan in accordance with such provisions and in lieu of any subsequent review of the matter by a court under section 502—

“(I) the aggrieved participant or beneficiary elects in the request for the review a procedure by which the dispute is resolved by binding arbitration which is available under the plan with respect to similarly situated participants and beneficiaries and which meets the requirements of subparagraph (B); or

“(II) in the case of any such plan or portion thereof which is established and maintained pursuant to a bona fide collective bargaining agreement, the plan provides for a procedure by which such disputes are resolved by means of binding arbitration which meets the requirements of subparagraph (B); and

“(ii) the additional requirements of subparagraph (B) are met.

“(B) ADDITIONAL REQUIREMENTS.—The Secretary shall prescribe by regulation requirements for arbitration procedures under this paragraph, including at least the following requirements:

“(i) ARBITRATION PANEL.—The arbitration shall be conducted by an arbitration panel meeting the requirements of subparagraph (C).

“(ii) FAIR PROCESS; DE NOVO DETERMINATION.—The procedure shall provide for a fair, de novo determination.

“(iii) OPPORTUNITY TO SUBMIT EVIDENCE, HAVE REPRESENTATION, AND MAKE ORAL PRESENTATION.—Each party to the arbitration procedure—

“(I) may submit and review evidence related to the issues in dispute;

“(II) may use the assistance or representation of one or more individuals (any of whom may be an attorney); and

“(III) may make an oral presentation.

“(iv) PROVISION OF INFORMATION.—The plan shall provide timely access to all its records relating to the matters under arbitration and to all provisions of the plan relating to such matters.

“(v) TIMELY DECISIONS.—A determination by the arbitration panel on the decision shall—

“(I) be made in writing;

“(II) be binding on the parties; and

“(III) be made in accordance with the medical exigencies of the case involved.

“(vi) EXHAUSTION OF EXTERNAL REVIEW REQUIRED.—The arbitration procedures under this paragraph shall not be available to party unless the party has exhausted external review procedures under section 804.

“(vii) VOLUNTARY ELECTION.—A group health plan may not require, through the plan document, a contract, or otherwise, that a participant or beneficiary make the election described in subparagraph (A)(i)(I).

“(C) ARBITRATION PANEL.—

“(i) IN GENERAL.—Arbitrations commenced pursuant to this paragraph shall be conducted by a panel of arbitrators selected by the parties made up of 3 individuals, including at least one practicing physician and one practicing attorney.

“(ii) QUALIFICATIONS.—Any individual who is a member of an arbitration panel shall meet the following requirements:

“(I) There is no real or apparent conflict of interest that would impede the individual conducting arbitration independent of the plan and meets the independence requirements of clause (iii).

“(II) The individual has sufficient medical or legal expertise to conduct the arbitration for the plan on a timely basis.

“(III) The individual has appropriate credentials and has attained recognized expertise in the applicable medical or legal field.

“(IV) The individual was not involved in the initial adverse coverage decision or any other review thereof.

“(iii) INDEPENDENCE REQUIREMENTS.—An individual described in clause (ii) meets the independence requirements of this clause if—

“(I) the individual is not affiliated with any related party,

“(II) any compensation received by such individual in connection with the binding arbitration procedure is reasonable and not contingent on any decision rendered by the individual,

“(III) under the terms of the plan, the plan has no recourse against the individual or entity in connection with the binding arbitration procedure, and

“(IV) the individual does not otherwise have a conflict of interest with a related party as determined under such regulations as the Secretary may prescribe.

“(iv) RELATED PARTY.—For purposes of clause (iii), the term ‘related party’ means—

“(I) the plan or any health insurance issuer offering health insurance coverage in connection with the plan (or any officer, director, or management employee of such plan or issuer),

“(II) the physician or other medical care provider that provided the medical care involved in the coverage decision,

“(III) the institution at which the medical care involved in the coverage decision is provided,

“(IV) the manufacturer of any drug or other item that was included in the medical care involved in the coverage decision, or

“(V) any other party determined under such regulations as the Secretary may prescribe to have a substantial interest in the coverage decision .

“(iv) AFFILIATED.—For purposes of clause (iii), the term ‘affiliated’ means, in connection with any entity, having a familial, financial, or professional relationship with, or interest in, such entity.

“(D) DECISIONS.—

“(i) IN GENERAL.—Decisions rendered by the arbitration panel shall be binding on all parties to the arbitration and shall be enforceable under section 502 as if the terms of the decision were the terms of the plan, except that the court may vacate any award made pursuant to the arbitration for any cause described in paragraph (1), (2), (3), (4), or (5) of section 10(a) of title 9, United States Code.

“(ii) ALLOWABLE REMEDIES.—The remedies which may be implemented by the arbitration panel shall consist of those remedies which would be available in an action timely commenced by a participant or beneficiary under section 502 after exhaustion of administrative remedies, except that a money award may be made in the arbitration proceedings in any amount not to exceed 3 times the maximum amount of damages that would be allowable in such case in an action described in section 502(n).”

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to adverse coverage decisions initially rendered by group health plans on or after the date of the enactment of this Act.

## **TITLE III— AMENDMENTS TO THE INTERNAL REVENUE CODE OF 1986**

### **SEC. 301. APPLICATION TO GROUP HEALTH PLANS UNDER THE INTERNAL REVENUE CODE OF 1986.**

Subchapter B of chapter 100 of the Internal Revenue Code of 1986 is amended—

(1) in the table of sections, by inserting after the item relating to section 9812 the following new item:

“Sec. 9813. Standard relating to chapter 101.”; and

(2) by inserting after section 9812 the following:

#### **“SEC. 9813. STANDARD RELATING TO CHAPTER 101.**

“A group health plan shall comply with the requirements of chapter 101 and such requirements shall be deemed to be incorporated into this section.”

### **SEC. 302. IMPROVING MANAGED CARE.**

(a) IN GENERAL.—The Internal Revenue Code of 1986 is amended by adding at the end the following new chapter:

#### **“CHAPTER 101—IMPROVING MANAGED CARE**

“Subchapter A. Access to care.

“Subchapter B. Access to information.

“Subchapter C. Protecting the doctor-patient relationship.  
 “Subchapter D. Definitions.

### “Subchapter A—Access to Care

“Sec. 9901. Choice of health care professional.  
 “Sec. 9902. Access to emergency care.  
 “Sec. 9903. Access to specialty care.  
 “Sec. 9904. Access to obstetrical and gynecological care.  
 “Sec. 9905. Access to pediatric care.  
 “Sec. 9906. Continuity of care.  
 “Sec. 9907. Network adequacy.  
 “Sec. 9908. Access to experimental or investigational prescription drugs.  
 “Sec. 9909. Coverage for individuals participating in approved cancer clinical trials.

#### “SEC. 9901. CHOICE OF HEALTH CARE PROFESSIONAL.

“(a) PRIMARY CARE.—If a group health plan requires or provides for designation by a participant or beneficiary of a participating primary care provider, then the plan shall permit each participant and beneficiary to designate any participating primary care provider who is available to accept such individual.

“(b) SPECIALISTS.—A group health plan shall permit each participant or beneficiary to receive medically necessary or appropriate specialty care, pursuant to appropriate referral procedures, from any qualified participating health care professional who is available to accept such individual for such care.

#### “SEC. 9902. ACCESS TO EMERGENCY CARE.

“(a) COVERAGE OF EMERGENCY SERVICES.—

“(1) IN GENERAL.—If a group health plan provides or covers any benefits with respect to services in an emergency department of a hospital, the plan shall cover emergency services (as defined in paragraph (2)(B))—

“(A) without the need for any prior authorization determination;

“(B) whether the health care provider furnishing such services is a participating provider with respect to such services;

“(C) in a manner so that, if such services are provided to a participant or beneficiary—

“(i) by a nonparticipating health care provider with or without prior authorization, or

“(ii) by a participating health care provider without prior authorization,

the participant or beneficiary is not liable for amounts that exceed the amounts of liability that would be incurred if the services were provided by a participating health care provider with prior authorization; and

“(D) without regard to any other term or condition of such coverage (other than exclusion or coordination of benefits, or an affiliation or waiting period, permitted under section 2701 of the Public Health Service Act, section 701 of the Employee Retirement Income Security Act of 1974, or section 9801 of the Internal Revenue Code of 1986, and other than applicable cost-sharing).

“(2) DEFINITIONS.—In this section:

“(A) EMERGENCY MEDICAL CONDITION.—The term ‘emergency medical condition’ means—

“(i) a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act; and

“(ii) a medical condition manifesting itself in a neonate by acute symptoms of sufficient severity (including severe pain) such that a prudent health care professional could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act.

“(B) EMERGENCY SERVICES.—The term ‘emergency services’ means—

“(i) with respect to an emergency medical condition described in subparagraph (A)(i)—

“(I) a medical screening examination (as required under section 1867 of the Social Security Act) that is within the capability of the emergency department of a hospital, including ancillary services routinely available to the emergency department to evaluate such emergency medical condition, and

“(II) within the capabilities of the staff and facilities available at the hospital, such further medical examination and treatment as are required under section 1867 of such Act to stabilize the patient; or

“(ii) with respect to an emergency medical condition described in subparagraph (A)(ii), medical treatment for such condition rendered by a health care provider in a hospital to a neonate, including available hospital ancillary services in response to an urgent request of a health care professional and to the extent necessary to stabilize the neonate.

“(C) STABILIZE.—The term ‘to stabilize’ means, with respect to an emergency medical condition, to provide such medical treatment of the condition as may be necessary to assure, within reasonable medical probability, that no material deterioration of the condition is likely to result from or occur during the transfer of the individual from a facility.

“(b) REIMBURSEMENT FOR MAINTENANCE CARE AND POST-STABILIZATION CARE.—If benefits are available under a group health plan with respect to maintenance care or post-stabilization care covered under the guidelines established under section 1852(d)(2) of the Social Security Act, the plan shall provide for reimbursement with respect to such services provided to a participant or beneficiary other than through a participating health care provider in

a manner consistent with subsection (a)(1)(C) (and shall otherwise comply with such guidelines).

“(c) COVERAGE OF EMERGENCY AMBULANCE SERVICES.—

“(1) IN GENERAL.—If a group health plan provides any benefits with respect to ambulance services and emergency services, the plan shall cover emergency ambulance services (as defined in paragraph (2))) furnished under the plan under the same terms and conditions under subparagraphs (A) through (D) of subsection (a)(1) under which coverage is provided for emergency services.

“(2) EMERGENCY AMBULANCE SERVICES.—For purposes of this subsection, the term ‘emergency ambulance services’ means ambulance services (as defined for purposes of section 1861(s)(7) of the Social Security Act) furnished to transport an individual who has an emergency medical condition (as defined in subsection (a)(2)(A)) to a hospital for the receipt of emergency services (as defined in subsection (a)(2)(B)) in a case in which the emergency services are covered under the plan pursuant to subsection (a)(1) and a prudent layperson, with an average knowledge of health and medicine, could reasonably expect that the absence of such transport would result in placing the health of the individual in serious jeopardy, serious impairment of bodily function, or serious dysfunction of any bodily organ or part.

“SEC. 9903. ACCESS TO SPECIALTY CARE.

“(a) SPECIALTY CARE FOR COVERED SERVICES.—

“(1) IN GENERAL.—If—

“(A) an individual is a participant or beneficiary under a group health plan,

“(B) the individual has a condition or disease of sufficient seriousness and complexity to require treatment by a specialist or the individual requires physician pathology services, and

“(C) benefits for such treatment or services are provided under the plan,

the plan shall make or provide for a referral to a specialist who is available and accessible (consistent with standards developed under section 9907) to provide the treatment for such condition or disease or to provide such services.

“(2) SPECIALIST DEFINED.—For purposes of this subsection, the term ‘specialist’ means, with respect to a condition or services, a health care practitioner, facility, or center or physician pathologist that has adequate expertise through appropriate training and experience (including, in the case of a child, appropriate pediatric expertise and in the case of a pregnant woman, appropriate obstetrical expertise) to provide high quality care in treating the condition or to provide physician pathology services.

“(3) CARE UNDER REFERRAL.—A group health plan may require that the care provided to an individual pursuant to such referral under paragraph (1) with respect to treatment be—

“(A) pursuant to a treatment plan, only if the treatment plan is developed by the specialist and approved by the plan, in consultation with the designated primary care pro-

vider or specialist and the individual (or the individual's designee), and

“(B) in accordance with applicable quality assurance and utilization review standards of the plan.

Nothing in this subsection shall be construed as preventing such a treatment plan for an individual from requiring a specialist to provide the primary care provider with regular updates on the specialty care provided, as well as all necessary medical information.

“(4) REFERRALS TO PARTICIPATING PROVIDERS.—A group health plan is not required under paragraph (1) to provide for a referral to a specialist that is not a participating provider, unless the plan does not have a specialist that is available and accessible to treat the individual's condition or provide physician pathology services and that is a participating provider with respect to such treatment or services.

“(5) REFERRALS TO NONPARTICIPATING PROVIDERS.—In a case in which a referral of an individual to a nonparticipating specialist is required under paragraph (1), the group health plan shall provide the individual the option of at least three nonparticipating specialists.

“(6) TREATMENT OF NONPARTICIPATING PROVIDERS.—If a plan refers an individual to a nonparticipating specialist pursuant to paragraph (1), services provided pursuant to the approved treatment plan (if any) shall be provided at no additional cost to the individual beyond what the individual would otherwise pay for services received by such a specialist that is a participating provider.

“(b) SPECIALISTS AS GATEKEEPER FOR TREATMENT OF ONGOING SPECIAL CONDITIONS.—

“(1) IN GENERAL.—A group health plan shall have a procedure by which an individual who is a participant or beneficiary and who has an ongoing special condition (as defined in paragraph (3)) may request and receive a referral to a specialist for such condition who shall be responsible for and capable of providing and coordinating the individual's care with respect to the condition. Under such procedures if such an individual's care would most appropriately be coordinated by such a specialist, such plan shall refer the individual to such specialist.

“(2) TREATMENT FOR RELATED REFERRALS.—Such specialists shall be permitted to treat the individual without a referral from the individual's primary care provider and may authorize such referrals, procedures, tests, and other medical services as the individual's primary care provider would otherwise be permitted to provide or authorize, subject to the terms of the treatment (referred to in subsection (a)(3)(A)) with respect to the ongoing special condition.

“(3) ONGOING SPECIAL CONDITION DEFINED.—In this subsection, the term ‘ongoing special condition’ means a condition or disease that—

“(A) is life-threatening, degenerative, or disabling, and

“(B) requires specialized medical care over a prolonged period of time.

“(4) TERMS OF REFERRAL.—The provisions of paragraphs (3) through (5) of subsection (a) apply with respect to referrals under paragraph (1) of this subsection in the same manner as they apply to referrals under subsection (a)(1).

“(5) CONSTRUCTION.—Nothing in this subsection shall be construed as preventing an individual who is a participant or beneficiary and who has an ongoing special condition from having the individual’s primary care physician assume the responsibilities for providing and coordinating care described in paragraph (1).

“(c) STANDING REFERRALS.—

“(1) IN GENERAL.—A group health plan shall have a procedure by which an individual who is a participant or beneficiary and who has a condition that requires ongoing care from a specialist may receive a standing referral to such specialist for treatment of such condition. If the plan, or if the primary care provider in consultation with the medical director of the plan and the specialist (if any), determines that such a standing referral is appropriate, the plan shall make such a referral to such a specialist if the individual so desires.

“(2) TERMS OF REFERRAL.—The provisions of paragraphs (3) through (5) of subsection (a) apply with respect to referrals under paragraph (1) of this subsection in the same manner as they apply to referrals under subsection (a)(1).

**“SEC. 9904. ACCESS TO OBSTETRICAL AND GYNECOLOGICAL CARE.**

“(a) IN GENERAL.—If a group health plan requires or provides for a participant or beneficiary to designate a participating primary care health care professional, the plan—

“(1) may not require authorization or a referral by the individual’s primary care health care professional or otherwise for covered gynecological care (including preventive women’s health examinations) or for covered pregnancy-related services provided by a participating physician (including a family practice physician) who specializes or is trained and experienced in gynecology or obstetrics, respectively, to the extent such care is otherwise covered; and

“(2) shall treat the ordering of other gynecological or obstetrical care by such a participating physician as the authorization of the primary care health care professional with respect to such care under the plan.

“(b) CONSTRUCTION.—Nothing in subsection (a) shall be construed to—

“(1) waive any exclusions of coverage under the terms of the plan with respect to coverage of gynecological or obstetrical care;

“(2) preclude the group health plan involved from requiring that the gynecologist or obstetrician notify the primary care health care professional or the plan of treatment decisions; or

“(3) prevent a plan from offering, in addition to physicians described in subsection (a)(1), non-physician health care professionals who are trained and experienced in gynecology or obstetrics.

**“SEC. 9905. ACCESS TO PEDIATRIC CARE.**

“(a) PEDIATRIC CARE.—If a group health plan requires or provides for a participant or beneficiary to designate a participating primary care provider for a child of such individual, the plan shall permit the individual to designate a physician (including a family practice physician) who specializes or is trained and experienced in pediatrics as the child’s primary care provider.

“(b) CONSTRUCTION.—Nothing in subsection (a) shall be construed to waive any exclusions of coverage under the terms of the plan with respect to coverage of pediatric care.

**“SEC. 9906. CONTINUITY OF CARE.**

“(a) IN GENERAL.—

“(1) TERMINATION OF PROVIDER.—If a contract between a group health plan and a health care provider is terminated (as defined in paragraph (3)(B)), or benefits or coverage provided by a health care provider are terminated because of a change in the terms of provider participation in a group health plan, and an individual who is a participant or beneficiary in the plan is undergoing treatment from the provider for an ongoing special condition (as defined in paragraph (3)(A)) at the time of such termination, the plan shall—

“(A) notify the individual on a timely basis of such termination and of the right to elect continuation of coverage of treatment by the provider under this section; and

“(B) subject to subsection (c), permit the individual to elect to continue to be covered with respect to treatment by the provider of such condition during a transitional period (provided under subsection (b)).

“(2) TREATMENT OF TERMINATION OF CONTRACT WITH HEALTH INSURANCE ISSUER.—If a contract for the provision of health insurance coverage between a group health plan and a health insurance issuer is terminated and, as a result of such termination, coverage of services of a health care provider is terminated with respect to an individual, the provisions of paragraph (1) (and the succeeding provisions of this section) shall apply under the plan in the same manner as if there had been a contract between the plan and the provider that had been terminated, but only with respect to benefits that are covered under the plan after the contract termination.

“(3) DEFINITIONS.—For purposes of this section:

“(A) ONGOING SPECIAL CONDITION.—The term ‘ongoing special condition’ has the meaning given such term in section 9903(b)(3), and also includes pregnancy.

“(B) TERMINATION.—The term ‘terminated’ includes, with respect to a contract, the expiration or nonrenewal of the contract, but does not include a termination of the contract by the plan for failure to meet applicable quality standards or for fraud.

“(b) TRANSITIONAL PERIOD.—

“(1) IN GENERAL.—Except as provided in paragraphs (2) through (4), the transitional period under this subsection shall extend up to 90 days (as determined by the treating health care professional) after the date of the notice described in subsection (a)(1)(A) of the provider’s termination.

“(2) SCHEDULED SURGERY AND ORGAN TRANSPLANTATION.—If surgery or organ transplantation was scheduled for an individual before the date of the announcement of the termination of the provider status under subsection (a)(1)(A) or if the individual on such date was on an established waiting list or otherwise scheduled to have such surgery or transplantation, the transitional period under this subsection with respect to the surgery or transplantation shall extend beyond the period under paragraph (1) and until the date of discharge of the individual after completion of the surgery or transplantation.

“(3) PREGNANCY.—If—

“(A) a participant or beneficiary was determined to be pregnant at the time of a provider’s termination of participation, and

“(B) the provider was treating the pregnancy before date of the termination,  
the transitional period under this subsection with respect to provider’s treatment of the pregnancy shall extend through the provision of post-partum care directly related to the delivery.

“(4) TERMINAL ILLNESS.—If—

“(A) a participant or beneficiary was determined to be terminally ill (as determined under section 1861(dd)(3)(A) of the Social Security Act) at the time of a provider’s termination of participation, and

“(B) the provider was treating the terminal illness before the date of termination,  
the transitional period under this subsection shall extend for the remainder of the individual’s life for care directly related to the treatment of the terminal illness or its medical manifestations.

“(c) PERMISSIBLE TERMS AND CONDITIONS.—A group health plan may condition coverage of continued treatment by a provider under subsection (a)(1)(B) upon the individual notifying the plan of the election of continued coverage and upon the provider agreeing to the following terms and conditions:

“(1) The provider agrees to accept reimbursement from the plan and individual involved (with respect to cost-sharing) at the rates applicable prior to the start of the transitional period as payment in full (or, in the case described in subsection (a)(2), at the rates applicable under the replacement plan after the date of the termination of the contract with the health insurance issuer) and not to impose cost-sharing with respect to the individual in an amount that would exceed the cost-sharing that could have been imposed if the contract referred to in subsection (a)(1) had not been terminated.

“(2) The provider agrees to adhere to the quality assurance standards of the plan responsible for payment under paragraph (1) and to provide to such plan necessary medical information related to the care provided.

“(3) The provider agrees otherwise to adhere to such plan’s policies and procedures, including procedures regarding referrals and obtaining prior authorization and providing services pursuant to a treatment plan (if any) approved by the plan.

“(d) CONSTRUCTION.—Nothing in this section shall be construed to require the coverage of benefits which would not have been covered if the provider involved remained a participating provider.

**“SEC. 9907. NETWORK ADEQUACY.**

“(a) REQUIREMENT.—A group health plan shall meet such standards for network adequacy as are established by law pursuant to this section.

“(b) DEVELOPMENT OF STANDARDS.—

“(1) ESTABLISHMENT OF PANEL.—There is established a panel to be known as the Health Care Panel to Establish Network Adequacy Standards (in this section referred to as the ‘Panel’).

“(2) DUTIES OF PANEL.—The Panel shall devise standards for group health plans and to ensure that—

“(A) participants and beneficiaries have access to a sufficient number, mix, and distribution of health care professionals and providers; and

“(B) covered items and services are available and accessible to each participant and beneficiary—

“(i) in the service area of the plan;

“(ii) at a variety of sites of service;

“(iii) with reasonable promptness (including reasonable hours of operation and after hours services);

“(iv) with reasonable proximity to the residences or workplaces of participants and beneficiaries; and

“(v) in a manner that takes into account the diverse needs of such individuals and reasonably assures continuity of care.

“(c) MEMBERSHIP.—

“(1) SIZE AND COMPOSITION.—The Panel shall be composed of 15 members. The Secretary of Health and Human Services, the Majority Leader of the Senate, and the Speaker of House of Representatives shall each appoint 1 member from representatives of private insurance organizations, consumer groups, State insurance commissioners, State medical societies, and State medical specialty societies.

“(2) TERMS OF APPOINTMENT.—The members of the Panel shall serve for the life of the Panel.

“(3) VACANCIES.—A vacancy in the Panel shall not affect the power of the remaining members to execute the duties of the Panel, but any such vacancy shall be filled in the same manner in which the original appointment was made.

“(d) PROCEDURES.—

“(1) MEETINGS.—The Panel shall meet at the call of a majority of its members.

“(2) FIRST MEETING.—The Panel shall convene not later than 60 days after the date of the enactment of the Health Care Quality and Choice Act of 1999.

“(3) QUORUM.—A quorum shall consist of a majority of the members of the Panel.

“(4) HEARINGS.—For the purpose of carrying out its duties, the Panel may hold such hearings and undertake such other activities as the Panel determines to be necessary to carry out its duties.

“(e) ADMINISTRATION.—

“(1) COMPENSATION.—Except as provided in paragraph (1), members of the Panel shall receive no additional pay, allowances, or benefits by reason of their service on the Panel.

“(2) TRAVEL EXPENSES AND PER DIEM.—Each member of the Panel who is not an officer or employee of the Federal Government shall receive travel expenses and per diem in lieu of subsistence in accordance with sections 5702 and 5703 of title 5, United States Code.

“(3) CONTRACT AUTHORITY.—The Panel may contract with and compensate government and private agencies or persons for items and services, without regard to section 3709 of the Revised Statutes (41 U.S.C. 5).

“(4) USE OF MAILS.—The Panel may use the United States mails in the same manner and under the same conditions as Federal agencies and shall, for purposes of the frank, be considered a commission of Congress as described in section 3215 of title 39, United States Code.

“(5) ADMINISTRATIVE SUPPORT SERVICES.—Upon the request of the Panel, the Secretary of Health and Human Services shall provide to the Panel on a reimbursable basis such administrative support services as the Panel may request.

“(f) REPORT AND ESTABLISHMENT OF STANDARDS.—Not later than 2 years after the first meeting, the Panel shall submit a report to Congress and the Secretary of Health and Human Services detailing the standards devised under subsection (b) and recommendations regarding the implementation of such standards. Such standards shall take effect to the extent provided by Federal law enacted after the date of the submission of such report.

“(g) TERMINATION.—The Panel shall terminate on the day after submitting its report to the Secretary of Health and Human Services under subsection (f).

**“SEC. 9908. ACCESS TO EXPERIMENTAL OR INVESTIGATIONAL PRESCRIPTION DRUGS.**

“No use of a prescription drug or medical device shall be considered experimental or investigational under a group health plan if such use is included in the labeling authorized by the U.S. Food and Drug Administration under section 505, 513 or 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or under section 351 of the Public Health Service Act (42 U.S.C. 262), unless such use is demonstrated to be unsafe or ineffective.

**“SEC. 9909. COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CANCER CLINICAL TRIALS.**

“(a) COVERAGE.—

“(1) IN GENERAL.—If a group health plan provides coverage to a qualified individual (as defined in subsection (b)), the plan—

“(A) may not deny the individual participation in the clinical trial referred to in subsection (b)(2);

“(B) subject to subsections (b), (c), and (d), may not deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and services furnished in connection with participation in the trial; and

“(C) may not discriminate against the individual on the basis of the individual’s participation in such trial.

“(2) EXCLUSION OF CERTAIN COSTS.—For purposes of paragraph (1)(B), routine patient costs do not include the cost of the tests or measurements conducted primarily for the purpose of the clinical trial involved.

“(3) USE OF IN-NETWORK PROVIDERS.—If one or more participating providers is participating in a clinical trial, nothing in paragraph (1) shall be construed as preventing a plan from requiring that a qualified individual participate in the trial through such a participating provider if the provider will accept the individual as a participant in the trial.

“(b) QUALIFIED INDIVIDUAL DEFINED.—For purposes of subsection (a), the term ‘qualified individual’ means an individual who is a participant or beneficiary in a group health plan and who meets the following conditions:

“(1)(A) The individual has been diagnosed with cancer.

“(B) The individual is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of such illness.

“(C) The individual’s participation in the trial offers meaningful potential for significant clinical benefit for the individual.

“(2) Either—

“(A) the referring physician is a participating health care professional and has concluded that the individual’s participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1); or

“(B) the individual provides medical and scientific information establishing that the individual’s participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1).

“(c) PAYMENT.—

“(1) IN GENERAL.—Under this section a group health plan shall provide for payment for routine patient costs described in subsection (a)(2) but is not required to pay for costs of items and services that are reasonably expected to be paid for by the sponsors of an approved clinical trial.

“(2) ROUTINE PATIENT CARE COSTS.—For purposes of this section—

“(A) IN GENERAL.—The term ‘routine patient care costs’ includes the costs associated with the provision of items and services that—

“(i) would otherwise be covered under the group health plan if such items and services were not provided in connection with an approved clinical trial program; and

“(ii) are furnished according to the protocol of an approved clinical trial program.

“(B) EXCLUSION.—Such term does include the costs associated with the provision of—

“(i) an investigational drug or device, unless the Secretary has authorized the manufacturer of such drug or device to charge for such drug or device; or

“(ii) any item or service supplied without charge by the sponsor of the approved clinical trial program.

“(3) PAYMENT RATE.—In the case of covered items and services provided by—

“(A) a participating provider, the payment rate shall be at the agreed upon rate, or

“(B) a nonparticipating provider, the payment rate shall be at the rate the plan would normally pay for comparable items or services under subparagraph (A).

“(d) APPROVED CLINICAL TRIAL DEFINED.—In this section, the term ‘approved clinical trial’ means a cancer clinical research study or cancer clinical investigation approved by an Institutional Review Board.

“(e) CONSTRUCTION.—Nothing in this section shall be construed to limit a plan’s coverage with respect to clinical trials.

“(f) PLAN SATISFACTION OF CERTAIN REQUIREMENTS; RESPONSIBILITIES OF FIDUCIARIES.—

“(1) IN GENERAL.—For purposes of this section, insofar as a group health plan provides benefits in the form of health insurance coverage through a health insurance issuer, the plan shall be treated as meeting the requirements of this section with respect to such benefits and not be considered as failing to meet such requirements because of a failure of the issuer to meet such requirements so long as the plan sponsor or its representatives did not cause such failure by the issuer.

“(2) CONSTRUCTION.—Nothing in this section shall be construed to affect or modify the responsibilities of the fiduciaries of a group health plan under part 4 of subtitle B of the Employee Retirement Income Security Act of 1974.

### “Subchapter B—Access to Information

“Sec. 9911. Patient access to information.

#### “SEC. 9911. PATIENT ACCESS TO INFORMATION.

“(a) DISCLOSURE REQUIREMENT.—A group health plan shall—

“(1) provide to participants and beneficiaries at the time of initial coverage under the plan (or the effective date of this section, in the case of individuals who are participants or beneficiaries as of such date), and at least annually thereafter, the information described in subsection (b);

“(2) provide to participants and beneficiaries, within a reasonable period (as specified by the Secretary) before or after the date of significant changes in the information described in subsection (b), information on such significant changes; and

“(3) upon request, make available to participants and beneficiaries, the Secretary, and prospective participants and beneficiaries, the information described in subsection (b) or (c).

The plan may charge a reasonable fee for provision in printed form of any of the information described in subsection (b) or (c) more than once during any plan year.

“(b) INFORMATION PROVIDED.—The information described in this subsection with respect to a group health plan shall be provided to a participant or beneficiary free of charge at least once a year and includes the following:

- “(1) SERVICE AREA.—The service area of the plan.
- “(2) BENEFITS.—Benefits offered under the plan, including—
- “(A) those that are covered benefits “(all of which shall be referred to by such relevant CPT and DRG codes as are available), limits and conditions on such benefits, and those benefits that are explicitly excluded from coverage (all of which shall be referred to by such relevant CPT and DRG codes as are available);
  - “(B) cost sharing, such as deductibles, coinsurance, and copayment amounts, including any liability for balance billing, any maximum limitations on out of pocket expenses, and the maximum out of pocket costs for services that are provided by nonparticipating providers or that are furnished without meeting the applicable utilization review requirements;
  - “(C) the extent to which benefits may be obtained from nonparticipating providers;
  - “(D) the extent to which a participant or beneficiary may select from among participating providers and the types of providers participating in the plan network;
  - “(E) process for determining experimental coverage; and
  - “(F) use of a prescription drug formulary.
- “(3) ACCESS.—A description of the following:
- “(A) The number, mix, and distribution of providers under the plan.
  - “(B) Out-of-network coverage (if any) provided by the plan.
  - “(C) Any point-of-service option (including any supplemental premium or cost-sharing for such option).
  - “(D) The procedures for participants and beneficiaries to select, access, and change participating primary and specialty providers.
  - “(E) The rights and procedures for obtaining referrals (including standing referrals) to participating and nonparticipating providers.
  - “(F) The name, address, and telephone number of participating health care providers and an indication of whether each such provider is available to accept new patients.
  - “(G) Any limitations imposed on the selection of qualifying participating health care providers, including any limitations imposed under section 9901(b)(2).
- “(4) OUT-OF-AREA COVERAGE.—Out-of-area coverage provided by the plan.
- “(5) EMERGENCY COVERAGE.—Coverage of emergency services, including—
- “(A) the appropriate use of emergency services, including use of the 911 telephone system or its local equivalent in emergency situations and an explanation of what constitutes an emergency situation;
  - “(B) the process and procedures of the plan for obtaining emergency services; and

“(C) the locations of (i) emergency departments, and (ii) other settings, in which plan physicians and hospitals provide emergency services and post-stabilization care.

“(6) PRIOR AUTHORIZATION RULES.—Rules regarding prior authorization or other review requirements that could result in noncoverage or nonpayment.

“(7) GRIEVANCE AND APPEALS PROCEDURES.—All appeal or grievance rights and procedures under the plan, including the method for filing grievances and the time frames and circumstances for acting on grievances and appeals.

“(8) ACCOUNTABILITY.—A description of the legal recourse options available for participants and beneficiaries under the plan including—

“(A) the preemption that applies under section 514 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1144) to certain actions arising out of the provision of health benefits; and

“(B) the extent to which coverage decisions made by the plan are subject to internal review or any external review and the proper time frames under

“(9) QUALITY ASSURANCE.—Any information made public by an accrediting organization in the process of accreditation of the plan or any additional quality indicators the plan makes available.

“(10) INFORMATION ON TREATMENT AUTHORIZATION.—Notice of appropriate mailing addresses and telephone numbers to be used by participants and beneficiaries in seeking information or authorization for treatment.

“(11) AVAILABILITY OF INFORMATION ON REQUEST.—Notice that the information described in subsection (c) is available upon request.

“(c) INFORMATION MADE AVAILABLE UPON REQUEST.—The information described in this subsection is the following:

“(1) UTILIZATION REVIEW ACTIVITIES.—A description of procedures used and requirements (including circumstances, time frames, and appeal rights) under any utilization review program maintained by the plan.

“(2) GRIEVANCE AND APPEALS INFORMATION.—Information on the number of grievances and appeals and on the disposition in the aggregate of such matters.

“(3) FORMULARY RESTRICTIONS.—A description of the nature of any drug formula restrictions.

“(4) PARTICIPATING PROVIDER LIST.—A list of current participating health care providers.

“(d) CONSTRUCTION.—Nothing in this section shall be construed as requiring public disclosure of individual contracts or financial arrangements between a group health plan or health insurance issuer and any provider.

### “Subchapter C—Protecting the Doctor-Patient Relationship

“Sec. 9921. Prohibition of interference with certain medical communications.

“Sec. 9922. Prohibition of discrimination against providers based on licensure.

“Sec. 9923. Prohibition against improper incentive arrangements.

“Sec. 9924. Payment of clean claims.

**“SEC. 9921. PROHIBITION OF INTERFERENCE WITH CERTAIN MEDICAL COMMUNICATIONS.**

“(a) GENERAL RULE.—The provisions of any contract or agreement, or the operation of any contract or agreement, between a group health plan (including any partnership, association, or other organization that enters into or administers such a contract or agreement) and a health care provider (or group of health care providers) shall not prohibit or otherwise restrict a health care professional from advising such a participant or beneficiary who is a patient of the professional about the health status of the individual or medical care or treatment for the individual’s condition or disease, regardless of whether benefits for such care or treatment are provided under the plan, if the professional is acting within the lawful scope of practice.

“(b) NULLIFICATION.—Any contract provision or agreement that restricts or prohibits medical communications in violation of subsection (a) shall be null and void.

**“SEC. 9922. PROHIBITION OF DISCRIMINATION AGAINST PROVIDERS BASED ON LICENSURE.**

“(a) IN GENERAL.—A group health plan shall not discriminate with respect to participation or indemnification as to any provider who is acting within the scope of the provider’s license or certification under applicable State law, solely on the basis of such license or certification.

“(b) CONSTRUCTION.—Subsection (a) shall not be construed—

“(1) as requiring the coverage under a group health plan of particular benefits or services or to prohibit a plan from including providers only to the extent necessary to meet the needs of the plan’s participants or beneficiaries or from establishing any measure designed to maintain quality and control costs consistent with the responsibilities of the plan;

“(2) to override any State licensure or scope-of-practice law;

“(3) as requiring a plan that offers network coverage to include for participation every willing provider who meets the terms and conditions of the plan; or

“(4) as prohibiting a family practice physician with appropriate expertise from providing pediatric or obstetrical or gynecological care.

**“SEC. 9923. PROHIBITION AGAINST IMPROPER INCENTIVE ARRANGEMENTS.**

“(a) IN GENERAL.—A group health plan may not operate any physician incentive plan (as defined in subparagraph (B) of section 1876(i)(8) of the Social Security Act) unless the requirements described in clauses (i), (ii)(I), and (iii) of subparagraph (A) of such section are met with respect to such a plan.

“(b) APPLICATION.—For purposes of carrying out paragraph (1), any reference in section 1876(i)(8) of the Social Security Act to the Secretary, an eligible organization, or an individual enrolled with the organization shall be treated as a reference to the Secretary of the Treasury, a group health plan, and a participant or beneficiary with the plan, respectively.

“(c) CONSTRUCTION.—Nothing in this section shall be construed as prohibiting all capitation and similar arrangements or all provider discount arrangements.

**“SEC. 9924. PAYMENT OF CLEAN CLAIMS.**

“A group health plan shall provide for prompt payment of claims submitted for health care services or supplies furnished to a participant or beneficiary with respect to benefits covered by the plan, in a manner consistent with the provisions of sections 1816(c)(2) and 1842(c)(2) of the Social Security Act (42 U.S.C. 1395h(c)(2) and 42 U.S.C. 1395u(c)(2)), except that for purposes of this section, subparagraph (C) of section 1816(c)(2) of the Social Security Act shall be treated as applying to claims received from a participant or beneficiary as well as claims referred to in such subparagraph.

**“Subchapter D—Definitions**

“Sec. 9931. Definitions.

“Sec. 9933. Exclusions.

“Sec. 9933. Coverage of limited scope plans.

“Sec. 9934. Regulations; coordination; application under different laws.

**“SEC. 9931. DEFINITIONS.**

For purposes of this chapter—

“(a) INCORPORATION OF GENERAL DEFINITIONS.—Except as otherwise provided, the provisions of section 9831 shall apply for purposes of this chapter in the same manner as they apply for purposes of chapter 100.

“(b) ADDITIONAL DEFINITIONS.—For purposes of this chapter:

“(1) CLINICAL PEER.—The term ‘clinical peer’ means, with respect to a review or appeal, a practicing physician or other health care professional who holds a nonrestricted license and who is—

“(A) appropriately certified by a nationally recognized, peer reviewed accrediting body in the same or similar specialty as typically manages the medical condition, procedure, or treatment under review or appeal, or

“(B) is trained and experienced in managing such condition, procedure, or treatment,

and includes a pediatric specialist where appropriate; except that only a physician may be a clinical peer with respect to the review or appeal of treatment recommended or rendered by a physician.

“(2) HEALTH CARE PROFESSIONAL.—The term ‘health care professional’ means an individual who is licensed, accredited, or certified under State law to provide specified health care services and who is operating within the scope of such licensure, accreditation, or certification.

“(3) HEALTH CARE PROVIDER.—The term ‘health care provider’ includes a physician or other health care professional, as well as an institutional or other facility or agency that provides health care services and that is licensed, accredited, or certified to provide health care items and services under applicable State law.

“(4) NETWORK.—The term ‘network’ means, with respect to a group health plan, the participating health care professionals

and providers through whom the plan provides health care items and services to participants or beneficiaries.

“(5) NONPARTICIPATING.—The term ‘nonparticipating’ means, with respect to a health care provider that provides health care items and services to a participant or beneficiary under group health plan, a health care provider that is not a participating health care provider with respect to such items and services.

“(6) PARTICIPATING.—The term ‘participating’ means, with respect to a health care provider that provides health care items and services to a participant or beneficiary under group health plan, a health care provider that furnishes such items and services under a contract or other arrangement with the plan.

“(7) PHYSICIAN.—The term ‘physician’ means an allopathic or osteopathic physician.

“(8) PRACTICING PHYSICIAN.—The term ‘practicing physician’ means a physician who is licensed in the State in which the physician furnishes professional services and who provides professional services to individual patients on average at least two full days per week.

“(9) PRIOR AUTHORIZATION.—The term ‘prior authorization’ means the process of obtaining prior approval from a group health plan for the provision or coverage of medical services.

**“SEC. 9932. EXCLUSIONS.**

“(a) NO BENEFIT REQUIREMENTS.—Nothing in this chapter shall be construed to require a group health plan to provide specific benefits under the terms of such plan, other than those provided under the terms of such plan.

“(b) EXCLUSION FOR FEE-FOR-SERVICE COVERAGE.—

“(1) GROUP HEALTH PLANS.—The provisions of sections 9901 through 9911 shall not apply to a group health plan if the only coverage offered under the plan is fee-for-service coverage (as defined in paragraph (2)).

“(2) FEE-FOR-SERVICE COVERAGE DEFINED.—For purposes of this subsection, the term ‘fee-for-service coverage’ means coverage under a group health plan that—

“(A) reimburses hospitals, health professionals, and other providers on a fee-for-service basis without placing the provider at financial risk;

“(B) does not vary reimbursement for such a provider based on an agreement to contract terms and conditions or the utilization of health care items or services relating to such provider;

“(C) allows access to any provider that is lawfully authorized to provide the covered services and agree to accept the terms and conditions of payment established under the plan; and

“(D) for which the plan does not require prior authorization before providing for any health care services.

**“SEC. 9933. COVERAGE OF LIMITED SCOPE PLANS.**

“Only for purposes of applying the requirements of this chapter under section 9813, section 9832(c)(2)(A) shall be deemed not to apply.

**“SEC. 9934. REGULATIONS.**

“The Secretary of the Treasury shall issue such regulations as may be necessary or appropriate to carry out this chapter under section 9813. The Secretary may promulgate such regulations in the form of interim final rules as may be necessary to carry out this chapter in a timely manner.”.

(b) CLERICAL AMENDMENT.—The table of chapters for subtitle K of the Internal Revenue Code of 1986 is amended by adding at the end the following new item:

“CHAPTER 101. Improving managed care.”

## **TITLE IV—EFFECTIVE DATES; COORDINATION IN IMPLEMENTATION**

**SEC. 401. EFFECTIVE DATES.****(a) GROUP HEALTH COVERAGE.—**

(1) IN GENERAL.—Subject to paragraph (2), the amendments made by title I (other than section 102), sections 201 and 202, and title III shall apply with respect to group health plans, and health insurance coverage offered in connection with group health plans, for plan years beginning on or after January 1, 2000 (in this section referred to as the “general effective date”) and also shall apply to portions of plan years occurring on and after such date.

(2) TREATMENT OF COLLECTIVE BARGAINING AGREEMENTS.—In the case of a group health plan maintained pursuant to 1 or more collective bargaining agreements between employee representatives and 1 or more employers ratified before the date of enactment of this Act, the amendments made by title I (other than section 102), sections 201 and 202, and title III shall not apply to plan years beginning before the later of—

(A) the date on which the last collective bargaining agreements relating to the plan terminates (determined without regard to any extension thereof agreed to after the date of enactment of this Act), or

(B) the general effective date.

For purposes of subparagraph (A), any plan amendment made pursuant to a collective bargaining agreement relating to the plan which amends the plan solely to conform to any requirement added by this Act shall not be treated as a termination of such collective bargaining agreement.

(b) INDIVIDUAL HEALTH INSURANCE COVERAGE.—The amendments made by section 102 shall apply with respect to individual health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market on or after the general effective date.

**(c) TREATMENT OF RELIGIOUS NONMEDICAL PROVIDERS.—**

(1) IN GENERAL.—Nothing in this Act (or the amendments made thereby) shall be construed to—

(A) restrict or limit the right of group health plans, and of health insurance issuers offering health insurance coverage, to include as providers religious nonmedical providers;

- (B) require such plans or issuers to—
- (i) utilize medically based eligibility standards or criteria in deciding provider status of religious non-medical providers;
  - (ii) use medical professionals or criteria to decide patient access to religious nonmedical providers;
  - (iii) utilize medical professionals or criteria in making decisions in internal or external appeals regarding coverage for care by religious nonmedical providers; or
  - (iv) compel a participant or beneficiary to undergo a medical examination or test as a condition of receiving health insurance coverage for treatment by a religious nonmedical provider; or
- (C) require such plans or issuers to exclude religious nonmedical providers because they do not provide medical or other required data, if such data is inconsistent with the religious nonmedical treatment or nursing care provided by the provider.

(2) RELIGIOUS NONMEDICAL PROVIDER.—For purposes of this subsection, the term “religious nonmedical provider” means a provider who provides no medical care but who provides only religious nonmedical treatment or religious nonmedical nursing care.

**SEC. 402. COORDINATION IN IMPLEMENTATION.**

The Secretary of Labor, the Secretary of Health and Human Services, and the Secretary of the Treasury shall ensure, through the execution of an interagency memorandum of understanding among such Secretaries, that—

- (1) regulations, rulings, and interpretations issued by such Secretaries relating to the same matter over which both Secretaries have responsibility under the provisions of this Act (and the amendments made thereby) are administered so as to have the same effect at all times; and
- (2) coordination of policies relating to enforcing the same requirements through such Secretaries in order to have a coordinated enforcement strategy that avoids duplication of enforcement efforts and assigns priorities in enforcement.

## **TITLE V—OTHER PROVISIONS**

### **Subtitle A—Protection of Information**

**SEC. 501. PROTECTION FOR CERTAIN INFORMATION.**

(a) PROTECTION OF CERTAIN INFORMATION.—Notwithstanding any other provision of Federal or State law, health care response information shall be exempt from any disclosure requirement (regardless of whether the requirement relates to subpoenas, discover, introduction of evidence, testimony, or any other form of disclosure), in connection with a civil or administrative proceeding under Federal or State law, to the same extent as information developed by a health care provider with respect to any of the following:

- (1) Peer review.

- (2) Utilization review.
- (3) Quality management or improvement.
- (4) Quality control.
- (5) Risk management.
- (6) Internal review for purposes of reducing mortality, morbidity, or for improving patient care or safety.

(b) **NO WAIVER OF PROTECTION THROUGH INTERACTION WITH ACCREDITING BODY.**—Notwithstanding any other provision of Federal or State law, the protection of health care response information from disclosure provided under subsection (a) shall not be deemed to be modified or in any way waived by—

- (1) the development of such information in connection with a request or requirement of an accrediting body; or
- (2) the transfer of such information to an accrediting body.

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

(1) **ACCREDITING BODY.**—The term “accrediting body” means a national, not-for-profit organization that—

- (A) accredits health care providers; and
- (B) is recognized as an accrediting body by statute or by a Federal or State agency that regulates health care providers.

(2) **HEALTH CARE RESPONSE INFORMATION.**—The term “health care response information” means information (including any data, report, record, memorandum, analysis, statement, or other communication) developed by, or on behalf of, a health care provider in response to a serious, adverse, patient related event—

- (A) during the course of analyzing or studying the event and its causes; and

(B) for the purposes of—

- (i) reducing mortality or morbidity; or
- (ii) improving patient care or safety (including the provider’s notification to an accrediting body and the provider’s plans of action in response to such event).

(3) **HEALTH CARE PROVIDER.**—The term “health care provider” means a person, who with respect to a specific item of protected health information, receives, creates, uses, maintains, or discloses the information while acting in whole or in part in the capacity of—

(A) a person who is licensed, certified, registered, or otherwise authorized by Federal or State law to provide an item or service that constitutes health care in the ordinary course of business, or practice of a profession;

(B) a Federal, State, or employer-sponsored or any other privately-sponsored program that directly provides items or services that constitute health care to beneficiaries; or

(C) an officer or employee of a person described in subparagraph (A) or (B).

(4) **STATE.**—The term “State” includes a State, the District of Columbia, the Northern Mariana Islands, any political subdivisions of a State or such Islands, or any agency or instrumentality of either.

(d) **EFFECTIVE DATE.**—The provisions of this section are effective on the date of the enactment of this Act.

## Subtitle B—Other Matters

### SEC. 511. HEALTH CARE PAPERWORK SIMPLIFICATION.

#### (a) ESTABLISHMENT OF PANEL.—

(1) ESTABLISHMENT.—There is established a panel to be known as the Health Care Panel to Devise a Uniform Explanation of Benefits (in this section referred to as the “Panel”).

#### (2) DUTIES OF PANEL.—

(A) IN GENERAL.—The Panel shall devise a single form for use by third-party health care payers for the remittance of claims to providers.

(B) DEFINITION.—For purposes of this section, the term “third-party health care payer” means any entity that contractually pays health care bills for an individual.

#### (3) MEMBERSHIP.—

(A) SIZE AND COMPOSITION.—The Secretary of Health and Human Services, in consultation with the Majority Leader of the Senate and the Speaker of the House of Representatives, shall determine the number of members and the composition of the Panel. Such Panel shall include equal numbers of representatives of private insurance organizations, consumer groups, State insurance commissioners, State medical societies, State hospital associations, and State medical specialty societies.

(B) TERMS OF APPOINTMENT.—The members of the Panel shall serve for the life of the Panel.

(C) VACANCIES.—A vacancy in the Panel shall not affect the power of the remaining members to execute the duties of the Panel, but any such vacancy shall be filled in the same manner in which the original appointment was made.

#### (4) PROCEDURES.—

(A) MEETINGS.—The Panel shall meet at the call of a majority of its members.

(B) FIRST MEETING.—The Panel shall convene not later than 60 days after the date of the enactment of the Health Care Quality and Choice Act of 1999.

(C) QUORUM.—A quorum shall consist of a majority of the members of the Panel.

(D) HEARINGS.—For the purpose of carrying out its duties, the Panel may hold such hearings and undertake such other activities as the Panel determines to be necessary to carry out its duties.

#### (5) ADMINISTRATION.—

(A) COMPENSATION.—Except as provided in subparagraph (B), members of the Panel shall receive no additional pay, allowances, or benefits by reason of their service on the Panel.

(B) TRAVEL EXPENSES AND PER DIEM.—Each member of the Panel who is not an officer or employee of the Federal Government shall receive travel expenses and per diem in lieu of subsistence in accordance with sections 5702 and 5703 of title 5, United States Code.

(C) **CONTRACT AUTHORITY.**—The Panel may contract with and compensate government and private agencies or persons for items and services, without regard to section 3709 of the Revised Statutes (41 U.S.C. 5).

(D) **USE OF MAILS.**—The Panel may use the United States mails in the same manner and under the same conditions as Federal agencies and shall, for purposes of the frank, be considered a commission of Congress as described in section 3215 of title 39, United States Code.

(E) **ADMINISTRATIVE SUPPORT SERVICES.**—Upon the request of the Panel, the Secretary of Health and Human Services shall provide to the Panel on a reimbursable basis such administrative support services as the Panel may request.

(6) **SUBMISSION OF FORM.**—Not later than 2 years after the first meeting, the Panel shall submit a form to the Secretary of Health and Human Services for use by third-party health care payers.

(7) **TERMINATION.**—The Panel shall terminate on the day after submitting its the form under paragraph (6).

(b) **REQUIREMENT FOR USE OF FORM BY THIRD-PARTY CARE PAYERS.**—A third-party health care payer shall be required to use the form devised under subsection (a) for plan years beginning on or after 5 years following the date of the enactment of this Act.

### 3. AN AMENDMENT TO BE OFFERED BY REPRESENTATIVE HOUGHTON OF NEW YORK, OR REPRESENTATIVE GRAHAM OF SOUTH CAROLINA, OR A DESIGNEE, DEBATABLE FOR 60 MINUTES

Strike out 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 “Bipartisan Consensus Managed Care Improvement Act of 1999”.

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

Sec. 1. Short title; table of contents.

#### TITLE I—IMPROVING MANAGED CARE

##### Subtitle A—Grievances and Appeals

- Sec. 101. Utilization review activities.
- Sec. 102. Internal appeals procedures.
- Sec. 103. External appeals procedures.
- Sec. 104. Establishment of a grievance process.

##### Subtitle B—Access to Care

- Sec. 111. Consumer choice option.
- Sec. 112. Choice of health care professional.
- Sec. 113. Access to emergency care.
- Sec. 114. Access to specialty care.
- Sec. 115. Access to obstetrical and gynecological care.
- Sec. 116. Access to pediatric care.
- Sec. 117. Continuity of care.
- Sec. 118. Access to needed prescription drugs.
- Sec. 119. Coverage for individuals participating in approved clinical trials.

##### Subtitle C—Access to Information

- Sec. 121. Patient access to information.

Subtitle D—Protecting the Doctor-Patient Relationship

- Sec. 131. Prohibition of interference with certain medical communications.  
 Sec. 132. Prohibition of discrimination against providers based on licensure.  
 Sec. 133. Prohibition against improper incentive arrangements.  
 Sec. 134. Payment of claims.  
 Sec. 135. Protection for patient advocacy.

Subtitle E—Definitions

- Sec. 151. Definitions.  
 Sec. 152. Preemption; State flexibility; construction.  
 Sec. 153. Exclusions.  
 Sec. 154. Coverage of limited scope plans.  
 Sec. 155. Regulations.

**TITLE II—APPLICATION OF QUALITY STANDARDS TO GROUP HEALTH PLANS AND HEALTH INSURANCE COVERAGE UNDER THE PUBLIC HEALTH SERVICE ACT**

- Sec. 201. Application to group health plans and group health insurance coverage.  
 Sec. 202. Application to individual health insurance coverage.

**TITLE III—AMENDMENTS TO THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974**

- Sec. 301. Application of patient protection standards to group health plans and group health insurance coverage under the Employee Retirement Income Security Act of 1974.  
 Sec. 302. Additional judicial remedies.  
 Sec. 303. Availability of binding arbitration.

**TITLE IV—APPLICATION TO GROUP HEALTH PLANS UNDER THE INTERNAL REVENUE CODE OF 1986**

- Sec. 401. Amendments to the Internal Revenue Code of 1986.

**TITLE V—EFFECTIVE DATES; COORDINATION IN IMPLEMENTATION**

- Sec. 501. Effective dates.  
 Sec. 502. Coordination in implementation.

**TITLE VI—HEALTH CARE PAPERWORK SIMPLIFICATION**

- Sec. 601. Health care paperwork simplification.

## **TITLE I—IMPROVING MANAGED CARE**

### **Subtitle A—Grievance and Appeals**

**SEC. 101. UTILIZATION REVIEW ACTIVITIES.**

(a) **COMPLIANCE WITH REQUIREMENTS.—**

(1) **IN GENERAL.—**A group health plan, and a health insurance issuer that provides health insurance coverage, shall conduct utilization review activities in connection with the provision of benefits under such plan or coverage only in accordance with a utilization review program that meets the requirements of this section.

(2) **USE OF OUTSIDE AGENTS.—**Nothing in this section shall be construed as preventing a group health plan or health insurance issuer from arranging through a contract or otherwise for persons or entities to conduct utilization review activities on behalf of the plan or issuer, so long as such activities are conducted in accordance with a utilization review program that meets the requirements of this section.

- (3) UTILIZATION REVIEW DEFINED.—For purposes of this section, the terms “utilization review” and “utilization review activities” mean procedures used to monitor or evaluate the use or coverage, clinical necessity, appropriateness, efficacy, or efficiency of health care services, procedures or settings, and includes prospective review, concurrent review, second opinions, case management, discharge planning, or retrospective review.
- (b) WRITTEN POLICIES AND CRITERIA.—
- (1) WRITTEN POLICIES.—A utilization review program shall be conducted consistent with written policies and procedures that govern all aspects of the program.
- (2) USE OF WRITTEN CRITERIA.—
- (A) IN GENERAL.—Such a program shall utilize written clinical review criteria developed with input from a range of appropriate actively practicing health care professionals, as determined by the plan, pursuant to the program. Such criteria shall include written clinical review criteria that are based on valid clinical evidence where available and that are directed specifically at meeting the needs of at-risk populations and covered individuals with chronic conditions or severe illnesses, including gender-specific criteria and pediatric-specific criteria where available and appropriate.
- (B) CONTINUING USE OF STANDARDS IN RETROSPECTIVE REVIEW.—If a health care service has been specifically pre-authorized or approved for an enrollee under such a program, the program shall not, pursuant to retrospective review, revise or modify the specific standards, criteria, or procedures used for the utilization review for procedures, treatment, and services delivered to the enrollee during the same course of treatment.
- (C) REVIEW OF SAMPLE OF CLAIMS DENIALS.—Such a program shall provide for an evaluation of the clinical appropriateness of at least a sample of denials of claims for benefits.
- (c) CONDUCT OF PROGRAM ACTIVITIES.—
- (1) ADMINISTRATION BY HEALTH CARE PROFESSIONALS.—A utilization review program shall be administered by qualified health care professionals who shall oversee review decisions.
- (2) USE OF QUALIFIED, INDEPENDENT PERSONNEL.—
- (A) IN GENERAL.—A utilization review program shall provide for the conduct of utilization review activities only through personnel who are qualified and have received appropriate training in the conduct of such activities under the program.
- (B) PROHIBITION OF CONTINGENT COMPENSATION ARRANGEMENTS.—Such a program shall not, with respect to utilization review activities, permit or provide compensation or anything of value to its employees, agents, or contractors in a manner that encourages denials of claims for benefits.
- (C) PROHIBITION OF CONFLICTS.—Such a program shall not permit a health care professional who is providing health care services to an individual to perform utilization

review activities in connection with the health care services being provided to the individual.

(3) ACCESSIBILITY OF REVIEW.—Such a program shall provide that appropriate personnel performing utilization review activities under the program, including the utilization review administrator, are reasonably accessible by toll-free telephone during normal business hours to discuss patient care and allow response to telephone requests, and that appropriate provision is made to receive and respond promptly to calls received during other hours.

(4) LIMITS ON FREQUENCY.—Such a program shall not provide for the performance of utilization review activities with respect to a class of services furnished to an individual more frequently than is reasonably required to assess whether the services under review are medically necessary or appropriate.

(d) DEADLINE FOR DETERMINATIONS.—

(1) PRIOR AUTHORIZATION SERVICES.—

(A) IN GENERAL.—Except as provided in paragraph (2), in the case of a utilization review activity involving the prior authorization of health care items and services for an individual, the utilization review program shall make a determination concerning such authorization, and provide notice of the determination to the individual or the individual's designee and the individual's health care provider by telephone and in printed form, as soon as possible in accordance with the medical exigencies of the case, and in no event later than the deadline specified in subparagraph (B).

(B) DEADLINE.—

(i) IN GENERAL.—Subject to clauses (ii) and (iii), the deadline specified in this subparagraph is 14 days after the date of receipt of the request for prior authorization.

(ii) EXTENSION PERMITTED WHERE NOTICE OF ADDITIONAL INFORMATION REQUIRED.—If a utilization review program—

(I) receives a request for a prior authorization,

(II) determines that additional information is necessary to complete the review and make the determination on the request, and

(III) notifies the requester, not later than 5 business days after the date of receiving the request, of the need for such specified additional information,

the deadline specified in this subparagraph is 14 days after the date the program receives the specified additional information, but in no case later than 28 days after the date of receipt of the request for the prior authorization. This clause shall not apply if the deadline is specified in clause (iii).

(iii) EXPEDITED CASES.—In the case of a situation described in section 102(c)(1)(A), the deadline specified in this subparagraph is 72 hours after the time of the request for prior authorization.

## (2) ONGOING CARE.—

## (A) CONCURRENT REVIEW.—

(i) IN GENERAL.—Subject to subparagraph (B), in the case of a concurrent review of ongoing care (including hospitalization), which results in a termination or reduction of such care, the plan must provide by telephone and in printed form notice of the concurrent review determination to the individual or the individual's designee and the individual's health care provider as soon as possible in accordance with the medical exigencies of the case, with sufficient time prior to the termination or reduction to allow for an appeal under section 102(c)(1)(A) to be completed before the termination or reduction takes effect.

(ii) CONTENTS OF NOTICE.—Such notice shall include, with respect to ongoing health care items and services, the number of ongoing services approved, the new total of approved services, the date of onset of services, and the next review date, if any, as well as a statement of the individual's rights to further appeal.

(B) EXCEPTION.—Subparagraph (A) shall not be interpreted as requiring plans or issuers to provide coverage of care that would exceed the coverage limitations for such care.

(3) PREVIOUSLY PROVIDED SERVICES.—In the case of a utilization review activity involving retrospective review of health care services previously provided for an individual, the utilization review program shall make a determination concerning such services, and provide notice of the determination to the individual or the individual's designee and the individual's health care provider by telephone and in printed form, within 30 days of the date of receipt of information that is reasonably necessary to make such determination, but in no case later than 60 days after the date of receipt of the claim for benefits.

(4) FAILURE TO MEET DEADLINE.—In a case in which a group health plan or health insurance issuer fails to make a determination on a claim for benefit under paragraph (1), (2)(A), or (3) by the applicable deadline established under the respective paragraph, the failure shall be treated under this subtitle as a denial of the claim as of the date of the deadline.

(5) REFERENCE TO SPECIAL RULES FOR EMERGENCY SERVICES, MAINTENANCE CARE, AND POST-STABILIZATION CARE.—For waiver of prior authorization requirements in certain cases involving emergency services and maintenance care and post-stabilization care, see subsections (a)(1) and (b) of section 113, respectively.

## (e) NOTICE OF DENIALS OF CLAIMS FOR BENEFITS.—

(1) IN GENERAL.—Notice of a denial of claims for benefits under a utilization review program shall be provided in printed form and written in a manner calculated to be understood by the participant, beneficiary, or enrollee and shall include—

(A) the reasons for the denial (including the clinical rationale);

(B) instructions on how to initiate an appeal under section 102; and

(C) notice of the availability, upon request of the individual (or the individual's designee) of the clinical review criteria relied upon to make such denial.

(2) SPECIFICATION OF ANY ADDITIONAL INFORMATION.—Such a notice shall also specify what (if any) additional necessary information must be provided to, or obtained by, the person making the denial in order to make a decision on such an appeal.

(f) CLAIM FOR BENEFITS AND DENIAL OF CLAIM FOR BENEFITS DEFINED.—For purposes of this subtitle:

(1) CLAIM FOR BENEFITS.—The term “claim for benefits” means any request for coverage (including authorization of coverage), for eligibility, or for payment in whole or in part, for an item or service under a group health plan or health insurance coverage.

(2) DENIAL OF CLAIM FOR BENEFITS.—The term “denial” means, with respect to a claim for benefits, means a denial, or a failure to act on a timely basis upon, in whole or in part, the claim for benefits and includes a failure to provide benefits (including items and services) required to be provided under this title.

#### SEC. 102. INTERNAL APPEALS PROCEDURES.

(a) RIGHT OF REVIEW.—

(1) IN GENERAL.—Each group health plan, and each health insurance issuer offering health insurance coverage—

(A) shall provide adequate notice in writing to any participant or beneficiary under such plan, or enrollee under such coverage, whose claim for benefits under the plan or coverage has been denied (within the meaning of section 101(f)(2)), setting forth the specific reasons for such denial of claim for benefits and rights to any further review or appeal, written in a manner calculated to be understood by the participant, beneficiary, or enrollee; and

(B) shall afford such a participant, beneficiary, or enrollee (and any provider or other person acting on behalf of such an individual with the individual's consent or without such consent if the individual is medically unable to provide such consent) who is dissatisfied with such a denial of claim for benefits a reasonable opportunity (of not less than 180 days) to request and obtain a full and fair review by a named fiduciary (with respect to such plan) or named appropriate individual (with respect to such coverage) of the decision denying the claim.

(2) TREATMENT OF ORAL REQUESTS.—The request for review under paragraph (1)(B) may be made orally, but, in the case of an oral request, shall be followed by a request in writing.

(b) INTERNAL REVIEW PROCESS.—

(1) CONDUCT OF REVIEW.—

(A) IN GENERAL.—A review of a denial of claim under this section shall be made by an individual who—

(i) in a case involving medical judgment, shall be a physician or, in the case of limited scope coverage (as

defined in subparagraph (B), shall be an appropriate specialist;

(ii) has been selected by the plan or issuer; and

(iii) did not make the initial denial in the internally appealable decision.

(B) LIMITED SCOPE COVERAGE DEFINED.—For purposes of subparagraph (A), the term “limited scope coverage” means a group health plan or health insurance coverage the only benefits under which are for benefits described in section 2791(c)(2)(A) of the Public Health Service Act (42 U.S.C. 300gg–91(c)(2)).

(2) TIME LIMITS FOR INTERNAL REVIEWS.—

(A) IN GENERAL.—Having received such a request for review of a denial of claim, the plan or issuer shall, in accordance with the medical exigencies of the case but not later than the deadline specified in subparagraph (B), complete the review on the denial and transmit to the participant, beneficiary, enrollee, or other person involved a decision that affirms, reverses, or modifies the denial. If the decision does not reverse the denial, the plan or issuer shall transmit, in printed form, a notice that sets forth the grounds for such decision and that includes a description of rights to any further appeal. Such decision shall be treated as the final decision of the plan. Failure to issue such a decision by such deadline shall be treated as a final decision affirming the denial of claim.

(B) DEADLINE.—

(i) IN GENERAL.—Subject to clauses (ii) and (iii), the deadline specified in this subparagraph is 14 days after the date of receipt of the request for internal review.

(ii) EXTENSION PERMITTED WHERE NOTICE OF ADDITIONAL INFORMATION REQUIRED.—If a group health plan or health insurance issuer—

(I) receives a request for internal review,

(II) determines that additional information is necessary to complete the review and make the determination on the request, and

(III) notifies the requester, not later than 5 business days after the date of receiving the request, of the need for such specified additional information,

the deadline specified in this subparagraph is 14 days after the date the plan or issuer receives the specified additional information, but in no case later than 28 days after the date of receipt of the request for the internal review. This clause shall not apply if the deadline is specified in clause (iii).

(iii) EXPEDITED CASES.—In the case of a situation described in subsection (c)(1)(A), the deadline specified in this subparagraph is 72 hours after the time of the request for review.

(c) EXPEDITED REVIEW PROCESS.—

(1) **IN GENERAL.**—A group health plan, and a health insurance issuer, shall establish procedures in writing for the expedited consideration of requests for review under subsection (b) in situations—

(A) in which, as determined by the plan or issuer or as certified in writing by a treating health care professional, the application of the normal timeframe for making a determination could seriously jeopardize the life or health of the participant, beneficiary, or enrollee or such an individual's ability to regain maximum function; or

(B) described in section 101(d)(2) (relating to requests for continuation of ongoing care which would otherwise be reduced or terminated).

(2) **PROCESS.**—Under such procedures—

(A) the request for expedited review may be submitted orally or in writing by an individual or provider who is otherwise entitled to request the review;

(B) all necessary information, including the plan's or issuer's decision, shall be transmitted between the plan or issuer and the requester by telephone, facsimile, or other similarly expeditious available method; and

(C) the plan or issuer shall expedite the review in the case of any of the situations described in subparagraph (A) or (B) of paragraph (1).

(3) **DEADLINE FOR DECISION.**—The decision on the expedited review must be made and communicated to the parties as soon as possible in accordance with the medical exigencies of the case, and in no event later than 72 hours after the time of receipt of the request for expedited review, except that in a case described in paragraph (1)(B), the decision must be made before the end of the approved period of care.

(d) **WAIVER OF PROCESS.**—A plan or issuer may waive its rights for an internal review under subsection (b). In such case the participant, beneficiary, or enrollee involved (and any designee or provider involved) shall be relieved of any obligation to complete the review involved and may, at the option of such participant, beneficiary, enrollee, designee, or provider, proceed directly to seek further appeal through any applicable external appeals process.

### **SEC. 103. EXTERNAL APPEALS PROCEDURES.**

(a) **RIGHT TO EXTERNAL APPEAL.**—

(1) **IN GENERAL.**—A group health plan, and a health insurance issuer offering health insurance coverage, shall provide for an external appeals process that meets the requirements of this section in the case of an externally appealable decision described in paragraph (2), for which an appeal is made, within 180 days after completion of the plan's internal appeals process under section 102, either by the plan or issuer or by the participant, beneficiary, or enrollee (and any provider or other person acting on behalf of such an individual with the individual's consent or without such consent if such an individual is medically unable to provide such consent). The appropriate Secretary shall establish standards to carry out such requirements.

(2) **EXTERNALLY APPEALABLE DECISION DEFINED.**—

- (A) **IN GENERAL.**—For purposes of this section, the term “externally appealable decision” means a denial of claim for benefits (as defined in section 101(f)(2))—
- (i) that is based in whole or in part on a decision that the item or service is not medically necessary or appropriate or is investigational or experimental; or
  - (ii) in which the decision as to whether a benefit is covered involves a medical judgment.
- (B) **INCLUSION.**—Such term also includes a failure to meet an applicable deadline for internal review under section 102.
- (C) **EXCLUSIONS.**—Such term does not include—
- (i) specific exclusions or express limitations on the amount, duration, or scope of coverage that do not involve medical judgment; or
  - (ii) a decision regarding whether an individual is a participant, beneficiary, or enrollee under the plan or coverage.
- (3) **EXHAUSTION OF INTERNAL REVIEW PROCESS.**—Except as provided under section 102(d), a plan or issuer may condition the use of an external appeal process in the case of an externally appealable decision upon a final decision in an internal review under section 102, but only if the decision is made in a timely basis consistent with the deadlines provided under this subtitle.
- (4) **FILING FEE REQUIREMENT.**—
- (A) **IN GENERAL.**—Subject to subparagraph (B), a plan or issuer may condition the use of an external appeal process upon payment to the plan or issuer of a filing fee that does not exceed \$25.
- (B) **EXCEPTION FOR INDIGENCY.**—The plan or issuer may not require payment of the filing fee in the case of an individual participant, beneficiary, or enrollee who certifies (in a form and manner specified in guidelines established by the Secretary of Health and Human Services) that the individual is indigent (as defined in such guidelines).
- (C) **REFUNDING FEE IN CASE OF SUCCESSFUL APPEALS.**—The plan or issuer shall refund payment of the filing fee under this paragraph if the recommendation of the external appeal entity is to reverse or modify the denial of a claim for benefits which is the subject of the appeal.
- (b) **GENERAL ELEMENTS OF EXTERNAL APPEALS PROCESS.**—
- (1) **CONTRACT WITH QUALIFIED EXTERNAL APPEAL ENTITY.**—
- (A) **CONTRACT REQUIREMENT.**—Except as provided in subparagraph (D), the external appeal process under this section of a plan or issuer shall be conducted under a contract between the plan or issuer and one or more qualified external appeal entities (as defined in subsection (c)).
- (B) **LIMITATION ON PLAN OR ISSUER SELECTION.**—The applicable authority shall implement procedures—
- (i) to assure that the selection process among qualified external appeal entities will not create any incentives for external appeal entities to make a decision in a biased manner, and

(ii) for auditing a sample of decisions by such entities to assure that no such decisions are made in a biased manner.

(C) OTHER TERMS AND CONDITIONS.—The terms and conditions of a contract under this paragraph shall be consistent with the standards the appropriate Secretary shall establish to assure there is no real or apparent conflict of interest in the conduct of external appeal activities. Such contract shall provide that all costs of the process (except those incurred by the participant, beneficiary, enrollee, or treating professional in support of the appeal) shall be paid by the plan or issuer, and not by the participant, beneficiary, or enrollee. The previous sentence shall not be construed as applying to the imposition of a filing fee under subsection (a)(4).

(D) STATE AUTHORITY WITH RESPECT QUALIFIED EXTERNAL APPEAL ENTITY FOR HEALTH INSURANCE ISSUERS.—With respect to health insurance issuers offering health insurance coverage in a State, the State may provide for external review activities to be conducted by a qualified external appeal entity that is designated by the State or that is selected by the State in a manner determined by the State to assure an unbiased determination.

(2) ELEMENTS OF PROCESS.—An external appeal process shall be conducted consistent with standards established by the appropriate Secretary that include at least the following:

(A) FAIR AND DE NOVO DETERMINATION.—The process shall provide for a fair, de novo determination. However, nothing in this paragraph shall be construed as providing for coverage of items and services for which benefits are specifically excluded under the plan or coverage.

(B) STANDARD OF REVIEW.—An external appeal entity shall determine whether the plan's or issuer's decision is in accordance with the medical needs of the patient involved (as determined by the entity) taking into account, as of the time of the entity's determination, the patient's medical condition and any relevant and reliable evidence the entity obtains under subparagraph (D). If the entity determines the decision is in accordance with such needs, the entity shall affirm the decision and to the extent that the entity determines the decision is not in accordance with such needs, the entity shall reverse or modify the decision.

(C) CONSIDERATION OF PLAN OR COVERAGE DEFINITIONS.—In making such determination, the external appeal entity shall consider (but not be bound by) any language in the plan or coverage document relating to the definitions of the terms medical necessity, medically necessary or appropriate, or experimental, investigational, or related terms.

(D) EVIDENCE.—

(i) IN GENERAL.—An external appeal entity shall include, among the evidence taken into consideration—

(I) the decision made by the plan or issuer upon internal review under section 102 and any guidelines or standards used by the plan or issuer in reaching such decision;

(II) any personal health and medical information supplied with respect to the individual whose denial of claim for benefits has been appealed; and

(III) the opinion of the individual's treating physician or health care professional.

(ii) ADDITIONAL EVIDENCE.—Such entity may also take into consideration but not be limited to the following evidence (to the extent available):

(I) The results of studies that meet professionally recognized standards of validity and replicability or that have been published in peer-reviewed journals.

(II) The results of professional consensus conferences conducted or financed in whole or in part by one or more government agencies.

(III) Practice and treatment guidelines prepared or financed in whole or in part by government agencies.

(IV) Government-issued coverage and treatment policies.

(V) Community standard of care and generally accepted principles of professional medical practice.

(VI) To the extent that the entity determines it to be free of any conflict of interest, the opinions of individuals who are qualified as experts in one or more fields of health care which are directly related to the matters under appeal.

(VII) To the extent that the entity determines it to be free of any conflict of interest, the results of peer reviews conducted by the plan or issuer involved.

(E) DETERMINATION CONCERNING EXTERNALLY APPEALABLE DECISIONS.—A qualified external appeal entity shall determine—

(i) whether a denial of claim for benefits is an externally appealable decision (within the meaning of subsection (a)(2));

(ii) whether an externally appealable decision involves an expedited appeal; and

(iii) for purposes of initiating an external review, whether the internal review process has been completed.

(F) OPPORTUNITY TO SUBMIT EVIDENCE.—Each party to an externally appealable decision may submit evidence related to the issues in dispute.

(G) PROVISION OF INFORMATION.—The plan or issuer involved shall provide timely access to the external appeal entity to information and to provisions of the plan or

health insurance coverage relating to the matter of the externally appealable decision, as determined by the entity.

(H) **TIMELY DECISIONS.**—A determination by the external appeal entity on the decision shall—

(i) be made orally or in writing and, if it is made orally, shall be supplied to the parties in writing as soon as possible;

(ii) be made in accordance with the medical exigencies of the case involved, but in no event later than 21 days after the date (or, in the case of an expedited appeal, 72 hours after the time) of requesting an external appeal of the decision;

(iii) state, in layperson's language, the basis for the determination, including, if relevant, any basis in the terms or conditions of the plan or coverage; and

(iv) inform the participant, beneficiary, or enrollee of the individual's rights (including any limitation on such rights) to seek further review by the courts (or other process) of the external appeal determination.

(I) **COMPLIANCE WITH DETERMINATION.**—If the external appeal entity reverses or modifies the denial of a claim for benefits, the plan or issuer shall—

(i) upon the receipt of the determination, authorize benefits in accordance with such determination;

(ii) take such actions as may be necessary to provide benefits (including items or services) in a timely manner consistent with such determination; and

(iii) submit information to the entity documenting compliance with the entity's determination and this subparagraph.

(c) **QUALIFICATIONS OF EXTERNAL APPEAL ENTITIES.**—

(1) **IN GENERAL.**—For purposes of this section, the term “qualified external appeal entity” means, in relation to a plan or issuer, an entity that is certified under paragraph (2) as meeting the following requirements:

(A) The entity meets the independence requirements of paragraph (3).

(B) The entity conducts external appeal activities through a panel of not fewer than 3 clinical peers.

(C) The entity has sufficient medical, legal, and other expertise and sufficient staffing to conduct external appeal activities for the plan or issuer on a timely basis consistent with subsection (b)(2)(G).

(D) The entity meets such other requirements as the appropriate Secretary may impose.

(2) **INITIAL CERTIFICATION OF EXTERNAL APPEAL ENTITIES.**—

(A) **IN GENERAL.**—In order to be treated as a qualified external appeal entity with respect to—

(i) a group health plan, the entity must be certified (and, in accordance with subparagraph (B), periodically recertified) as meeting the requirements of paragraph (1)—

(I) by the Secretary of Labor;

(II) under a process recognized or approved by the Secretary of Labor; or

(III) to the extent provided in subparagraph (C)(i), by a qualified private standard-setting organization (certified under such subparagraph); or

(ii) a health insurance issuer operating in a State, the entity must be certified (and, in accordance with subparagraph (B), periodically recertified) as meeting such requirements—

(I) by the applicable State authority (or under a process recognized or approved by such authority); or

(II) if the State has not established a certification and recertification process for such entities, by the Secretary of Health and Human Services, under a process recognized or approved by such Secretary, or to the extent provided in subparagraph (C)(ii), by a qualified private standard-setting organization (certified under such subparagraph).

(B) RECERTIFICATION PROCESS.—The appropriate Secretary shall develop standards for the recertification of external appeal entities. Such standards shall include a review of—

(i) the number of cases reviewed;

(ii) a summary of the disposition of those cases;

(iii) the length of time in making determinations on those cases;

(iv) updated information of what was required to be submitted as a condition of certification for the entity's performance of external appeal activities; and

(v) such information as may be necessary to assure the independence of the entity from the plans or issuers for which external appeal activities are being conducted.

(C) CERTIFICATION OF QUALIFIED PRIVATE STANDARD-SETTING ORGANIZATIONS.—

(i) FOR EXTERNAL REVIEWS UNDER GROUP HEALTH PLANS.—For purposes of subparagraph (A)(i)(III), the Secretary of Labor may provide for a process for certification (and periodic recertification) of qualified private standard-setting organizations which provide for certification of external review entities. Such an organization shall only be certified if the organization does not certify an external review entity unless it meets standards required for certification of such an entity by such Secretary under subparagraph (A)(i)(I).

(ii) FOR EXTERNAL REVIEWS OF HEALTH INSURANCE ISSUERS.—For purposes of subparagraph (A)(ii)(II), the Secretary of Health and Human Services may provide for a process for certification (and periodic recertification) of qualified private standard-setting organizations which provide for certification of external review entities. Such an organization shall only be certified if

the organization does not certify an external review entity unless it meets standards required for certification of such an entity by such Secretary under subparagraph (A)(ii)(II).

(3) INDEPENDENCE REQUIREMENTS.—

(A) IN GENERAL.—A clinical peer or other entity meets the independence requirements of this paragraph if—

(i) the peer or entity does not have a familial, financial, or professional relationship with any related party;

(ii) any compensation received by such peer or entity in connection with the external review is reasonable and not contingent on any decision rendered by the peer or entity;

(iii) except as provided in paragraph (4), the plan and the issuer have no recourse against the peer or entity in connection with the external review; and

(iv) the peer or entity does not otherwise have a conflict of interest with a related party as determined under any regulations which the Secretary may prescribe.

(B) RELATED PARTY.—For purposes of this paragraph, the term “related party” means—

(i) with respect to—

(I) a group health plan or health insurance coverage offered in connection with such a plan, the plan or the health insurance issuer offering such coverage, or

(II) individual health insurance coverage, the health insurance issuer offering such coverage, or any plan sponsor, fiduciary, officer, director, or management employee of such plan or issuer;

(ii) the health care professional that provided the health care involved in the coverage decision;

(iii) the institution at which the health care involved in the coverage decision is provided;

(iv) the manufacturer of any drug or other item that was included in the health care involved in the coverage decision; or

(v) any other party determined under any regulations which the Secretary may prescribe to have a substantial interest in the coverage decision.

(4) LIMITATION ON LIABILITY OF REVIEWERS.—No qualified external appeal entity having a contract with a plan or issuer under this part and no person who is employed by any such entity or who furnishes professional services to such entity, shall be held by reason of the performance of any duty, function, or activity required or authorized pursuant to this section, to have violated any criminal law, or to be civilly liable under any law of the United States or of any State (or political subdivision thereof) if due care was exercised in the performance of such duty, function, or activity and there was no actual malice or gross misconduct in the performance of such duty, function, or activity.

(d) EXTERNAL APPEAL DETERMINATION BINDING ON PLAN.—The determination by an external appeal entity under this section is binding on the plan and issuer involved in the determination.

(e) PENALTIES AGAINST AUTHORIZED OFFICIALS FOR REFUSING TO AUTHORIZE THE DETERMINATION OF AN EXTERNAL REVIEW ENTITY.—

(1) MONETARY PENALTIES.—In any case in which the determination of an external review entity is not followed by a group health plan, or by a health insurance issuer offering health insurance coverage, any person who, acting in the capacity of authorizing the benefit, causes such refusal may, in the discretion in a court of competent jurisdiction, be liable to an aggrieved participant, beneficiary, or enrollee for a civil penalty in an amount of up to \$1,000 a day from the date on which the determination was transmitted to the plan or issuer by the external review entity until the date the refusal to provide the benefit is corrected.

(2) CEASE AND DESIST ORDER AND ORDER OF ATTORNEY'S FEES.—In any action described in paragraph (1) brought by a participant, beneficiary, or enrollee with respect to a group health plan, or a health insurance issuer offering health insurance coverage, in which a plaintiff alleges that a person referred to in such paragraph has taken an action resulting in a refusal of a benefit determined by an external appeal entity in violation of such terms of the plan, coverage, or this subtitle, or has failed to take an action for which such person is responsible under the plan, coverage, or this title and which is necessary under the plan or coverage for authorizing a benefit, the court shall cause to be served on the defendant an order requiring the defendant—

(A) to cease and desist from the alleged action or failure to act; and

(B) to pay to the plaintiff a reasonable attorney's fee and other reasonable costs relating to the prosecution of the action on the charges on which the plaintiff prevails.

(3) ADDITIONAL CIVIL PENALTIES.—

(A) IN GENERAL.—In addition to any penalty imposed under paragraph (1) or (2), the appropriate Secretary may assess a civil penalty against a person acting in the capacity of authorizing a benefit determined by an external review entity for one or more group health plans, or health insurance issuers offering health insurance coverage, for—

(i) any pattern or practice of repeated refusal to authorize a benefit determined by an external appeal entity in violation of the terms of such a plan, coverage, or this title; or

(ii) any pattern or practice of repeated violations of the requirements of this section with respect to such plan or plans or coverage.

(B) STANDARD OF PROOF AND AMOUNT OF PENALTY.—Such penalty shall be payable only upon proof by clear and convincing evidence of such pattern or practice and shall be in an amount not to exceed the lesser of—

- (i) 25 percent of the aggregate value of benefits shown by the appropriate Secretary to have not been provided, or unlawfully delayed, in violation of this section under such pattern or practice, or
- (ii) \$500,000.

(4) REMOVAL AND DISQUALIFICATION.—Any person acting in the capacity of authorizing benefits who has engaged in any such pattern or practice described in paragraph (3)(A) with respect to a plan or coverage, upon the petition of the appropriate Secretary, may be removed by the court from such position, and from any other involvement, with respect to such a plan or coverage, and may be precluded from returning to any such position or involvement for a period determined by the court.

(f) PROTECTION OF LEGAL RIGHTS.—Nothing in this subtitle shall be construed as altering or eliminating any cause of action or legal rights or remedies of participants, beneficiaries, enrollees, and others under State or Federal law (including sections 502 and 503 of the Employee Retirement Income Security Act of 1974), including the right to file judicial actions to enforce actions.

**SEC. 104. ESTABLISHMENT OF A GRIEVANCE PROCESS.**

(a) ESTABLISHMENT OF GRIEVANCE SYSTEM.—

(1) IN GENERAL.—A group health plan, and a health insurance issuer in connection with the provision of health insurance coverage, shall establish and maintain a system to provide for the presentation and resolution of oral and written grievances brought by individuals who are participants, beneficiaries, or enrollees, or health care providers or other individuals acting on behalf of an individual and with the individual's consent or without such consent if the individual is medically unable to provide such consent, regarding any aspect of the plan's or issuer's services.

(2) GRIEVANCE DEFINED.—In this section, the term "grievance" means any question, complaint, or concern brought by a participant, beneficiary or enrollee that is not a claim for benefits (as defined in section 101(f)(1)).

(b) GRIEVANCE SYSTEM.—Such system shall include the following components with respect to individuals who are participants, beneficiaries, or enrollees:

(1) Written notification to all such individuals and providers of the telephone numbers and business addresses of the plan or issuer personnel responsible for resolution of grievances and appeals.

(2) A system to record and document, over a period of at least 3 previous years, all grievances and appeals made and their status.

(3) A process providing for timely processing and resolution of grievances.

(4) Procedures for follow-up action, including the methods to inform the person making the grievance of the resolution of the grievance.

Grievances are not subject to appeal under the previous provisions of this subtitle.

## **Subtitle B—Access to Care**

### **SEC. 111. CONSUMER CHOICE OPTION.**

(a) **IN GENERAL.**—If a health insurance issuer offers to enrollees health insurance coverage in connection with a group health plan which provides for coverage of services only if such services are furnished through health care professionals and providers who are members of a network of health care professionals and providers who have entered into a contract with the issuer to provide such services, the issuer shall also offer to such enrollees (at the time of enrollment and during an annual open season as provided under subsection (c)) the option of health insurance coverage which provides for coverage of such services which are not furnished through health care professionals and providers who are members of such a network unless enrollees are offered such non-network coverage through another group health plan or through another health insurance issuer in the group market.

(b) **ADDITIONAL COSTS.**—The amount of any additional premium charged by the health insurance issuer for the additional cost of the creation and maintenance of the option described in subsection (a) and the amount of any additional cost sharing imposed under such option shall be borne by the enrollee unless it is paid by the health plan sponsor through agreement with the health insurance issuer.

(c) **OPEN SEASON.**—An enrollee may change to the offering provided under this section only during a time period determined by the health insurance issuer. Such time period shall occur at least annually.

### **SEC. 112. CHOICE OF HEALTH CARE PROFESSIONAL.**

(a) **PRIMARY CARE.**—If a group health plan, or a health insurance issuer that offers health insurance coverage, requires or provides for designation by a participant, beneficiary, or enrollee of a participating primary care provider, then the plan or issuer shall permit each participant, beneficiary, and enrollee to designate any participating primary care provider who is available to accept such individual.

(b) **SPECIALISTS.**—

(1) **IN GENERAL.**—Subject to paragraph (2), a group health plan and a health insurance issuer that offers health insurance coverage shall permit each participant, beneficiary, or enrollee to receive medically necessary or appropriate specialty care, pursuant to appropriate referral procedures, from any qualified participating health care professional who is available to accept such individual for such care.

(2) **LIMITATION.**—Paragraph (1) shall not apply to specialty care if the plan or issuer clearly informs participants, beneficiaries, and enrollees of the limitations on choice of participating health care professionals with respect to such care.

### **SEC. 113. ACCESS TO EMERGENCY CARE.**

(a) **COVERAGE OF EMERGENCY SERVICES.**—

(1) **IN GENERAL.**—If a group health plan, or health insurance coverage offered by a health insurance issuer, provides any benefits with respect to services in an emergency department

of a hospital, the plan or issuer shall cover emergency services (as defined in paragraph (2)(B))—

(A) without the need for any prior authorization determination;

(B) whether or not the health care provider furnishing such services is a participating provider with respect to such services;

(C) in a manner so that, if such services are provided to a participant, beneficiary, or enrollee—

(i) by a nonparticipating health care provider with or without prior authorization, or

(ii) by a participating health care provider without prior authorization,

the participant, beneficiary, or enrollee is not liable for amounts that exceed the amounts of liability that would be incurred if the services were provided by a participating health care provider with prior authorization; and

(D) without regard to any other term or condition of such coverage (other than exclusion or coordination of benefits, or an affiliation or waiting period, permitted under section 2701 of the Public Health Service Act, section 701 of the Employee Retirement Income Security Act of 1974, or section 9801 of the Internal Revenue Code of 1986, and other than applicable cost-sharing).

(2) DEFINITIONS.—In this section:

(A) EMERGENCY MEDICAL CONDITION BASED ON PRUDENT LAYPERSON STANDARD.—The term “emergency medical condition” means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act.

(B) EMERGENCY SERVICES.—The term “emergency services” means—

(i) a medical screening examination (as required under section 1867 of the Social Security Act) that is within the capability of the emergency department of a hospital, including ancillary services routinely available to the emergency department to evaluate an emergency medical condition (as defined in subparagraph (A)), and

(ii) within the capabilities of the staff and facilities available at the hospital, such further medical examination and treatment as are required under section 1867 of such Act to stabilize the patient.

(C) STABILIZE.—The term “to stabilize” means, with respect to an emergency medical condition, to provide such medical treatment of the condition as may be necessary to assure, within reasonable medical probability, that no material deterioration of the condition is likely to result from or occur during the transfer of the individual from a facility.

(b) **REIMBURSEMENT FOR MAINTENANCE CARE AND POST-STABILIZATION CARE.**—If benefits are available under a group health plan, or under health insurance coverage offered by a health insurance issuer, with respect to maintenance care or post-stabilization care covered under the guidelines established under section 1852(d)(2) of the Social Security Act, the plan or issuer shall provide for reimbursement with respect to such services provided to a participant, beneficiary, or enrollee other than through a participating health care provider in a manner consistent with subsection (a)(1)(C) (and shall otherwise comply with such guidelines).

**SEC. 114. ACCESS TO SPECIALTY CARE.**

(a) **SPECIALTY CARE FOR COVERED SERVICES.**—

(1) **IN GENERAL.**—If—

(A) an individual is a participant or beneficiary under a group health plan or an enrollee who is covered under health insurance coverage offered by a health insurance issuer,

(B) the individual has a condition or disease of sufficient seriousness and complexity to require treatment by a specialist, and

(C) benefits for such treatment are provided under the plan or coverage,

the plan or issuer shall make or provide for a referral to a specialist who is available and accessible to provide the treatment for such condition or disease.

(2) **SPECIALIST DEFINED.**—For purposes of this subsection, the term “specialist” means, with respect to a condition, a health care practitioner, facility, or center that has adequate expertise through appropriate training and experience (including, in the case of a child, appropriate pediatric expertise) to provide high quality care in treating the condition.

(3) **CARE UNDER REFERRAL.**—A group health plan or health insurance issuer may require that the care provided to an individual pursuant to such referral under paragraph (1) be—

(A) pursuant to a treatment plan, only if the treatment plan is developed by the specialist and approved by the plan or issuer, in consultation with the designated primary care provider or specialist and the individual (or the individual’s designee), and

(B) in accordance with applicable quality assurance and utilization review standards of the plan or issuer.

Nothing in this subsection shall be construed as preventing such a treatment plan for an individual from requiring a specialist to provide the primary care provider with regular updates on the specialty care provided, as well as all necessary medical information.

(4) **REFERRALS TO PARTICIPATING PROVIDERS.**—A group health plan or health insurance issuer is not required under paragraph (1) to provide for a referral to a specialist that is not a participating provider, unless the plan or issuer does not have an appropriate specialist that is available and accessible to treat the individual’s condition and that is a participating provider with respect to such treatment.

(5) TREATMENT OF NONPARTICIPATING PROVIDERS.—If a plan or issuer refers an individual to a nonparticipating specialist pursuant to paragraph (1), services provided pursuant to the approved treatment plan (if any) shall be provided at no additional cost to the individual beyond what the individual would otherwise pay for services received by such a specialist that is a participating provider.

(b) SPECIALISTS AS GATEKEEPER FOR TREATMENT OF ONGOING SPECIAL CONDITIONS.—

(1) IN GENERAL.—A group health plan, or a health insurance issuer, in connection with the provision of health insurance coverage, shall have a procedure by which an individual who is a participant, beneficiary, or enrollee and who has an ongoing special condition (as defined in paragraph (3)) may request and receive a referral to a specialist for such condition who shall be responsible for and capable of providing and coordinating the individual's care with respect to the condition. Under such procedures if such an individual's care would most appropriately be coordinated by such a specialist, such plan or issuer shall refer the individual to such specialist.

(2) TREATMENT FOR RELATED REFERRALS.—Such specialists shall be permitted to treat the individual without a referral from the individual's primary care provider and may authorize such referrals, procedures, tests, and other medical services as the individual's primary care provider would otherwise be permitted to provide or authorize, subject to the terms of the treatment (referred to in subsection (a)(3)(A)) with respect to the ongoing special condition.

(3) ONGOING SPECIAL CONDITION DEFINED.—In this subsection, the term "ongoing special condition" means a condition or disease that—

(A) is life-threatening, degenerative, or disabling, and

(B) requires specialized medical care over a prolonged period of time.

(4) TERMS OF REFERRAL.—The provisions of paragraphs (3) through (5) of subsection (a) apply with respect to referrals under paragraph (1) of this subsection in the same manner as they apply to referrals under subsection (a)(1).

(c) STANDING REFERRALS.—

(1) IN GENERAL.—A group health plan, and a health insurance issuer in connection with the provision of health insurance coverage, shall have a procedure by which an individual who is a participant, beneficiary, or enrollee and who has a condition that requires ongoing care from a specialist may receive a standing referral to such specialist for treatment of such condition. If the plan or issuer, or if the primary care provider in consultation with the medical director of the plan or issuer and the specialist (if any), determines that such a standing referral is appropriate, the plan or issuer shall make such a referral to such a specialist if the individual so desires.

(2) TERMS OF REFERRAL.—The provisions of paragraphs (3) through (5) of subsection (a) apply with respect to referrals under paragraph (1) of this subsection in the same manner as they apply to referrals under subsection (a)(1).

**SEC. 115. ACCESS TO OBSTETRICAL AND GYNECOLOGICAL CARE.**

(a) **IN GENERAL.**—If a group health plan, or a health insurance issuer in connection with the provision of health insurance coverage, requires or provides for a participant, beneficiary, or enrollee to designate a participating primary care health care professional, the plan or issuer—

(1) may not require authorization or a referral by the individual's primary care health care professional or otherwise for coverage of gynecological care (including preventive women's health examinations) and pregnancy-related services provided by a participating health care professional, including a physician, who specializes in obstetrics and gynecology to the extent such care is otherwise covered, and

(2) shall treat the ordering of other obstetrical or gynecological care by such a participating professional as the authorization of the primary care health care professional with respect to such care under the plan or coverage.

(b) **CONSTRUCTION.**—Nothing in subsection (a) shall be construed to—

(1) waive any exclusions of coverage under the terms of the plan or health insurance coverage with respect to coverage of obstetrical or gynecological care; or

(2) preclude the group health plan or health insurance issuer involved from requiring that the obstetrical or gynecological provider notify the primary care health care professional or the plan or issuer of treatment decisions.

**SEC. 116. ACCESS TO PEDIATRIC CARE.**

(a) **PEDIATRIC CARE.**—If a group health plan, or a health insurance issuer in connection with the provision of health insurance coverage, requires or provides for an enrollee to designate a participating primary care provider for a child of such enrollee, the plan or issuer shall permit the enrollee to designate a physician who specializes in pediatrics as the child's primary care provider.

(b) **CONSTRUCTION.**—Nothing in subsection (a) shall be construed to waive any exclusions of coverage under the terms of the plan or health insurance coverage with respect to coverage of pediatric care.

**SEC. 117. CONTINUITY OF CARE.**

(a) **IN GENERAL.**—

(1) **TERMINATION OF PROVIDER.**—If a contract between a group health plan, or a health insurance issuer in connection with the provision of health insurance coverage, and a health care provider is terminated (as defined in paragraph (3)(B)), or benefits or coverage provided by a health care provider are terminated because of a change in the terms of provider participation in a group health plan, and an individual who is a participant, beneficiary, or enrollee in the plan or coverage is undergoing treatment from the provider for an ongoing special condition (as defined in paragraph (3)(A)) at the time of such termination, the plan or issuer shall—

(A) notify the individual on a timely basis of such termination and of the right to elect continuation of coverage of treatment by the provider under this section; and

(B) subject to subsection (c), permit the individual to elect to continue to be covered with respect to treatment by the provider of such condition during a transitional period (provided under subsection (b)).

(2) TREATMENT OF TERMINATION OF CONTRACT WITH HEALTH INSURANCE ISSUER.—If a contract for the provision of health insurance coverage between a group health plan and a health insurance issuer is terminated and, as a result of such termination, coverage of services of a health care provider is terminated with respect to an individual, the provisions of paragraph (1) (and the succeeding provisions of this section) shall apply under the plan in the same manner as if there had been a contract between the plan and the provider that had been terminated, but only with respect to benefits that are covered under the plan after the contract termination.

(3) DEFINITIONS.—For purposes of this section:

(A) ONGOING SPECIAL CONDITION.—The term “ongoing special condition” has the meaning given such term in section 114(b)(3), and also includes pregnancy.

(B) TERMINATION.—The term “terminated” includes, with respect to a contract, the expiration or nonrenewal of the contract, but does not include a termination of the contract by the plan or issuer for failure to meet applicable quality standards or for fraud.

(b) TRANSITIONAL PERIOD.—

(1) IN GENERAL.—Except as provided in paragraphs (2) through (4), the transitional period under this subsection shall extend up to 90 days (as determined by the treating health care professional) after the date of the notice described in subsection (a)(1)(A) of the provider’s termination.

(2) SCHEDULED SURGERY AND ORGAN TRANSPLANTATION.—If surgery or organ transplantation was scheduled for an individual before the date of the announcement of the termination of the provider status under subsection (a)(1)(A) or if the individual on such date was on an established waiting list or otherwise scheduled to have such surgery or transplantation, the transitional period under this subsection with respect to the surgery or transplantation shall extend beyond the period under paragraph (1) and until the date of discharge of the individual after completion of the surgery or transplantation.

(3) PREGNANCY.—If—

(A) a participant, beneficiary, or enrollee was determined to be pregnant at the time of a provider’s termination of participation, and

(B) the provider was treating the pregnancy before date of the termination,

the transitional period under this subsection with respect to provider’s treatment of the pregnancy shall extend through the provision of post-partum care directly related to the delivery.

(4) TERMINAL ILLNESS.—If—

(A) a participant, beneficiary, or enrollee was determined to be terminally ill (as determined under section 1861(dd)(3)(A) of the Social Security Act) at the time of a provider’s termination of participation, and

(B) the provider was treating the terminal illness before the date of termination, the transitional period under this subsection shall extend for the remainder of the individual's life for care directly related to the treatment of the terminal illness or its medical manifestations.

(c) **PERMISSIBLE TERMS AND CONDITIONS.**—A group health plan or health insurance issuer may condition coverage of continued treatment by a provider under subsection (a)(1)(B) upon the individual notifying the plan of the election of continued coverage and upon the provider agreeing to the following terms and conditions:

(1) The provider agrees to accept reimbursement from the plan or issuer and individual involved (with respect to cost-sharing) at the rates applicable prior to the start of the transitional period as payment in full (or, in the case described in subsection (a)(2), at the rates applicable under the replacement plan or issuer after the date of the termination of the contract with the health insurance issuer) and not to impose cost-sharing with respect to the individual in an amount that would exceed the cost-sharing that could have been imposed if the contract referred to in subsection (a)(1) had not been terminated.

(2) The provider agrees to adhere to the quality assurance standards of the plan or issuer responsible for payment under paragraph (1) and to provide to such plan or issuer necessary medical information related to the care provided.

(3) The provider agrees otherwise to adhere to such plan's or issuer's policies and procedures, including procedures regarding referrals and obtaining prior authorization and providing services pursuant to a treatment plan (if any) approved by the plan or issuer.

(d) **CONSTRUCTION.**—Nothing in this section shall be construed to require the coverage of benefits which would not have been covered if the provider involved remained a participating provider.

**SEC. 118. ACCESS TO NEEDED PRESCRIPTION DRUGS.**

If a group health plan, or health insurance issuer that offers health insurance coverage, provides benefits with respect to prescription drugs but the coverage limits such benefits to drugs included in a formulary, the plan or issuer shall—

(1) ensure participation of participating physicians and pharmacists in the development of the formulary;

(2) disclose to providers and, disclose upon request under section 121(c)(5) to participants, beneficiaries, and enrollees, the nature of the formulary restrictions; and

(3) consistent with the standards for a utilization review program under section 101, provide for exceptions from the formulary limitation when a non-formulary alternative is medically indicated.

**SEC. 119. COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CLINICAL TRIALS.**

(a) **COVERAGE.**—

(1) **IN GENERAL.**—If a group health plan, or health insurance issuer that is providing health insurance coverage, provides

coverage to a qualified individual (as defined in subsection (b)), the plan or issuer—

(A) may not deny the individual participation in the clinical trial referred to in subsection (b)(2);

(B) subject to subsection (c), may not deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and services furnished in connection with participation in the trial; and

(C) may not discriminate against the individual on the basis of the enrollee's participation in such trial.

(2) EXCLUSION OF CERTAIN COSTS.—For purposes of paragraph (1)(B), routine patient costs do not include the cost of the tests or measurements conducted primarily for the purpose of the clinical trial involved.

(3) USE OF IN-NETWORK PROVIDERS.—If one or more participating providers is participating in a clinical trial, nothing in paragraph (1) shall be construed as preventing a plan or issuer from requiring that a qualified individual participate in the trial through such a participating provider if the provider will accept the individual as a participant in the trial.

(b) QUALIFIED INDIVIDUAL DEFINED.—For purposes of subsection (a), the term “qualified individual” means an individual who is a participant or beneficiary in a group health plan, or who is an enrollee under health insurance coverage, and who meets the following conditions:

(1)(A) The individual has a life-threatening or serious illness for which no standard treatment is effective.

(B) The individual is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of such illness.

(C) The individual's participation in the trial offers meaningful potential for significant clinical benefit for the individual.

(2) Either—

(A) the referring physician is a participating health care professional and has concluded that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1); or

(B) the participant, beneficiary, or enrollee provides medical and scientific information establishing that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1).

(c) PAYMENT.—

(1) IN GENERAL.—Under this section a group health plan or health insurance issuer shall provide for payment for routine patient costs described in subsection (a)(2) but is not required to pay for costs of items and services that are reasonably expected (as determined by the Secretary) to be paid for by the sponsors of an approved clinical trial.

(2) PAYMENT RATE.—In the case of covered items and services provided by—

(A) a participating provider, the payment rate shall be at the agreed upon rate, or

- (B) a nonparticipating provider, the payment rate shall be at the rate the plan or issuer would normally pay for comparable services under subparagraph (A).
- (d) APPROVED CLINICAL TRIAL DEFINED.—
- (1) IN GENERAL.—In this section, the term “approved clinical trial” means a clinical research study or clinical investigation approved and funded (which may include funding through in-kind contributions) by one or more of the following:
- (A) The National Institutes of Health.
- (B) A cooperative group or center of the National Institutes of Health.
- (C) Either of the following if the conditions described in paragraph (2) are met:
- (i) The Department of Veterans Affairs.
- (ii) The Department of Defense.
- (2) CONDITIONS FOR DEPARTMENTS.—The conditions described in this paragraph, for a study or investigation conducted by a Department, are that the study or investigation has been reviewed and approved through a system of peer review that the Secretary determines—
- (A) to be comparable to the system of peer review of studies and investigations used by the National Institutes of Health, and
- (B) assures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review.
- (e) CONSTRUCTION.—Nothing in this section shall be construed to limit a plan’s or issuer’s coverage with respect to clinical trials.

## Subtitle C—Access to Information

### SEC. 121. PATIENT ACCESS TO INFORMATION.

- (a) DISCLOSURE REQUIREMENT.—
- (1) GROUP HEALTH PLANS.—A group health plan shall—
- (A) provide to participants and beneficiaries at the time of initial coverage under the plan (or the effective date of this section, in the case of individuals who are participants or beneficiaries as of such date), and at least annually thereafter, the information described in subsection (b) in printed form;
- (B) provide to participants and beneficiaries, within a reasonable period (as specified by the appropriate Secretary) before or after the date of significant changes in the information described in subsection (b), information in printed form on such significant changes; and
- (C) upon request, make available to participants and beneficiaries, the applicable authority, and prospective participants and beneficiaries, the information described in subsection (b) or (c) in printed form.
- (2) HEALTH INSURANCE ISSUERS.—A health insurance issuer in connection with the provision of health insurance coverage shall—

- (A) provide to individuals enrolled under such coverage at the time of enrollment, and at least annually thereafter, the information described in subsection (b) in printed form;
  - (B) provide to enrollees, within a reasonable period (as specified by the appropriate Secretary) before or after the date of significant changes in the information described in subsection (b), information in printed form on such significant changes; and
  - (C) upon request, make available to the applicable authority, to individuals who are prospective enrollees, and to the public the information described in subsection (b) or (c) in printed form.
- (b) INFORMATION PROVIDED.—The information described in this subsection with respect to a group health plan or health insurance coverage offered by a health insurance issuer includes the following:
- (1) SERVICE AREA.—The service area of the plan or issuer.
  - (2) BENEFITS.—Benefits offered under the plan or coverage, including—
    - (A) covered benefits, including benefit limits and coverage exclusions;
    - (B) cost sharing, such as deductibles, coinsurance, and copayment amounts, including any liability for balance billing, any maximum limitations on out of pocket expenses, and the maximum out of pocket costs for services that are provided by nonparticipating providers or that are furnished without meeting the applicable utilization review requirements;
    - (C) the extent to which benefits may be obtained from nonparticipating providers;
    - (D) the extent to which a participant, beneficiary, or enrollee may select from among participating providers and the types of providers participating in the plan or issuer network;
    - (E) process for determining experimental coverage; and
    - (F) use of a prescription drug formulary.
  - (3) ACCESS.—A description of the following:
    - (A) The number, mix, and distribution of providers under the plan or coverage.
    - (B) Out-of-network coverage (if any) provided by the plan or coverage.
    - (C) Any point-of-service option (including any supplemental premium or cost-sharing for such option).
    - (D) The procedures for participants, beneficiaries, and enrollees to select, access, and change participating primary and specialty providers.
    - (E) The rights and procedures for obtaining referrals (including standing referrals) to participating and nonparticipating providers.
    - (F) The name, address, and telephone number of participating health care providers and an indication of whether each such provider is available to accept new patients.

(G) Any limitations imposed on the selection of qualifying participating health care providers, including any limitations imposed under section 112(b)(2).

(H) How the plan or issuer addresses the needs of participants, beneficiaries, and enrollees and others who do not speak English or who have other special communications needs in accessing providers under the plan or coverage, including the provision of information described in this subsection and subsection (c) to such individuals.

(4) OUT-OF-AREA COVERAGE.—Out-of-area coverage provided by the plan or issuer.

(5) EMERGENCY COVERAGE.—Coverage of emergency services, including—

(A) the appropriate use of emergency services, including use of the 911 telephone system or its local equivalent in emergency situations and an explanation of what constitutes an emergency situation;

(B) the process and procedures of the plan or issuer for obtaining emergency services; and

(C) the locations of (i) emergency departments, and (ii) other settings, in which plan physicians and hospitals provide emergency services and post-stabilization care.

(6) PERCENTAGE OF PREMIUMS USED FOR BENEFITS (LOSS-RATIOS).—In the case of health insurance coverage only (and not with respect to group health plans that do not provide coverage through health insurance coverage), a description of the overall loss-ratio for the coverage (as defined in accordance with rules established or recognized by the Secretary of Health and Human Services).

(7) PRIOR AUTHORIZATION RULES.—Rules regarding prior authorization or other review requirements that could result in noncoverage or nonpayment.

(8) GRIEVANCE AND APPEALS PROCEDURES.—All appeal or grievance rights and procedures under the plan or coverage, including the method for filing grievances and the time frames and circumstances for acting on grievances and appeals, who is the applicable authority with respect to the plan or issuer.

(9) QUALITY ASSURANCE.—Any information made public by an accrediting organization in the process of accreditation of the plan or issuer or any additional quality indicators the plan or issuer makes available.

(10) INFORMATION ON ISSUER.—Notice of appropriate mailing addresses and telephone numbers to be used by participants, beneficiaries, and enrollees in seeking information or authorization for treatment.

(11) NOTICE OF REQUIREMENTS.—Notice of the requirements of this title.

(12) AVAILABILITY OF INFORMATION ON REQUEST.—Notice that the information described in subsection (c) is available upon request.

(c) INFORMATION MADE AVAILABLE UPON REQUEST.—The information described in this subsection is the following:

(1) UTILIZATION REVIEW ACTIVITIES.—A description of procedures used and requirements (including circumstances, time

frames, and appeal rights) under any utilization review program under section 101, including under any drug formulary program under section 118.

(2) GRIEVANCE AND APPEALS INFORMATION.—Information on the number of grievances and appeals and on the disposition in the aggregate of such matters.

(3) METHOD OF PHYSICIAN COMPENSATION.—A general description by category (including salary, fee-for-service, capitation, and such other categories as may be specified in regulations of the Secretary) of the applicable method by which a specified prospective or treating health care professional is (or would be) compensated in connection with the provision of health care under the plan or coverage.

(4) SPECIFIC INFORMATION ON CREDENTIALS OF PARTICIPATING PROVIDERS.—In the case of each participating provider, a description of the credentials of the provider.

(5) FORMULARY RESTRICTIONS.—A description of the nature of any drug formula restrictions.

(6) PARTICIPATING PROVIDER LIST.—A list of current participating health care providers.

(d) CONSTRUCTION.—Nothing in this section shall be construed as requiring public disclosure of individual contracts or financial arrangements between a group health plan or health insurance issuer and any provider.

## **Subtitle D—Protecting the Doctor-Patient Relationship**

### **SEC. 131. PROHIBITION OF INTERFERENCE WITH CERTAIN MEDICAL COMMUNICATIONS.**

(a) GENERAL RULE.—The provisions of any contract or agreement, or the operation of any contract or agreement, between a group health plan or health insurance issuer in relation to health insurance coverage (including any partnership, association, or other organization that enters into or administers such a contract or agreement) and a health care provider (or group of health care providers) shall not prohibit or otherwise restrict a health care professional from advising such a participant, beneficiary, or enrollee who is a patient of the professional about the health status of the individual or medical care or treatment for the individual's condition or disease, regardless of whether benefits for such care or treatment are provided under the plan or coverage, if the professional is acting within the lawful scope of practice.

(b) NULLIFICATION.—Any contract provision or agreement that restricts or prohibits medical communications in violation of subsection (a) shall be null and void.

### **SEC. 132. PROHIBITION OF DISCRIMINATION AGAINST PROVIDERS BASED ON LICENSURE.**

(a) IN GENERAL.—A group health plan and a health insurance issuer offering health insurance coverage shall not discriminate with respect to participation or indemnification as to any provider who is acting within the scope of the provider's license or certifi-

cation under applicable State law, solely on the basis of such license or certification.

(b) CONSTRUCTION.—Subsection (a) shall not be construed—

(1) as requiring the coverage under a group health plan or health insurance coverage of particular benefits or services or to prohibit a plan or issuer from including providers only to the extent necessary to meet the needs of the plan's or issuer's participants, beneficiaries, or enrollees or from establishing any measure designed to maintain quality and control costs consistent with the responsibilities of the plan or issuer;

(2) to override any State licensure or scope-of-practice law; or

(3) as requiring a plan or issuer that offers network coverage to include for participation every willing provider who meets the terms and conditions of the plan or issuer.

**SEC. 133. PROHIBITION AGAINST IMPROPER INCENTIVE ARRANGEMENTS.**

(a) IN GENERAL.—A group health plan and a health insurance issuer offering health insurance coverage may not operate any physician incentive plan (as defined in subparagraph (B) of section 1876(i)(8) of the Social Security Act) unless the requirements described in clauses (i), (ii)(I), and (iii) of subparagraph (A) of such section are met with respect to such a plan.

(b) APPLICATION.—For purposes of carrying out paragraph (1), any reference in section 1876(i)(8) of the Social Security Act to the Secretary, an eligible organization, or an individual enrolled with the organization shall be treated as a reference to the applicable authority, a group health plan or health insurance issuer, respectively, and a participant, beneficiary, or enrollee with the plan or organization, respectively.

(c) CONSTRUCTION.—Nothing in this section shall be construed as prohibiting all capitation and similar arrangements or all provider discount arrangements.

**SEC. 134. PAYMENT OF CLAIMS.**

A group health plan, and a health insurance issuer offering group health insurance coverage, shall provide for prompt payment of claims submitted for health care services or supplies furnished to a participant, beneficiary, or enrollee with respect to benefits covered by the plan or issuer, in a manner consistent with the provisions of sections 1816(c)(2) and 1842(c)(2) of the Social Security Act (42 U.S.C. 1395h(c)(2) and 42 U.S.C. 1395u(c)(2)), except that for purposes of this section, subparagraph (C) of section 1816(c)(2) of the Social Security Act shall be treated as applying to claims received from a participant, beneficiary, or enrollee as well as claims referred to in such subparagraph.

**SEC. 135. PROTECTION FOR PATIENT ADVOCACY.**

(a) PROTECTION FOR USE OF UTILIZATION REVIEW AND GRIEVANCE PROCESS.—A group health plan, and a health insurance issuer with respect to the provision of health insurance coverage, may not retaliate against a participant, beneficiary, enrollee, or health care provider based on the participant's, beneficiary's, enrollee's or provider's use of, or participation in, a utilization review process or a grievance process of the plan or issuer (including an internal or external review or appeal process) under this title.

## (b) PROTECTION FOR QUALITY ADVOCACY BY HEALTH CARE PROFESSIONALS.—

(1) IN GENERAL.—A group health plan or health insurance issuer may not retaliate or discriminate against a protected health care professional because the professional in good faith—

(A) discloses information relating to the care, services, or conditions affecting one or more participants, beneficiaries, or enrollees of the plan or issuer to an appropriate public regulatory agency, an appropriate private accreditation body, or appropriate management personnel of the plan or issuer; or

(B) initiates, cooperates, or otherwise participates in an investigation or proceeding by such an agency with respect to such care, services, or conditions.

If an institutional health care provider is a participating provider with such a plan or issuer or otherwise receives payments for benefits provided by such a plan or issuer, the provisions of the previous sentence shall apply to the provider in relation to care, services, or conditions affecting one or more patients within an institutional health care provider in the same manner as they apply to the plan or issuer in relation to care, services, or conditions provided to one or more participants, beneficiaries, or enrollees; and for purposes of applying this sentence, any reference to a plan or issuer is deemed a reference to the institutional health care provider.

(2) GOOD FAITH ACTION.—For purposes of paragraph (1), a protected health care professional is considered to be acting in good faith with respect to disclosure of information or participation if, with respect to the information disclosed as part of the action—

(A) the disclosure is made on the basis of personal knowledge and is consistent with that degree of learning and skill ordinarily possessed by health care professionals with the same licensure or certification and the same experience;

(B) the professional reasonably believes the information to be true;

(C) the information evidences either a violation of a law, rule, or regulation, of an applicable accreditation standard, or of a generally recognized professional or clinical standard or that a patient is in imminent hazard of loss of life or serious injury; and

(D) subject to subparagraphs (B) and (C) of paragraph (3), the professional has followed reasonable internal procedures of the plan, issuer, or institutional health care provider established for the purpose of addressing quality concerns before making the disclosure.

## (3) EXCEPTION AND SPECIAL RULE.—

(A) GENERAL EXCEPTION.—Paragraph (1) does not protect disclosures that would violate Federal or State law or diminish or impair the rights of any person to the continued protection of confidentiality of communications provided by such law.

(B) NOTICE OF INTERNAL PROCEDURES.—Subparagraph (D) of paragraph (2) shall not apply unless the internal procedures involved are reasonably expected to be known to the health care professional involved. For purposes of this subparagraph, a health care professional is reasonably expected to know of internal procedures if those procedures have been made available to the professional through distribution or posting.

(C) INTERNAL PROCEDURE EXCEPTION.—Subparagraph (D) of paragraph (2) also shall not apply if—

(i) the disclosure relates to an imminent hazard of loss of life or serious injury to a patient;

(ii) the disclosure is made to an appropriate private accreditation body pursuant to disclosure procedures established by the body; or

(iii) the disclosure is in response to an inquiry made in an investigation or proceeding of an appropriate public regulatory agency and the information disclosed is limited to the scope of the investigation or proceeding.

(4) ADDITIONAL CONSIDERATIONS.—It shall not be a violation of paragraph (1) to take an adverse action against a protected health care professional if the plan, issuer, or provider taking the adverse action involved demonstrates that it would have taken the same adverse action even in the absence of the activities protected under such paragraph.

(5) NOTICE.—A group health plan, health insurance issuer, and institutional health care provider shall post a notice, to be provided or approved by the Secretary of Labor, setting forth excerpts from, or summaries of, the pertinent provisions of this subsection and information pertaining to enforcement of such provisions.

(6) CONSTRUCTIONS.—

(A) DETERMINATIONS OF COVERAGE.—Nothing in this subsection shall be construed to prohibit a plan or issuer from making a determination not to pay for a particular medical treatment or service or the services of a type of health care professional.

(B) ENFORCEMENT OF PEER REVIEW PROTOCOLS AND INTERNAL PROCEDURES.—Nothing in this subsection shall be construed to prohibit a plan, issuer, or provider from establishing and enforcing reasonable peer review or utilization review protocols or determining whether a protected health care professional has complied with those protocols or from establishing and enforcing internal procedures for the purpose of addressing quality concerns.

(C) RELATION TO OTHER RIGHTS.—Nothing in this subsection shall be construed to abridge rights of participants, beneficiaries, enrollees, and protected health care professionals under other applicable Federal or State laws.

(7) PROTECTED HEALTH CARE PROFESSIONAL DEFINED.—For purposes of this subsection, the term “protected health care professional” means an individual who is a licensed or certified health care professional and who—

(A) with respect to a group health plan or health insurance issuer, is an employee of the plan or issuer or has a contract with the plan or issuer for provision of services for which benefits are available under the plan or issuer; or

(B) with respect to an institutional health care provider, is an employee of the provider or has a contract or other arrangement with the provider respecting the provision of health care services.

## **Subtitle E—Definitions**

### **SEC. 151. DEFINITIONS.**

(a) INCORPORATION OF GENERAL DEFINITIONS.—Except as otherwise provided, the provisions of section 2791 of the Public Health Service Act shall apply for purposes of this title in the same manner as they apply for purposes of title XXVII of such Act.

(b) SECRETARY.—Except as otherwise provided, the term “Secretary” means the Secretary of Health and Human Services, in consultation with the Secretary of Labor and the term “appropriate Secretary” means the Secretary of Health and Human Services in relation to carrying out this title under sections 2706 and 2751 of the Public Health Service Act and the Secretary of Labor in relation to carrying out this title under section 713 of the Employee Retirement Income Security Act of 1974.

(c) ADDITIONAL DEFINITIONS.—For purposes of this title:

(1) ACTIVELY PRACTICING.—The term “actively practicing” means, with respect to a physician or other health care professional, such a physician or professional who provides professional services to individual patients on average at least two full days per week.

(2) APPLICABLE AUTHORITY.—The term “applicable authority” means—

(A) in the case of a group health plan, the Secretary of Health and Human Services and the Secretary of Labor; and

(B) in the case of a health insurance issuer with respect to a specific provision of this title, the applicable State authority (as defined in section 2791(d) of the Public Health Service Act), or the Secretary of Health and Human Services, if such Secretary is enforcing such provision under section 2722(a)(2) or 2761(a)(2) of the Public Health Service Act.

(3) CLINICAL PEER.—The term “clinical peer” means, with respect to a review or appeal, an actively practicing physician (allopathic or osteopathic) or other actively practicing health care professional who holds a nonrestricted license, and who is appropriately credentialed in the same or similar specialty or subspecialty (as appropriate) as typically handles the medical condition, procedure, or treatment under review or appeal and includes a pediatric specialist where appropriate; except that only a physician (allopathic or osteopathic) may be a clinical peer with respect to the review or appeal of treatment recommended or rendered by a physician.

(4) **ENROLLEE.**—The term “enrollee” means, with respect to health insurance coverage offered by a health insurance issuer, an individual enrolled with the issuer to receive such coverage.

(5) **GROUP HEALTH PLAN.**—The term “group health plan” has the meaning given such term in section 733(a) of the Employee Retirement Income Security Act of 1974 and in section 2791(a)(1) of the Public Health Service Act.

(6) **HEALTH CARE PROFESSIONAL.**—The term “health care professional” means an individual who is licensed, accredited, or certified under State law to provide specified health care services and who is operating within the scope of such licensure, accreditation, or certification.

(7) **HEALTH CARE PROVIDER.**—The term “health care provider” includes a physician or other health care professional, as well as an institutional or other facility or agency that provides health care services and that is licensed, accredited, or certified to provide health care items and services under applicable State law.

(8) **NETWORK.**—The term “network” means, with respect to a group health plan or health insurance issuer offering health insurance coverage, the participating health care professionals and providers through whom the plan or issuer provides health care items and services to participants, beneficiaries, or enrollees.

(9) **NONPARTICIPATING.**—The term “nonparticipating” means, with respect to a health care provider that provides health care items and services to a participant, beneficiary, or enrollee under group health plan or health insurance coverage, a health care provider that is not a participating health care provider with respect to such items and services.

(10) **PARTICIPATING.**—The term “participating” means, with respect to a health care provider that provides health care items and services to a participant, beneficiary, or enrollee under group health plan or health insurance coverage offered by a health insurance issuer, a health care provider that furnishes such items and services under a contract or other arrangement with the plan or issuer.

(11) **PRIOR AUTHORIZATION.**—The term “prior authorization” means the process of obtaining prior approval from a health insurance issuer or group health plan for the provision or coverage of medical services.

**SEC. 152. PREEMPTION; STATE FLEXIBILITY; CONSTRUCTION.**

(a) **CONTINUED APPLICABILITY OF STATE LAW WITH RESPECT TO HEALTH INSURANCE ISSUERS.**—

(1) **IN GENERAL.**—Subject to paragraph (2), this title shall not be construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers (in connection with group health insurance coverage or otherwise) except to the extent that such standard or requirement prevents the application of a requirement of this title.

(2) **CONTINUED PREEMPTION WITH RESPECT TO GROUP HEALTH PLANS.**—Nothing in this title shall be construed to affect or modify the provisions of section 514 of the Employee Retirement

ment Income Security Act of 1974 with respect to group health plans.

(b) **DEFINITIONS.**—For purposes of this section:

(1) **STATE LAW.**—The term “State law” includes all laws, decisions, rules, regulations, or other State action having the effect of law, of any State. A law of the United States applicable only to the District of Columbia shall be treated as a State law rather than a law of the United States.

(2) **STATE.**—The term “State” includes a State, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, any political subdivisions of such, or any agency or instrumentality of such.

**SEC. 153. EXCLUSIONS.**

(a) **NO BENEFIT REQUIREMENTS.**—Nothing in this title shall be construed to require a group health plan or a health insurance issuer offering health insurance coverage to include specific items and services (including abortions) under the terms of such plan or coverage, other than those provided under the terms of such plan or coverage.

(b) **EXCLUSION FROM ACCESS TO CARE MANAGED CARE PROVISIONS FOR FEE-FOR-SERVICE COVERAGE.**—

(1) **IN GENERAL.**—The provisions of sections 111 through 117 shall not apply to a group health plan or health insurance coverage if the only coverage offered under the plan or coverage is fee-for-service coverage (as defined in paragraph (2)).

(2) **FEE-FOR-SERVICE COVERAGE DEFINED.**—For purposes of this subsection, the term “fee-for-service coverage” means coverage under a group health plan or health insurance coverage that—

(A) reimburses hospitals, health professionals, and other providers on the basis of a rate determined by the plan or issuer on a fee-for-service basis without placing the provider at financial risk;

(B) does not vary reimbursement for such a provider based on an agreement to contract terms and conditions or the utilization of health care items or services relating to such provider;

(C) does not restrict the selection of providers among those who are lawfully authorized to provide the covered services and agree to accept the terms and conditions of payment established under the plan or by the issuer; and

(D) for which the plan or issuer does not require prior authorization before providing coverage for any services.

**SEC. 154. COVERAGE OF LIMITED SCOPE PLANS.**

Only for purposes of applying the requirements of this title under sections 2707 and 2753 of the Public Health Service Act and section 714 of the Employee Retirement Income Security Act of 1974, section 2791(c)(2)(A), and section 733(c)(2)(A) of the Employee Retirement Income Security Act of 1974 shall be deemed not to apply.

**SEC. 155. REGULATIONS.**

The Secretaries of Health and Human Services and Labor shall issue such regulations as may be necessary or appropriate to carry out this title. Such regulations shall be issued consistent with sec-

tion 104 of Health Insurance Portability and Accountability Act of 1996. Such Secretaries may promulgate any interim final rules as the Secretaries determine are appropriate to carry out this title.

## **TITLE II—APPLICATION OF QUALITY CARE STANDARDS TO GROUP HEALTH PLANS AND HEALTH INSURANCE COVERAGE UNDER THE PUBLIC HEALTH SERVICE ACT**

### **SEC. 201. APPLICATION TO GROUP HEALTH PLANS AND GROUP HEALTH INSURANCE COVERAGE.**

(a) **IN GENERAL.**—Subpart 2 of part A of title XXVII of the Public Health Service Act is amended by adding at the end the following new section:

#### **“SEC. 2707. PATIENT PROTECTION STANDARDS.**

“(a) **IN GENERAL.**—Each group health plan shall comply with patient protection requirements under title I of the Bipartisan Consensus Managed Care Improvement Act of 1999, and each health insurance issuer shall comply with patient protection requirements under such title with respect to group health insurance coverage it offers, and such requirements shall be deemed to be incorporated into this subsection.

“(b) **NOTICE.**—A group health plan shall comply with the notice requirement under section 711(d) of the Employee Retirement Income Security Act of 1974 with respect to the requirements referred to in subsection (a) and a health insurance issuer shall comply with such notice requirement as if such section applied to such issuer and such issuer were a group health plan.”.

(b) **CONFORMING AMENDMENT.**—Section 2721(b)(2)(A) of such Act (42 U.S.C. 300gg-21(b)(2)(A)) is amended by inserting “(other than section 2707)” after “requirements of such subparts”.

### **SEC. 202. APPLICATION TO INDIVIDUAL HEALTH INSURANCE COVERAGE.**

Part B of title XXVII of the Public Health Service Act is amended by inserting after section 2752 the following new section:

#### **“SEC. 2753. PATIENT PROTECTION STANDARDS.**

“(a) **IN GENERAL.**—Each health insurance issuer shall comply with patient protection requirements under title I of the Bipartisan Consensus Managed Care Improvement Act of 1999 with respect to individual health insurance coverage it offers, and such requirements shall be deemed to be incorporated into this subsection.

“(b) **NOTICE.**—A health insurance issuer under this part shall comply with the notice requirement under section 711(d) of the Employee Retirement Income Security Act of 1974 with respect to the requirements of such title as if such section applied to such issuer and such issuer were a group health plan.”.

## TITLE III—AMENDMENTS TO THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974

### SEC. 301. APPLICATION OF PATIENT PROTECTION STANDARDS TO GROUP HEALTH PLANS AND GROUP HEALTH INSURANCE COVERAGE UNDER THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974.

Subpart B of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 is amended by adding at the end the following new section:

#### “SEC. 714. PATIENT PROTECTION STANDARDS.

“(a) IN GENERAL.—Subject to subsection (b), a group health plan (and a health insurance issuer offering group health insurance coverage in connection with such a plan) shall comply with the requirements of title I of the Bipartisan Consensus Managed Care Improvement Act of 1999 (as in effect as of the date of the enactment of such Act), and such requirements shall be deemed to be incorporated into this subsection.

#### “(b) PLAN SATISFACTION OF CERTAIN REQUIREMENTS.—

“(1) SATISFACTION OF CERTAIN REQUIREMENTS THROUGH INSURANCE.—For purposes of subsection (a), insofar as a group health plan provides benefits in the form of health insurance coverage through a health insurance issuer, the plan shall be treated as meeting the following requirements of title I of the Bipartisan Consensus Managed Care Improvement Act of 1999 with respect to such benefits and not be considered as failing to meet such requirements because of a failure of the issuer to meet such requirements so long as the plan sponsor or its representatives did not cause such failure by the issuer:

“(A) Section 112 (relating to choice of providers).

“(B) Section 113 (relating to access to emergency care).

“(C) Section 114 (relating to access to specialty care).

“(D) Section 115 (relating to access to obstetrical and gynecological care).

“(E) Section 116 (relating to access to pediatric care).

“(F) Section 117(a)(1) (relating to continuity in case of termination of provider contract) and section 117(a)(2) (relating to continuity in case of termination of issuer contract), but only insofar as a replacement issuer assumes the obligation for continuity of care.

“(G) Section 118 (relating to access to needed prescription drugs).

“(H) Section 119 (relating to coverage for individuals participating in approved clinical trials.)

“(I) Section 134 (relating to payment of claims).

“(2) INFORMATION.—With respect to information required to be provided or made available under section 121, in the case of a group health plan that provides benefits in the form of health insurance coverage through a health insurance issuer, the Secretary shall determine the circumstances under which the plan is not required to provide or make available the information (and is not liable for the issuer’s failure to provide or

make available the information), if the issuer is obligated to provide and make available (or provides and makes available) such information.

“(3) GRIEVANCE AND INTERNAL APPEALS.—With respect to the internal appeals process and the grievance system required to be established under sections 102 and 104, in the case of a group health plan that provides benefits in the form of health insurance coverage through a health insurance issuer, the Secretary shall determine the circumstances under which the plan is not required to provide for such process and system (and is not liable for the issuer’s failure to provide for such process and system), if the issuer is obligated to provide for (and provides for) such process and system.

“(4) EXTERNAL APPEALS.—Pursuant to rules of the Secretary, insofar as a group health plan enters into a contract with a qualified external appeal entity for the conduct of external appeal activities in accordance with section 103, the plan shall be treated as meeting the requirement of such section and is not liable for the entity’s failure to meet any requirements under such section.

“(5) APPLICATION TO PROHIBITIONS.—Pursuant to rules of the Secretary, if a health insurance issuer offers health insurance coverage in connection with a group health plan and takes an action in violation of any of the following sections, the group health plan shall not be liable for such violation unless the plan caused such violation:

“(A) Section 131 (relating to prohibition of interference with certain medical communications).

“(B) Section 132 (relating to prohibition of discrimination against providers based on licensure).

“(C) Section 133 (relating to prohibition against improper incentive arrangements).

“(D) Section 135 (relating to protection for patient advocacy).

“(6) CONSTRUCTION.—Nothing in this subsection shall be construed to affect or modify the responsibilities of the fiduciaries of a group health plan under part 4 of subtitle B.

“(7) APPLICATION TO CERTAIN PROHIBITIONS AGAINST RETALIATION.—With respect to compliance with the requirements of section 135(b)(1) of the Bipartisan Consensus Managed Care Improvement Act of 1999, for purposes of this subtitle the term ‘group health plan’ is deemed to include a reference to an institutional health care provider.

“(c) ENFORCEMENT OF CERTAIN REQUIREMENTS.—

“(1) COMPLAINTS.—Any protected health care professional who believes that the professional has been retaliated or discriminated against in violation of section 135(b)(1) of the Bipartisan Consensus Managed Care Improvement Act of 1999 may file with the Secretary a complaint within 180 days of the date of the alleged retaliation or discrimination.

“(2) INVESTIGATION.—The Secretary shall investigate such complaints and shall determine if a violation of such section has occurred and, if so, shall issue an order to ensure that the protected health care professional does not suffer any loss of

position, pay, or benefits in relation to the plan, issuer, or provider involved, as a result of the violation found by the Secretary.

“(d) CONFORMING REGULATIONS.—The Secretary may issue regulations to coordinate the requirements on group health plans under this section with the requirements imposed under the other provisions of this title.”

(b) SATISFACTION OF ERISA CLAIMS PROCEDURE REQUIREMENT.—Section 503 of such Act (29 U.S.C. 1133) is amended by inserting “(a)” after “SEC. 503.” and by adding at the end the following new subsection:

“(b) In the case of a group health plan (as defined in section 733) compliance with the requirements of subtitle A of title I of the Bipartisan Consensus Managed Care Improvement Act of 1999 in the case of a claims denial shall be deemed compliance with subsection (a) with respect to such claims denial.”

(c) CONFORMING AMENDMENTS.—(1) Section 732(a) of such Act (29 U.S.C. 1185(a)) is amended by striking “section 711” and inserting “sections 711 and 714”.

(2) The table of contents in section 1 of such Act is amended by inserting after the item relating to section 713 the following new item:

“Sec. 714. Patient protection standards.”

(3) Section 502(b)(3) of such Act (29 U.S.C. 1132(b)(3)) is amended by inserting “(other than section 135(b))” after “part 7”.

#### **SEC. 302. ADDITIONAL JUDICIAL REMEDIES.**

(a) CAUSE OF ACTION RELATING TO DENIAL OF HEALTH BENEFITS.—Section 502(a) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1132(a)) is amended—

(1) by striking “or” at the end of paragraph (8);

(2) by striking “amounts.” at the end of paragraph (9) and inserting “amounts; or”; and

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

“(10) by a participant or beneficiary of a group health plan (or the estate of such a participant or beneficiary), for relief described in subsection (n), against a person who—

“(A) is a fiduciary of such plan, a health insurance issuer offering health insurance coverage in connection with such plan, or an agent of such plan or the plan sponsor,

“(B) under such plan, has authority to make the sole final decision described in subsection (n)(2) regarding claims for benefits, and

“(C) has exercised such authority in making such final decision denying such a claim by such participant or beneficiary in violation of the terms of the plan or this title and, in making such final decision, failed to exercise ordinary care in making an incorrect determination in the case of such participant or beneficiary that an item or service is excluded from coverage under the terms of the plan, if the denial is the proximate cause of personal injury to, or the wrongful death of, such participant or beneficiary.”

(b) JUDICIAL REMEDIES FOR DENIAL OF HEALTH BENEFITS.—Section 502 of such Act (29 U.S.C. 1132) is amended by adding at the end the following new subsections:

“(n) ADDITIONAL REMEDIES FOR DENIAL OF HEALTH BENEFITS.—

“(1) IN GENERAL.—In an action commenced under paragraph (10) of subsection (a) by a participant or beneficiary of a group health plan (or by the estate of such a participant or beneficiary) against a person described in subparagraphs (A), (B), and (C) of such paragraph, the court may award, in addition to other appropriate equitable relief under this section, monetary compensatory relief which may include both economic and noneconomic damages (but which shall exclude punitive damages). The amount of any such noneconomic damages awarded as monetary compensatory relief—

“(A) in a case in which 2 times the amount of the economic damages awarded as monetary compensatory relief is less than or equal to \$250,000, may not exceed the greater of—

“(i) 2 times the amount of such economic damages so awarded, or

“(ii) \$250,000; and

“(B) in a case in which 2 times the amount of the economic damages awarded as monetary compensatory relief is greater than \$250,000, may not exceed \$500,000.

“(2) APPLICATION TO DECISIONS INVOLVING MEDICAL NECESSITY AND MEDICAL JUDGMENT.—This subsection and subsection (a)(10) apply only with respect to final decisions described in section 103(a)(2) of the Bipartisan Consensus Managed Care Improvement Act of 1999.

“(3) DEFINITIONS.—For purposes of this subsection and subsection (a)(10)—

“(A) GROUP HEALTH PLAN; HEALTH INSURANCE ISSUER; HEALTH INSURANCE COVERAGE.—The terms ‘group health plan’, ‘health insurance issuer’, and ‘health insurance coverage’ shall have the meanings provided such terms under section 733, respectively.

“(B) FINAL DECISION.—The term ‘final decision’ means, with respect to a group health plan, the final decision of the plan under section 102 of the Bipartisan Consensus Managed Care Improvement Act of 1999.

“(C) PERSONAL INJURY.—The term ‘personal injury’ means loss of life, loss or significant impairment of limb or bodily function, significant disfigurement, or severe and chronic physical pain, and includes a physical injury arising out of a failure to treat a mental illness or disease.

“(D) CLAIM FOR BENEFITS.—The term ‘claim for benefits’ has the meaning provided in section 101(f)(1) of the Bipartisan Consensus Managed Care Improvement Act of 1999.

“(E) FAILURE TO EXERCISE ORDINARY CARE.—The term ‘failure to exercise ordinary care’ means a negligent failure to provide—

“(i) the consideration of appropriate medical evidence, or

“(ii) the regard for the health and safety of the participant or beneficiary, that a prudent individual acting in a like capacity and familiar with such matters would use in the conduct of an enterprise of a like character and with same or similar circumstances.

“(4) EXCEPTION FOR DENIALS IN ACCORDANCE WITH RECOMMENDATION OF EXTERNAL APPEAL ENTITY.—No person shall be liable under subsection (a)(10) for additional monetary compensatory relief described in paragraph (1) in any case in which the denial referred to in subsection (a)(10) is upheld by the recommendation of an external appeal entity issued with respect to such denial under section 103 of the Bipartisan Consensus Managed Care Improvement Act of 1999.

“(5) EXCEPTION FOR EMPLOYERS AND OTHER PLAN SPONSORS.—

“(A) IN GENERAL.—Subject to subparagraph (B), subsection (a)(10) does not authorize—

“(i) any cause of action against an employer or other plan sponsor maintaining a group health plan (or against an employee of such an employer or sponsor acting within the scope of employment), or

“(ii) a right of recovery or indemnity by a person against such an employer or sponsor (or such an employee) for relief assessed against the person pursuant to a cause of action under subsection (a)(10).

“(B) SPECIAL RULE.—Subparagraph (A) shall not preclude any cause of action under subsection (a)(10) commenced against an employer or other plan sponsor (or against an employee of such an employer or sponsor acting within the scope of employment), if—

“(i) such action is based on the direct participation of the employer or sponsor (or employee) in the sole final decision of the plan referred to in paragraph (2) with respect to a specific participant or beneficiary on a claim for benefits covered under the plan or health insurance coverage in the case at issue; and

“(ii) the decision on the claim resulted in personal injury to, or the wrongful death of, such participant or beneficiary.

“(C) DIRECT PARTICIPATION.—For purposes of this subsection, in determining whether an employer or other plan sponsor (or employee of an employer or other plan sponsor) is engaged in direct participation in the sole final decision of the plan on a claim under section 102 of the Bipartisan Consensus Managed Care Improvement Act of 1999, the employer or plan sponsor (or employee) shall not be construed to be engaged in such direct participation solely because of any form of decisionmaking or conduct, whether or not fiduciary in nature, that does not involve the final decision with respect to a specific claim for benefits by a specific participant or beneficiary, including (but not limited to) any participation in a decision relating to:

“(i) the selection or retention of the group health plan or health insurance coverage involved or the third party administrator or other agent, including any related cost-benefit analysis undertaken in connection with the selection of, or continued maintenance of, the plan or coverage involved;

“(ii) the creation, continuation, modification, or termination of the plan or of any coverage, benefit, or item or service covered by the plan affecting a cross-section of the plan participants and beneficiaries;

“(iii) the design of any coverage, benefit, or item or service covered by the plan, including the amount of copayments and limits connected with such coverage, and the specification of protocols, procedures, or policies for determining whether any such coverage, benefit, or item or service is medically necessary and appropriate or is experimental or investigational;

“(iv) any action by an agent of the employer or plan sponsor (other than an employee of the employer or plan sponsor) in making such a final decision on behalf of such employer or plan sponsor;

“(v) any decision by an employer or plan sponsor (or employee) or agent acting on behalf of an employer or plan sponsor either to authorize coverage for, or to intercede or not to intercede as an advocate for or on behalf of, any specific participant or beneficiary (or group of participants or beneficiaries) under the plan; or

“(vi) any other form of decisionmaking or other conduct performed by the employer or plan sponsor (or employee) in connection with the plan or coverage involved, unless the employer makes the sole final decision of the plan consisting of a failure described in paragraph (1)(A) as to specific participants or beneficiaries who suffer personal injury or wrongful death as a proximate cause of such decision.

“(6) REQUIRED DEMONSTRATION OF DIRECT PARTICIPATION.—An action under subsection (a)(10) against an employer or plan sponsor (or employee thereof) for remedies described in paragraph (1) shall be immediately dismissed—

“(A) in the absence of an evidentiary demonstration in the complaint of direct participation by the employer or plan sponsor (or employee) in the sole final decision of the plan with respect to a specific participant or beneficiary who suffers personal injury or wrongful death,

“(B) upon a demonstration to the court that such employer or plan sponsor (or employee) did not directly participate in the final decision of the plan, or

“(C) in the absence of an evidentiary demonstration that a personal injury to, or wrongful death of, the participant or beneficiary resulted.

“(7) TREATMENT OF THIRD-PARTY PROVIDERS OF NONDISCRETIONARY ADMINISTRATIVE SERVICES.—Subsection (a)(10) does not authorize any action against any person providing

nondiscretionary administrative services to employers or other plan sponsors.

“(8) REQUIREMENT OF EXHAUSTION OF ADMINISTRATIVE REMEDIES.—

“(A) IN GENERAL.—Subsection (a)(10) applies in the case of any cause of action only if all remedies under section 503 (including remedies under sections 102 and 103 of the Bipartisan Consensus Managed Care Improvement Act of 1999 made applicable under section 714) with respect to such cause of action have been exhausted.

“(B) EXTERNAL REVIEW REQUIRED.—For purposes of subparagraph (A), administrative remedies under section 503 shall not be deemed exhausted until available remedies under section 103 of the Bipartisan Consensus Managed Care Improvement Act of 1999 have been elected and are exhausted.

“(C) CONSIDERATION OF ADMINISTRATIVE DETERMINATIONS.—Any determinations under section 102 or 103 of the Bipartisan Consensus Managed Care Improvement Act of 1999 made while an action under subsection (a)(10) is pending shall be given due consideration by the court in such action.

“(9) SUBSTANTIAL WEIGHT GIVEN TO EXTERNAL REVIEW DECISIONS.—In the case of any action under subsection (a)(10) for remedies described in paragraph (1), the external review decision under section 103 shall be given substantial weight when considered along with other available evidence.

“(10) LIMITATION OF ACTION.—Subsection (a)(10) shall not apply in connection with any action commenced after the later of—

“(A) 1 year after (i) the date of the last action which constituted a part of the failure, or (ii) in the case of an omission, the latest date on which the fiduciary could have cured the failure, or

“(B) 1 year after the earliest date on which the plaintiff first knew, or reasonably should have known, of the personal injury or wrongful death resulting from the failure.

“(11) COORDINATION WITH FIDUCIARY REQUIREMENTS.—A fiduciary shall not be treated as failing to meet any requirement of part 4 solely by reason of any action taken by the fiduciary which consists of full compliance with the reversal under section 103 of the Bipartisan Consensus Managed Care Improvement Act of 1999 of a denial of a claim for benefits.

“(12) CONSTRUCTION.—Nothing in this subsection or subsection (a)(10) shall be construed as authorizing an action—

“(A) for the failure to provide an item or service which is not covered under the group health plan involved, or

“(B) for any action taken by a fiduciary which consists of compliance with the reversal or modification under section 103 of the Bipartisan Consensus Managed Care Improvement Act of 1999 of a final decision under section 102 of such Act.

“(13) PROTECTION OF MEDICAL MALPRACTICE UNDER STATE LAW.—This subsection and subsection (a)(10) shall not be con-

strued to preclude any action under State law not otherwise preempted under this section or section 503 or 514 with respect to the exercise of a specified professional standard of care in the provision of medical services.

“(14) REFERENCES TO THE BIPARTISAN CONSENSUS MANAGED CARE IMPROVEMENT ACT OF 1999.—Any reference in this subsection to any provision of the Bipartisan Consensus Managed Care Improvement Act of 1999 shall be deemed a reference to such provision as in effect on the date of the enactment of such Act.

“(o) EXPEDITED COURT REVIEW.—In any case in which exhaustion of administrative remedies in accordance with section 102 or 103 of the Bipartisan Consensus Managed Care Improvement Act of 1999 otherwise necessary for an action for injunctive relief under paragraph (1)(B) or (3) of subsection (a) has not been obtained and it is demonstrated to the court by clear and convincing evidence that such exhaustion is not reasonably attainable under the facts and circumstances without any further undue risk of irreparable harm to the health of the participant or beneficiary, a civil action may be brought by a participant or beneficiary to obtain such relief. Any determinations which already have been made under section 102 or 103 in such case, or which are made in such case while an action under this paragraph is pending, shall be given due consideration by the court in any action under this subsection in such case.”

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to acts and omissions (from which a cause of action arises) occurring on or after the date of the enactment of this Act.

**SEC. 304. AVAILABILITY OF BINDING ARBITRATION.**

(a) IN GENERAL.—Section 502 of the Employee Retirement Income Security Act of 1974 (as amended by the preceding provisions of this Act) is amended further by adding at the end the following new subsection:

“(p) BINDING ARBITRATION PERMITTED AS ALTERNATIVE MEANS OF DISPUTE RESOLUTION.—

“(1) IN GENERAL.—This subsection shall apply with respect to any adverse coverage decision rendered under a group health plan under section 102 or 103, if—

“(A) all administrative remedies under section 503 required for an action in court under this section have been exhausted,

“(B) under the terms of the plan, the aggrieved participant or beneficiary may elect to resolve the dispute by means of a procedure of binding arbitration which is available with respect to all similarly situated participants and beneficiaries (or which is available under the plan pursuant to a bona fide collective bargaining agreement pursuant to which the plan is established and maintained), and which meets the requirements of paragraph (3), and

“(C) the participant or beneficiary has elected such procedure in accordance with the terms of the plan.

“(2) EFFECT OF ELECTION.—In the case of an election by a participant or beneficiary pursuant to paragraph (1)—

“(A) decisions rendered under the procedure of binding arbitration shall be binding on all parties to the procedure and shall be enforceable under the preceding subsections of this section as if the terms of the decision were the terms of the plan, except that the court in an action brought under this section may vacate any award made pursuant to the arbitration for any cause described in paragraph (1), (2), (3), (4), or (5) of section 10(a) of title 9, United States Code, and

“(B) subject to subparagraph (A), such participant or beneficiary shall be treated as having effectively waived any right to further review of the decision by a court under the preceding subsections of this section.

“(3) ADDITIONAL REQUIREMENTS.—The requirements of this paragraph consist of the following:

“(A) ARBITRATION PANEL.—The arbitration shall be conducted by an arbitration panel meeting the requirements of paragraph (4).

“(B) FAIR PROCESS; DE NOVO DETERMINATION.—The procedure shall provide for a fair, de novo determination.

“(C) OPPORTUNITY TO SUBMIT EVIDENCE, HAVE REPRESENTATION, AND MAKE ORAL PRESENTATION.—Each party to the arbitration procedure—

“(i) may submit and review evidence related to the issues in dispute;

“(ii) may use the assistance or representation of one or more individuals (any of whom may be an attorney); and

“(iii) may make an oral presentation.

“(D) PROVISION OF INFORMATION.—The plan shall provide timely access to all its records relating to the matters under arbitration and to all provisions of the plan relating to such matters.

“(E) TIMELY DECISIONS.—A determination by the arbitration panel on the decision shall—

“(i) be made in writing;

“(ii) be binding on the parties; and

“(iii) be made in accordance with the medical exigencies of the case involved.

“(4) ARBITRATION PANEL.—

“(A) IN GENERAL.—Arbitrations commenced pursuant to this subsection shall be conducted by a panel of arbitrators selected by the parties made up of 3 individuals, including at least one physician and one attorney.

“(B) QUALIFICATIONS.—Any individual who is a member of an arbitration panel shall meet the following requirements:

“(i) There is no real or apparent conflict of interest that would impede the individual conducting arbitration independent of the plan and meets the independence requirements of subparagraph (C).

“(ii) The individual has sufficient medical or legal expertise to conduct the arbitration for the plan on a timely basis.

“(iii) The individual has appropriate credentials and has attained recognized expertise in the applicable medical or legal field.

“(iv) The individual was not involved in the initial adverse coverage decision or any other review thereof.

“(C) INDEPENDENCE REQUIREMENTS.—An individual described in subparagraph (B) meets the independence requirements of this subparagraph if—

“(i) the individual is not affiliated with any related party,

“(ii) any compensation received by such individual in connection with the binding arbitration procedure is reasonable and not contingent on any decision rendered by the individual,

“(iii) under the terms of the plan, the plan has no recourse against the individual or entity in connection with the binding arbitration procedure, and

“(iv) the individual does not otherwise have a conflict of interest with a related party as determined under such regulations as the Secretary may prescribe.

“(D) RELATED PARTY.—For purposes of subparagraph (C), the term ‘related party’ means—

“(i) the plan or any health insurance issuer offering health insurance coverage in connection with the plan (or any officer, director, or management employee of such plan or issuer),

“(ii) the physician or other medical care provider that provided the medical care involved in the coverage decision,

“(iii) the institution at which the medical care involved in the coverage decision is provided,

“(iv) the manufacturer of any drug or other item that was included in the medical care involved in the coverage decision, or

“(v) any other party determined under such regulations as the Secretary may prescribe to have a substantial interest in the coverage decision .

“(E) AFFILIATED.—For purposes of subparagraph (C), the term ‘affiliated’ means, in connection with any entity, having a familial, financial, or professional relationship with, or interest in, such entity.

“(5) ALLOWABLE REMEDIES.—The remedies which may be implemented by the arbitration panel shall consist of those remedies which would be available in an action timely commenced by a participant or beneficiary under section 502, taking into account the administrative remedies exhausted by the participant or beneficiary under section 503.”.

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to adverse coverage decisions initially rendered by group health plans on or after the date of the enactment of this Act.

## **TITLE IV—APPLICATION TO GROUP HEALTH PLANS UNDER THE INTERNAL REVENUE CODE OF 1986**

### **SEC. 401. AMENDMENTS TO THE INTERNAL REVENUE CODE OF 1986.**

Subchapter B of chapter 100 of the Internal Revenue Code of 1986 is amended—

(1) in the table of sections, by inserting after the item relating to section 9812 the following new item:

“Sec. 9813. Standard relating to patient freedom of choice.”;

and

(2) by inserting after section 9812 the following:

#### **“SEC. 9813. STANDARD RELATING TO PATIENTS’ BILL OF RIGHTS.**

“A group health plan shall comply with the requirements of title I of the Bipartisan Consensus Managed Care Improvement Act of 1999 (as in effect as of the date of the enactment of such Act), and such requirements shall be deemed to be incorporated into this section.”.

## **TITLE V—EFFECTIVE DATES; COORDINATION IN IMPLEMENTATION**

### **SEC. 501. EFFECTIVE DATES.**

(a) **GROUP HEALTH COVERAGE.**—

(1) **IN GENERAL.**—Subject to paragraph (2), the amendments made by sections 201(a), 301, and 401 (and title I insofar as it relates to such sections) shall apply with respect to group health plans, and health insurance coverage offered in connection with group health plans, for plan years beginning on or after January 1, 2000 (in this section referred to as the “general effective date”) and also shall apply to portions of plan years occurring on and after such date.

(2) **TREATMENT OF COLLECTIVE BARGAINING AGREEMENTS.**—In the case of a group health plan maintained pursuant to 1 or more collective bargaining agreements between employee representatives and 1 or more employers ratified before the date of enactment of this Act, the amendments made by sections 201(a), 301, and 401 (and title I insofar as it relates to such sections) shall not apply to plan years beginning before the later of—

(A) the date on which the last collective bargaining agreements relating to the plan terminates (determined without regard to any extension thereof agreed to after the date of enactment of this Act), or

(B) the general effective date.

For purposes of subparagraph (A), any plan amendment made pursuant to a collective bargaining agreement relating to the plan which amends the plan solely to conform to any requirement added by this Act shall not be treated as a termination of such collective bargaining agreement.

(b) **INDIVIDUAL HEALTH INSURANCE COVERAGE.**—The amendments made by section 202 shall apply with respect to individual health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market on or after the general effective date.

**SEC. 502. COORDINATION IN IMPLEMENTATION.**

The Secretary of Labor, the Secretary of Health and Human Services, and the Secretary of the Treasury shall ensure, through the execution of an interagency memorandum of understanding among such Secretaries, that—

- (1) regulations, rulings, and interpretations issued by such Secretaries relating to the same matter over which such Secretaries have responsibility under the provisions of this Act (and the amendments made thereby) are administered so as to have the same effect at all times; and
- (2) coordination of policies relating to enforcing the same requirements through such Secretaries in order to have a coordinated enforcement strategy that avoids duplication of enforcement efforts and assigns priorities in enforcement.

## **TITLE VI—HEALTH CARE PAPERWORK SIMPLIFICATION**

**SEC. 601. HEALTH CARE PAPERWORK SIMPLIFICATION.**

(a) **ESTABLISHMENT OF PANEL.**—

(1) **ESTABLISHMENT.**—There is established a panel to be known as the Health Care Panel to Devise a Uniform Explanation of Benefits (in this section referred to as the “Panel”).

(2) **DUTIES OF PANEL.**—

(A) **IN GENERAL.**—The Panel shall devise a single form for use by third-party health care payers for the remittance of claims to providers.

(B) **DEFINITION.**—For purposes of this section, the term “third-party health care payer” means any entity that contractually pays health care bills for an individual.

(3) **MEMBERSHIP.**—

(A) **SIZE AND COMPOSITION.**—The Secretary of Health and Human Services shall determine the number of members and the composition of the Panel. Such Panel shall include equal numbers of representatives of private insurance organizations, consumer groups, State insurance commissioners, State medical societies, State hospital associations, and State medical specialty societies.

(B) **TERMS OF APPOINTMENT.**—The members of the Panel shall serve for the life of the Panel.

(C) **VACANCIES.**—A vacancy in the Panel shall not affect the power of the remaining members to execute the duties of the Panel, but any such vacancy shall be filled in the same manner in which the original appointment was made.

(4) **PROCEDURES.**—

(A) **MEETINGS.**—The Panel shall meet at the call of a majority of its members.

(B) **FIRST MEETING.**—The Panel shall convene not later than 60 days after the date of the enactment of the Bipartisan Consensus Managed Care Improvement Act of 1999.

(C) **QUORUM.**—A quorum shall consist of a majority of the members of the Panel.

(D) **HEARINGS.**—For the purpose of carrying out its duties, the Panel may hold such hearings and undertake such other activities as the Panel determines to be necessary to carry out its duties.

(5) **ADMINISTRATION.**—

(A) **COMPENSATION.**—Except as provided in subparagraph (B), members of the Panel shall receive no additional pay, allowances, or benefits by reason of their service on the Panel.

(B) **TRAVEL EXPENSES AND PER DIEM.**—Each member of the Panel who is not an officer or employee of the Federal Government shall receive travel expenses and per diem in lieu of subsistence in accordance with sections 5702 and 5703 of title 5, United States Code.

(C) **CONTRACT AUTHORITY.**—The Panel may contract with and compensate government and private agencies or persons for items and services, without regard to section 3709 of the Revised Statutes (41 U.S.C. 5).

(D) **USE OF MAILS.**—The Panel may use the United States mails in the same manner and under the same conditions as Federal agencies and shall, for purposes of the frank, be considered a commission of Congress as described in section 3215 of title 39, United States Code.

(E) **ADMINISTRATIVE SUPPORT SERVICES.**—Upon the request of the Panel, the Secretary of Health and Human Services shall provide to the Panel on a reimbursable basis such administrative support services as the Panel may request.

(6) **SUBMISSION OF FORM.**—Not later than 2 years after the first meeting, the Panel shall submit a form to the Secretary of Health and Human Services for use by third-party health care payers.

(7) **TERMINATION.**—The Panel shall terminate on the day after submitting the form under paragraph (6).

(b) **REQUIREMENT FOR USE OF FORM BY THIRD-PARTY CARE PAYERS.**—A third-party health care payer shall be required to use the form devised under subsection (a) for plan years beginning on or after 5 years following the date of the enactment of this Act.