108TH CONGRESS
2D SESSION

S. 2083

To amend the Public Health Service Act and the Employee Retirement Income Security Act of 1974 to protect consumers in managed care plans and other health coverage.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 12, 2004

Mrs. BOXER introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To amend the Public Health Service Act and the Employee Retirement Income Security Act of 1974 to protect consumers in managed care plans and other health coverage.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Bipartisan Patient Protection Act of 2004''.

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

TITLE I—IMPROVING MANAGED CARE

Subtitle A—Utilization Review; Claims; and Internal and External 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 and section 102.

(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 a participant, beneficiary, or 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 a periodic 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 and appropriate.

SEC. 102. PROCEDURES FOR INITIAL CLAIMS FOR BENEFITS AND PRIOR AUTHORIZATION DETERMINATIONS.

(a) PROCEDURES OF INITIAL CLAIMS FOR BENEFITS.—

(1) IN GENERAL.—A group health plan, or health insurance issuer offering health insurance coverage, shall—

(A) make a determination on an initial claim for benefits by a participant, beneficiary, or enrollee (or authorized representative) regarding payment or coverage for items or services under the terms and conditions of the plan or coverage involved, including any cost-sharing amount that the participant, beneficiary, or enrollee is required to pay with respect to such claim for benefits; and

(B) notify a participant, beneficiary, or enrollee (or authorized representative) and the treating health care professional involved regarding a determination on an initial claim for benefits made under the terms and conditions of the plan or coverage, including any cost-sharing amounts that the participant, beneficiary, or enrollee may be required to make with respect to such claim for benefits, and of the

right of the participant, beneficiary, or enrollee to an internal appeal under section 103.

(2) ACCESS TO INFORMATION.—

(A) TIMELY PROVISION OF NECESSARY INFORMATION.—With respect to an initial claim for benefits, the participant, beneficiary, or enrollee (or authorized representative) and the treating health care professional (if any) shall provide the plan or issuer with access to information requested by the plan or issuer that is necessary to make a determination relating to the claim. Such access shall be provided not later than 5 days after the date on which the request for information is received, or, in a case described in subparagraph (B) or (C) of subsection (b)(1), by such earlier time as may be necessary to comply with the applicable timeline under such subparagraph.

(B) LIMITED EFFECT OF FAILURE ON PLAN OR ISSUER'S OBLIGATIONS.—Failure of the participant, beneficiary, or enrollee to comply with the requirements of subparagraph (A) shall not remove the obligation of the plan or issuer to make a decision in accordance with the medical exigencies of the case and as soon

as possible, based on the available information, and failure to comply with the time limit established by this paragraph shall not remove the obligation of the plan or issuer to comply with the requirements of this section.

(3) ORAL REQUESTS.—In the case of a claim for benefits involving an expedited or concurrent determination, a participant, beneficiary, or enrollee (or authorized representative) may make an initial claim for benefits orally, but a group health plan, or health insurance issuer offering health insurance coverage, may require that the participant, beneficiary, or enrollee (or authorized representative) provide written confirmation of such request in a timely manner on a form provided by the plan or issuer. In the case of such an oral request for benefits, the making of the request (and the timing of such request) shall be treated as the making at that time of a claims for such benefits without regard to whether and when a written confirmation of such request is made.

(b) TIMELINE FOR MAKING DETERMINATIONS.—

(1) PRIOR AUTHORIZATION DETERMINATION.—

(A) IN GENERAL.—A group health plan, or health insurance issuer offering health insur-

ance coverage, shall make a prior authorization determination on a claim for benefits (whether oral or written) in accordance with the medical exigencies of the case and as soon as possible, but in no case later than 14 days from the date on which the plan or issuer receives information that is reasonably necessary to enable the plan or issuer to make a determination on the request for prior authorization and in no case later than 28 days after the date of the claim for benefits is received.

(B) EXPEDITED DETERMINATION.—Notwithstanding subparagraph (A), a group health plan, or health insurance issuer offering health insurance coverage, shall expedite a prior authorization determination on a claim for benefits described in such subparagraph when a request for such an expedited determination is made by a participant, beneficiary, or enrollee (or authorized representative) at any time during the process for making a determination and a health care professional certifies, with the request, that a determination under the procedures described in subparagraph (A) would seriously jeopardize the life or health of the partici-

pant, beneficiary, or enrollee or the ability of the participant, beneficiary, or enrollee to maintain or regain maximum function. Such determination shall be made in accordance with the medical exigencies of the case and as soon as possible, but in no case later than 72 hours after the time the request is received by the plan or issuer under this subparagraph.

(C) ONGOING CARE.—

(i) CONCURRENT REVIEW.—

(I) IN GENERAL.—Subject to clause (ii), in the case of a concurrent review of ongoing care (including hospitalization), which results in a termination or reduction of such care, the plan or issuer 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 in accordance with the medical exigencies of the case and as soon as possible, with sufficient time prior to the termination or reduction to allow for an appeal under section

103(b)(3) 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.

(ii) RULE OF CONSTRUCTION.—Clause (i) shall not be construed as requiring plans or issuers to provide coverage of care that would exceed the coverage limitations for such care.

(2) RETROSPECTIVE DETERMINATION.—A group health plan, or health insurance issuer offering health insurance coverage, shall make a retrospective determination on a claim for benefits in accordance with the medical exigencies of the case and as soon as possible, but not later than 30 days after the date on which the plan or issuer receives information that is reasonably necessary to enable the plan or issuer to make a determination on the claim,

or, if earlier, 60 days after the date of receipt of the claim for benefits.

(c) NOTICE OF A DENIAL OF A CLAIM FOR BENEFITS.—Written notice of a denial made under an initial claim for benefits shall be issued to the participant, beneficiary, or enrollee (or authorized representative) and the treating health care professional in accordance with the medical exigencies of the case and as soon as possible, but in no case later than 2 days after the date of the determination (or, in the case described in subparagraph (B) or (C) of subsection (b)(1), within the 72-hour or applicable period referred to in such subparagraph).

(d) REQUIREMENTS OF NOTICE OF DETERMINATIONS.—The written notice of a denial of a claim for benefits determination under subsection (c) shall be provided in printed form and written in a manner calculated to be understood by the participant, beneficiary, or enrollee and shall include—

(1) the specific reasons for the determination (including a summary of the clinical or scientific evidence used in making the determination);

(2) the procedures for obtaining additional information concerning the determination; and

(3) notification of the right to appeal the determination and instructions on how to initiate an appeal in accordance with section 103.

(e) DEFINITIONS.—For purposes of this part:

(1) AUTHORIZED REPRESENTATIVE.—The term ''authorized representative'' means, with respect to an individual who is a participant, beneficiary, or enrollee, any health care professional or other person acting on behalf of the individual with the individual's consent or without such consent if the individual is medically unable to provide such consent.

(2) 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.

(3) DENIAL OF CLAIM FOR BENEFITS.—The term ''denial'' means, with respect to a claim for benefits, a denial (in whole or in part) of, or a failure to act on a timely basis upon, the claim for benefits and includes a failure to provide benefits (including items and services) required to be provided under this title.

(4) TREATING HEALTH CARE PROFESSIONAL.—The term ''treating health care professional'' means, with respect to services to be provided to a participant, beneficiary, or enrollee, a health care professional who is primarily responsible for delivering those services to the participant, beneficiary, or enrollee.

SEC. 103. INTERNAL APPEALS OF CLAIMS DENIALS.

(a) RIGHT TO INTERNAL APPEAL.—

(1) IN GENERAL.—A participant, beneficiary, or enrollee (or authorized representative) may appeal any denial of a claim for benefits under section 102 under the procedures described in this section.

(2) TIME FOR APPEAL.—

(A) IN GENERAL.—A group health plan, or health insurance issuer offering health insurance coverage, shall ensure that a participant, beneficiary, or enrollee (or authorized representative) has a period of not less than 180 days beginning on the date of a denial of a claim for benefits under section 102 in which to appeal such denial under this section.

(B) DATE OF DENIAL.—For purposes of subparagraph (A), the date of the denial shall be deemed to be the date as of which the partic-

ipant, beneficiary, or enrollee knew of the denial of the claim for benefits.

(3) FAILURE TO ACT.—The failure of a plan or issuer to issue a determination on a claim for benefits under section 102 within the applicable timeline established for such a determination under such section is a denial of a claim for benefits for purposes this subtitle as of the date of the applicable deadline.

(4) PLAN WAIVER OF INTERNAL REVIEW.—A group health plan, or health insurance issuer offering health insurance coverage, may waive the internal review process under this section. In such case the plan or issuer shall provide notice to the participant, beneficiary, or enrollee (or authorized representative) involved, the participant, beneficiary, or enrollee (or authorized representative) involved shall be relieved of any obligation to complete the internal review involved, and may, at the option of such participant, beneficiary, enrollee, or representative proceed directly to seek further appeal through external review under section 104 or otherwise.

(b) TIMELINES FOR MAKING DETERMINATIONS.—

(1) ORAL REQUESTS.—In the case of an appeal of a denial of a claim for benefits under this section that involves an expedited or concurrent determina-

tion, a participant, beneficiary, or enrollee (or authorized representative) may request such appeal orally. A group health plan, or health insurance issuer offering health insurance coverage, may require that the participant, beneficiary, or enrollee (or authorized representative) provide written confirmation of such request in a timely manner on a form provided by the plan or issuer. In the case of such an oral request for an appeal of a denial, the making of the request (and the timing of such request) shall be treated as the making at that time of a request for an appeal without regard to whether and when a written confirmation of such request is made.

(2) ACCESS TO INFORMATION.—

(A) TIMELY PROVISION OF NECESSARY INFORMATION.—With respect to an appeal of a denial of a claim for benefits, the participant, beneficiary, or enrollee (or authorized representative) and the treating health care professional (if any) shall provide the plan or issuer with access to information requested by the plan or issuer that is necessary to make a determination relating to the appeal. Such access shall be provided not later than 5 days after the date on

which the request for information is received, or, in a case described in subparagraph (B) or (C) of paragraph (3), by such earlier time as may be necessary to comply with the applicable timeline under such subparagraph.

(B) LIMITED EFFECT OF FAILURE ON PLAN OR ISSUER'S OBLIGATIONS.—Failure of the participant, beneficiary, or enrollee to comply with the requirements of subparagraph (A) shall not remove the obligation of the plan or issuer to make a decision in accordance with the medical exigencies of the case and as soon as possible, based on the available information, and failure to comply with the time limit established by this paragraph shall not remove the obligation of the plan or issuer to comply with the requirements of this section.

(3) PRIOR AUTHORIZATION DETERMINATIONS.—

(A) IN GENERAL.—A group health plan, or health insurance issuer offering health insurance coverage, shall make a determination on an appeal of a denial of a claim for benefits under this subsection in accordance with the medical exigencies of the case and as soon as

possible, but in no case later than 14 days from the date on which the plan or issuer receives information that is reasonably necessary to enable the plan or issuer to make a determination on the appeal and in no case later than 28 days after the date the request for the appeal is received.

(B) EXPEDITED DETERMINATION.—Notwithstanding subparagraph (A), a group health plan, or health insurance issuer offering health insurance coverage, shall expedite a prior authorization determination on an appeal of a denial of a claim for benefits described in subparagraph (A), when a request for such an expedited determination is made by a participant, beneficiary, or enrollee (or authorized representative) at any time during the process for making a determination and a health care professional certifies, with the request, that a determination under the procedures described in subparagraph (A) would seriously jeopardize the life or health of the participant, beneficiary, or enrollee or the ability of the participant, beneficiary, or enrollee to maintain or regain maximum function. Such determination shall be

made in accordance with the medical exigencies of the case and as soon as possible, but in no case later than 72 hours after the time the request for such appeal is received by the plan or issuer under this subparagraph.

(C) ONGOING CARE DETERMINATIONS.—

(i) IN GENERAL.—Subject to clause (ii), in the case of a concurrent review determination described in section 102(b)(1)(C)(i)(I), which results in a termination or reduction of such care, the plan or issuer must provide notice of the determination on the appeal under this section by telephone and in printed form to the individual or the individual's designee and the individual's health care provider in accordance with the medical exigencies of the case and as soon as possible, with sufficient time prior to the termination or reduction to allow for an external appeal under section 104 to be completed before the termination or reduction takes effect.

(ii) RULE OF CONSTRUCTION.—Clause (i) shall not be construed as requiring plans or issuers to provide coverage of care

that would exceed the coverage limitations for such care.

(4) RETROSPECTIVE DETERMINATION.—A group health plan, or health insurance issuer offering health insurance coverage, shall make a retrospective determination on an appeal of a claim for benefits in no case later than 30 days after the date on which the plan or issuer receives necessary information that is reasonably necessary to enable the plan or issuer to make a determination on the appeal and in no case later than 60 days after the date the request for the appeal is received.

(c) CONDUCT OF REVIEW.—

(1) IN GENERAL.—A review of a denial of a claim for benefits under this section shall be conducted by an individual with appropriate expertise who was not involved in the initial determination.

(2) PEER REVIEW OF MEDICAL DECISIONS BY HEALTH CARE PROFESSIONALS.—A review of an appeal of a denial of a claim for benefits that is based on a lack of medical necessity and appropriateness, or based on an experimental or investigational treatment, or requires an evaluation of medical facts—

(A) shall be made by a physician (allopathic or osteopathic); or

(B) in a claim for benefits provided by a non-physician health professional, shall be made by reviewer (or reviewers) including at least one practicing non-physician health professional of the same or similar specialty;

with appropriate expertise (including, in the case of a child, appropriate pediatric expertise) and acting within the appropriate scope of practice within the State in which the service is provided or rendered, who was not involved in the initial determination.

(d) NOTICE OF DETERMINATION.—

(1) IN GENERAL.—Written notice of a determination made under an internal appeal of a denial of a claim for benefits shall be issued to the participant, beneficiary, or enrollee (or authorized representative) and the treating health care professional in accordance with the medical exigencies of the case and as soon as possible, but in no case later than 2 days after the date of completion of the review (or, in the case described in subparagraph (B) or (C) of subsection (b)(3), within the 72-hour or applicable period referred to in such subparagraph).

(2) FINAL DETERMINATION.—The decision by a plan or issuer under this section shall be treated as the final determination of the plan or issuer on a de-

nial of a claim for benefits. The failure of a plan or issuer to issue a determination on an appeal of a denial of a claim for benefits under this section within the applicable timeline established for such a determination shall be treated as a final determination on an appeal of a denial of a claim for benefits for purposes of proceeding to external review under section 104.

(3) REQUIREMENTS OF NOTICE.—With respect to a determination made under this section, the notice described in paragraph (1) 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 specific reasons for the determination (including a summary of the clinical or scientific evidence used in making the determination);

(B) the procedures for obtaining additional information concerning the determination; and

(C) notification of the right to an independent external review under section 104 and instructions on how to initiate such a review.

SEC. 104. INDEPENDENT EXTERNAL APPEALS PROCEDURES.

(a) RIGHT TO EXTERNAL APPEAL.—A group health plan, and a health insurance issuer offering health insurance coverage, shall provide in accordance with this section participants, beneficiaries, and enrollees (or authorized representatives) with access to an independent external review for any denial of a claim for benefits.

(b) INITIATION OF THE INDEPENDENT EXTERNAL REVIEW PROCESS.—

(1) TIME TO FILE.—A request for an independent external review under this section shall be filed with the plan or issuer not later than 180 days after the date on which the participant, beneficiary, or enrollee receives notice of the denial under section 103(d) or notice of waiver of internal review under section 103(a)(4) or the date on which the plan or issuer has failed to make a timely decision under section 103(d)(2) and notifies the participant or beneficiary that it has failed to make a timely decision and that the beneficiary must file an appeal with an external review entity within 180 days if the participant or beneficiary desires to file such an appeal.

(2) FILING OF REQUEST.—

(A) IN GENERAL.—Subject to the succeeding provisions of this subsection, a group health plan, and a health insurance issuer offering health insurance coverage, may—

(i) except as provided in subparagraph (B)(i), require that a request for review be in writing;

(ii) limit the filing of such a request to the participant, beneficiary, or enrollee involved (or an authorized representative);

(iii) except if waived by the plan or issuer under section 103(a)(4), condition access to an independent external review under this section upon a final determination of a denial of a claim for benefits under the internal review procedure under section 103;

(iv) except as provided in subparagraph (B)(ii), require payment of a filing fee to the plan or issuer of a sum that does not exceed $25; and

(v) require that a request for review include the consent of the participant, beneficiary, or enrollee (or authorized representative) for the release of necessary

medical information or records of the participant, beneficiary, or enrollee to the qualified external review entity only for purposes of conducting external review activities.

(B) REQUIREMENTS AND EXCEPTION RELATING TO GENERAL RULE.—

(i) ORAL REQUESTS PERMITTED IN EXPEDITED OR CONCURRENT CASES.—In the case of an expedited or concurrent external review as provided for under subsection (e), the request may be made orally. A group health plan, or health insurance issuer offering health insurance coverage, may require that the participant, beneficiary, or enrollee (or authorized representative) provide written confirmation of such request in a timely manner on a form provided by the plan or issuer. Such written confirmation shall be treated as a consent for purposes of subparagraph (A)(v). In the case of such an oral request for such a review, the making of the request (and the timing of such request) shall be treated as the making at that time

of a request for such an external review without regard to whether and when a written confirmation of such request is made.

(ii) EXCEPTION TO FILING FEE REQUIREMENT.—

(I) INDIGENCY.—Payment of a filing fee shall not be required under subparagraph (A)(iv) where there is a certification (in a form and manner specified in guidelines established by the appropriate Secretary) that the participant, beneficiary, or enrollee is indigent (as defined in such guidelines).

(II) FEE NOT REQUIRED.—Payment of a filing fee shall not be required under subparagraph (A)(iv) if the plan or issuer waives the internal appeals process under section 103(a)(4).

(III) REFUNDING OF FEE.—The filing fee paid under subparagraph (A)(iv) shall be refunded if the determination under the independent exter-

nal review is to reverse or modify the denial which is the subject of the review.

(IV) COLLECTION OF FILING FEE.—The failure to pay such a filing fee shall not prevent the consideration of a request for review but, subject to the preceding provisions of this clause, shall constitute a legal liability to pay.

(c) REFERRAL TO QUALIFIED EXTERNAL REVIEW ENTITY UPON REQUEST.—

(1) IN GENERAL.—Upon the filing of a request for independent external review with the group health plan, or health insurance issuer offering health insurance coverage, the plan or issuer shall immediately refer such request, and forward the plan or issuer's initial decision (including the information described in section 103(d)(3)(A)), to a qualified external review entity selected in accordance with this section.

(2) ACCESS TO PLAN OR ISSUER AND HEALTH PROFESSIONAL INFORMATION.—With respect to an independent external review conducted under this section, the participant, beneficiary, or enrollee (or authorized representative), the plan or issuer, and

the treating health care professional (if any) shall provide the external review entity with information that is necessary to conduct a review under this section, as determined and requested by the entity. Such information shall be provided not later than 5 days after the date on which the request for information is received, or, in a case described in clause (ii) or (iii) of subsection (e)(1)(A), by such earlier time as may be necessary to comply with the applicable timeline under such clause.

(3) SCREENING OF REQUESTS BY QUALIFIED EXTERNAL REVIEW ENTITIES.—

(A) IN GENERAL.—With respect to a request referred to a qualified external review entity under paragraph (1) relating to a denial of a claim for benefits, the entity shall refer such request for the conduct of an independent medical review unless the entity determines that—

(i) any of the conditions described in clauses (ii) or (iii) of subsection (b)(2)(A) have not been met;

(ii) the denial of the claim for benefits does not involve a medically reviewable decision under subsection (d)(2);

(iii) the denial of the claim for benefits relates to a decision regarding whether an individual is a participant, beneficiary, or enrollee who is enrolled under the terms and conditions of the plan or coverage (including the applicability of any waiting period under the plan or coverage); or

(iv) the denial of the claim for benefits is a decision as to the application of cost-sharing requirements or the application of a specific exclusion or express limitation on the amount, duration, or scope of coverage of items or services under the terms and conditions of the plan or coverage unless the decision is a denial described in subsection (d)(2).

Upon making a determination that any of clauses (i) through (iv) applies with respect to the request, the entity shall determine that the denial of a claim for benefits involved is not eligible for independent medical review under subsection (d), and shall provide notice in accordance with subparagraph (C).

(B) PROCESS FOR MAKING DETERMINATIONS.—

(i) NO DEFERENCE TO PRIOR DETERMINATIONS.—In making determinations under subparagraph (A), there shall be no deference given to determinations made by the plan or issuer or the recommendation of a treating health care professional (if any).

(ii) USE OF APPROPRIATE PERSONNEL.—A qualified external review entity shall use appropriately qualified personnel to make determinations under this section.

(C) NOTICES AND GENERAL TIMELINES FOR DETERMINATION.—

(i) NOTICE IN CASE OF DENIAL OF REFERRAL.—If the entity under this paragraph does not make a referral to an independent medical reviewer, the entity shall provide notice to the plan or issuer, the participant, beneficiary, or enrollee (or authorized representative) filing the request, and the treating health care professional (if any) that the denial is not subject to independent medical review. Such notice—

(I) shall be written (and, in addition, may be provided orally) in a manner calculated to be understood by a participant or enrollee;

(II) shall include the reasons for the determination;

(III) include any relevant terms and conditions of the plan or coverage; and

(IV) include a description of any further recourse available to the individual.

(ii) GENERAL TIMELINE FOR DETERMINATIONS.—Upon receipt of information under paragraph (2), the qualified external review entity, and if required the independent medical reviewer, shall make a determination within the overall timeline that is applicable to the case under review as described in subsection (e), except that if the entity determines that a referral to an independent medical reviewer is not required, the entity shall provide notice of such determination to the participant, beneficiary, or enrollee (or authorized rep-

resentative) within such timeline and within 2 days of the date of such determination.

(d) INDEPENDENT MEDICAL REVIEW.—

(1) IN GENERAL.—If a qualified external review entity determines under subsection (c) that a denial of a claim for benefits is eligible for independent medical review, the entity shall refer the denial involved to an independent medical reviewer for the conduct of an independent medical review under this subsection.

(2) MEDICALLY REVIEWABLE DECISIONS.—A denial of a claim for benefits is eligible for independent medical review if the benefit for the item or service for which the claim is made would be a covered benefit under the terms and conditions of the plan or coverage but for one (or more) of the following determinations:

(A) DENIALS BASED ON MEDICAL NECESSITY AND APPROPRIATENESS.—A determination that the item or service is not covered because it is not medically necessary and appropriate or based on the application of substantially equivalent terms.

(B) DENIALS BASED ON EXPERIMENTAL OR INVESTIGATIONAL TREATMENT.—A determination that the item or service is not covered because it is experimental or investigational or based on the application of substantially equivalent terms.

(C) DENIALS OTHERWISE BASED ON AN EVALUATION OF MEDICAL FACTS.—A determination that the item or service or condition is not covered based on grounds that require an evaluation of the medical facts by a health care professional in the specific case involved to determine the coverage and extent of coverage of the item or service or condition.

(3) INDEPENDENT MEDICAL REVIEW DETERMINATION.—

(A) IN GENERAL.—An independent medical reviewer under this section shall make a new independent determination with respect to whether or not the denial of a claim for a benefit that is the subject of the review should be upheld, reversed, or modified.

(B) STANDARD FOR DETERMINATION.—The independent medical reviewer's determination relating to the medical necessity and ap-

propriateness, or the experimental or investigation nature, or the evaluation of the medical facts of the item, service, or condition shall be based on the medical condition of the participant, beneficiary, or enrollee (including the medical records of the participant, beneficiary, or enrollee) and valid, relevant scientific evidence and clinical evidence, including peer-reviewed medical literature or findings and including expert opinion.

(C) NO COVERAGE FOR EXCLUDED BENEFITS.—Nothing in this subsection shall be construed to permit an independent medical reviewer to require that a group health plan, or health insurance issuer offering health insurance coverage, provide coverage for items or services for which benefits are specifically excluded or expressly limited under the plan or coverage in the plain language of the plan document (and which are disclosed under section 121(b)(1)(C)). Notwithstanding any other provision of this Act, any exclusion of an exact medical procedure, any exact time limit on the duration or frequency of coverage, and any exact dollar limit on the amount of coverage

that is specifically enumerated and defined (in the plain language of the plan or coverage documents) under the plan or coverage offered by a group health plan or health insurance issuer offering health insurance coverage and that is disclosed under section 121(b)(1) shall be considered to govern the scope of the benefits that may be required: *Provided,* That the terms and conditions of the plan or coverage relating to such an exclusion or limit are in compliance with the requirements of law.

(D) EVIDENCE AND INFORMATION TO BE USED IN MEDICAL REVIEWS.—In making a determination under this subsection, the independent medical reviewer shall also consider appropriate and available evidence and information, including the following:

(i) The determination made by the plan or issuer with respect to the claim upon internal review and the evidence, guidelines, or rationale used by the plan or issuer in reaching such determination.

(ii) The recommendation of the treating health care professional and the evidence, guidelines, and rationale used by

the treating health care professional in reaching such recommendation.

(iii) Additional relevant evidence or information obtained by the reviewer or submitted by the plan, issuer, participant, beneficiary, or enrollee (or an authorized representative), or treating health care professional.

(iv) The plan or coverage document.

(E) INDEPENDENT DETERMINATION.—In making determinations under this subtitle, a qualified external review entity and an independent medical reviewer shall—

(i) consider the claim under review without deference to the determinations made by the plan or issuer or the recommendation of the treating health care professional (if any); and

(ii) consider, but not be bound by the definition used by the plan or issuer of ''medically necessary and appropriate'', or ''experimental or investigational'', or other substantially equivalent terms that are used by the plan or issuer to describe medical necessity and appropriateness or ex-

perimental or investigational nature of the treatment.

(F) DETERMINATION OF INDEPENDENT MEDICAL REVIEWER.—An independent medical reviewer shall, in accordance with the deadlines described in subsection (e), prepare a written determination to uphold, reverse, or modify the denial under review. Such written determination shall include—

(i) the determination of the reviewer;

(ii) the specific reasons of the reviewer for such determination, including a summary of the clinical or scientific evidence used in making the determination; and

(iii) with respect to a determination to reverse or modify the denial under review, a timeframe within which the plan or issuer must comply with such determination.

(G) NONBINDING NATURE OF ADDITIONAL RECOMMENDATIONS.—In addition to the determination under subparagraph (F), the reviewer may provide the plan or issuer and the treating health care professional with additional rec-

ommendations in connection with such a determination, but any such recommendations shall not affect (or be treated as part of) the determination and shall not be binding on the plan or issuer.

(e) TIMELINES AND NOTIFICATIONS.—

(1) TIMELINES FOR INDEPENDENT MEDICAL REVIEW.—

(A) PRIOR AUTHORIZATION DETERMINATION.—

(i) IN GENERAL.—The independent medical reviewer (or reviewers) shall make a determination on a denial of a claim for benefits that is referred to the reviewer under subsection (c)(3) in accordance with the medical exigencies of the case and as soon as possible, but in no case later than 14 days after the date of receipt of information under subsection (c)(2) if the review involves a prior authorization of items or services and in no case later than 21 days after the date the request for external review is received.

(ii) EXPEDITED DETERMINATION.—Notwithstanding clause (i) and subject to

clause (iii), the independent medical reviewer (or reviewers) shall make an expedited determination on a denial of a claim for benefits described in clause (i), when a request for such an expedited determination is made by a participant, beneficiary, or enrollee (or authorized representative) at any time during the process for making a determination, and a health care professional certifies, with the request, that a determination under the timeline described in clause (i) would seriously jeopardize the life or health of the participant, beneficiary, or enrollee or the ability of the participant, beneficiary, or enrollee to maintain or regain maximum function. Such determination shall be made as soon in accordance with the medical exigencies of the case and as soon as possible, but in no case later than 72 hours after the time the request for external review is received by the qualified external review entity.

(iii) ONGOING CARE DETERMINATION.—Notwithstanding clause (i), in the case of a review described in such sub-

clause that involves a termination or reduction of care, the notice of the determination shall be completed not later than 24 hours after the time the request for external review is received by the qualified external review entity and before the end of the approved period of care.

(B) RETROSPECTIVE DETERMINATION.—The independent medical reviewer (or reviewers) shall complete a review in the case of a retrospective determination on an appeal of a denial of a claim for benefits that is referred to the reviewer under subsection (c)(3) in no case later than 30 days after the date of receipt of information under subsection (c)(2) and in no case later than 60 days after the date the request for external review is received by the qualified external review entity.

(2) NOTIFICATION OF DETERMINATION.—The external review entity shall ensure that the plan or issuer, the participant, beneficiary, or enrollee (or authorized representative) and the treating health care professional (if any) receives a copy of the written determination of the independent medical reviewer prepared under subsection (d)(3)(F). Nothing

in this paragraph shall be construed as preventing an entity or reviewer from providing an initial oral notice of the reviewer's determination.

(3) FORM OF NOTICES.—Determinations and notices under this subsection shall be written in a manner calculated to be understood by a participant.

(f) COMPLIANCE.—

(1) APPLICATION OF DETERMINATIONS.—

(A) EXTERNAL REVIEW DETERMINATIONS BINDING ON PLAN.—The determinations of an external review entity and an independent medical reviewer under this section shall be binding upon the plan or issuer involved.

(B) COMPLIANCE WITH DETERMINATION.—If the determination of an independent medical reviewer is to reverse or modify the denial, the plan or issuer, upon the receipt of such determination, shall authorize coverage to comply with the medical reviewer's determination in accordance with the timeframe established by the medical reviewer.

(2) FAILURE TO COMPLY.—

(A) IN GENERAL.—If a plan or issuer fails to comply with the timeframe established under paragraph (1)(B) with respect to a participant,

beneficiary, or enrollee, where such failure to comply is caused by the plan or issuer, the participant, beneficiary, or enrollee may obtain the items or services involved (in a manner consistent with the determination of the independent external reviewer) from any provider regardless of whether such provider is a participating provider under the plan or coverage.

(B) REIMBURSEMENT.—

(i) IN GENERAL.—Where a participant, beneficiary, or enrollee obtains items or services in accordance with subparagraph (A), the plan or issuer involved shall provide for reimbursement of the costs of such items or services. Such reimbursement shall be made to the treating health care professional or to the participant, beneficiary, or enrollee (in the case of a participant, beneficiary, or enrollee who pays for the costs of such items or services).

(ii) AMOUNT.—The plan or issuer shall fully reimburse a professional, participant, beneficiary, or enrollee under clause (i) for the total costs of the items or services provided (regardless of any plan limi-

tations that may apply to the coverage of such items or services) so long as the items or services were provided in a manner consistent with the determination of the independent medical reviewer.

(C) FAILURE TO REIMBURSE.—Where a plan or issuer fails to provide reimbursement to a professional, participant, beneficiary, or enrollee in accordance with this paragraph, the professional, participant, beneficiary, or enrollee may commence a civil action (or utilize other remedies available under law) to recover only the amount of any such reimbursement that is owed by the plan or issuer and any necessary legal costs or expenses (including attorney's fees) incurred in recovering such reimbursement.

(D) AVAILABLE REMEDIES.—The remedies provided under this paragraph are in addition to any other available remedies.

(3) PENALTIES AGAINST AUTHORIZED OFFICIALS FOR REFUSING TO AUTHORIZE THE DETERMINATION OF AN EXTERNAL REVIEW ENTITY.—

(A) MONETARY PENALTIES.—

(i) IN GENERAL.—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.

(ii) ADDITIONAL PENALTY FOR FAILING TO FOLLOW TIMELINE.—In any case in which treatment was not commenced by the plan in accordance with the determination of an independent external reviewer, the Secretary shall assess a civil penalty of $10,000 against the plan and the plan shall pay such penalty to the participant, beneficiary, or enrollee involved.

(B) CEASE AND DESIST ORDER AND ORDER OF ATTORNEY'S FEES.—In any action described in subparagraph (A) 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 subparagraph has taken an action resulting in a refusal of a benefit determined by an external appeal entity to be covered, or has failed to take an action for which such person is responsible under the terms and conditions of the plan or coverage 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—

(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.

(C) ADDITIONAL CIVIL PENALTIES.—

(i) IN GENERAL.—In addition to any penalty imposed under subparagraph (A) or (B), 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 to be covered; or

(II) any pattern or practice of repeated violations of the requirements of this section with respect to such plan or coverage.

(ii) 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 appro-

priate Secretary to have not been provided, or unlawfully delayed, in violation of this section under such pattern or practice; or

(II) $500,000.

(D) REMOVAL AND DISQUALIFICATION.—Any person acting in the capacity of authorizing benefits who has engaged in any such pattern or practice described in subparagraph (C)(i) 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.

(4) PROTECTION OF LEGAL RIGHTS.—Nothing in this subsection or 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 rights.

(g) QUALIFICATIONS OF INDEPENDENT MEDICAL REVIEWERS.—

(1) IN GENERAL.—In referring a denial to 1 or more individuals to conduct independent medical review under subsection (c), the qualified external review entity shall ensure that—

(A) each independent medical reviewer meets the qualifications described in paragraphs (2) and (3);

(B) with respect to each review at least 1 such reviewer meets the requirements described in paragraphs (4) and (5); and

(C) compensation provided by the entity to the reviewer is consistent with paragraph (6).

(2) LICENSURE AND EXPERTISE.—Each independent medical reviewer shall be a physician (allopathic or osteopathic) or health care professional who—

(A) is appropriately credentialed or licensed in 1 or more States to deliver health care services; and

(B) typically treats the condition, makes the diagnosis, or provides the type of treatment under review.

(3) INDEPENDENCE.—

(A) IN GENERAL.—Subject to subparagraph (B), each independent medical reviewer in a case shall—

(i) not be a related party (as defined in paragraph (7));

(ii) not have a material familial, financial, or professional relationship with such a party; and

(iii) not otherwise have a conflict of interest with such a party (as determined under regulations).

(B) EXCEPTION.—Nothing in subparagraph (A) shall be construed to—

(i) prohibit an individual, solely on the basis of affiliation with the plan or issuer, from serving as an independent medical reviewer if—

(I) a non-affiliated individual is not reasonably available;

(II) the affiliated individual is not involved in the provision of items or services in the case under review;

(III) the fact of such an affiliation is disclosed to the plan or issuer and the participant, beneficiary, or

enrollee (or authorized representative) and neither party objects; and

(IV) the affiliated individual is not an employee of the plan or issuer and does not provide services exclusively or primarily to or on behalf of the plan or issuer;

(ii) prohibit an individual who has staff privileges at the institution where the treatment involved takes place from serving as an independent medical reviewer merely on the basis of such affiliation if the affiliation is disclosed to the plan or issuer and the participant, beneficiary, or enrollee (or authorized representative), and neither party objects; or

(iii) prohibit receipt of compensation by an independent medical reviewer from an entity if the compensation is provided consistent with paragraph (6).

(4) PRACTICING HEALTH CARE PROFESSIONAL IN SAME FIELD.—

(A) IN GENERAL.—In a case involving treatment, or the provision of items or services—

(i) by a physician, a reviewer shall be a practicing physician (allopathic or osteopathic) of the same or similar specialty, as a physician who, acting within the appropriate scope of practice within the State in which the service is provided or rendered, typically treats the condition, makes the diagnosis, or provides the type of treatment under review; or

(ii) by a non-physician health care professional, a reviewer (or reviewers) shall include at least one practicing non-physician health care professional of the same or similar specialty as the non-physician health care professional who, acting within the appropriate scope of practice within the State in which the service is provided or rendered, typically treats the condition, makes the diagnosis, or provides the type of treatment under review.

(B) PRACTICING DEFINED.—For purposes of this paragraph, the term ''practicing'' means, with respect to an individual who is a physician or other health care professional that the indi-

vidual provides health care services to individual patients on average at least 2 days per week.

(5) PEDIATRIC EXPERTISE.—In the case of an external review relating to a child, a reviewer shall have expertise under paragraph (2) in pediatrics.

(6) LIMITATIONS ON REVIEWER COMPENSATION.—Compensation provided by a qualified external review entity to an independent medical reviewer in connection with a review under this section shall—

(A) not exceed a reasonable level; and

(B) not be contingent on the decision rendered by the reviewer.

(7) RELATED PARTY DEFINED.—For purposes of this section, the term ''related party'' means, with respect to a denial of a claim under a plan or coverage relating to a participant, beneficiary, or enrollee, any of the following:

(A) The plan, plan sponsor, or issuer involved, or any fiduciary, officer, director, or employee of such plan, plan sponsor, or issuer.

(B) The participant, beneficiary, or enrollee (or authorized representative).

(C) The health care professional that provides the items or services involved in the denial.

(D) The institution at which the items or services (or treatment) involved in the denial are provided.

(E) The manufacturer of any drug or other item that is included in the items or services involved in the denial.

(F) Any other party determined under any regulations to have a substantial interest in the denial involved.

(h) QUALIFIED EXTERNAL REVIEW ENTITIES.—

(1) SELECTION OF QUALIFIED EXTERNAL REVIEW ENTITIES.—

(A) LIMITATION ON PLAN OR ISSUER SELECTION.—The appropriate Secretary shall implement procedures—

(i) to assure that the selection process among qualified external review entities will not create any incentives for external review 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.

No such selection process under the procedures implemented by the appropriate Secretary may give either the patient or the plan or issuer any ability to determine or influence the selection of a qualified external review entity to review the case of any participant, beneficiary, or enrollee.

(B) STATE AUTHORITY WITH RESPECT TO QUALIFIED EXTERNAL REVIEW ENTITIES 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) CONTRACT WITH QUALIFIED EXTERNAL REVIEW ENTITY.—Except as provided in paragraph (1)(B), the external review process of a plan or issuer under this section shall be conducted under a contract between the plan or issuer and 1 or more

qualified external review entities (as defined in paragraph (4)(A)).

(3) TERMS AND CONDITIONS OF CONTRACT.—The terms and conditions of a contract under paragraph (2) shall—

(A) 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 review activities; and

(B) provide that the costs of the external review process shall be borne by the plan or issuer.

Subparagraph (B) shall not be construed as applying to the imposition of a filing fee under subsection (b)(2)(A)(iv) or costs incurred by the participant, beneficiary, or enrollee (or authorized representative) or treating health care professional (if any) in support of the review, including the provision of additional evidence or information.

(4) QUALIFICATIONS.—

(A) IN GENERAL.—In this section, the term ''qualified external review entity'' means, in relation to a plan or issuer, an entity that is initially certified (and periodically recertified)

under subparagraph (C) as meeting the following requirements:

(i) The entity has (directly or through contracts or other arrangements) sufficient medical, legal, and other expertise and sufficient staffing to carry out duties of a qualified external review entity under this section on a timely basis, including making determinations under subsection (b)(2)(A) and providing for independent medical reviews under subsection (d).

(ii) The entity is not a plan or issuer or an affiliate or a subsidiary of a plan or issuer, and is not an affiliate or subsidiary of a professional or trade association of plans or issuers or of health care providers.

(iii) The entity has provided assurances that it will conduct external review activities consistent with the applicable requirements of this section and standards specified in subparagraph (C), including that it will not conduct any external review activities in a case unless the independence requirements of subparagraph (B) are met with respect to the case.

(iv) The entity has provided assurances that it will provide information in a timely manner under subparagraph (D).

(v) The entity meets such other requirements as the appropriate Secretary provides by regulation.

(B) INDEPENDENCE REQUIREMENTS.—

(i) IN GENERAL.—Subject to clause (ii), an entity meets the independence requirements of this subparagraph with respect to any case if the entity—

(I) is not a related party (as defined in subsection (g)(7));

(II) does not have a material familial, financial, or professional relationship with such a party; and

(III) does not otherwise have a conflict of interest with such a party (as determined under regulations).

(ii) EXCEPTION FOR REASONABLE COMPENSATION.—Nothing in clause (i) shall be construed to prohibit receipt by a qualified external review entity of compensation from a plan or issuer for the conduct of external review activities under

this section if the compensation is provided consistent with clause (iii).

(iii) LIMITATIONS ON ENTITY COMPENSATION.—Compensation provided by a plan or issuer to a qualified external review entity in connection with reviews under this section shall—

(I) not exceed a reasonable level; and

(II) not be contingent on any decision rendered by the entity or by any independent medical reviewer.

(C) CERTIFICATION AND RECERTIFICATION PROCESS.—

(i) IN GENERAL.—The initial certification and recertification of a qualified external review entity shall be made—

(I) under a process that is recognized or approved by the appropriate Secretary; or

(II) by a qualified private standard-setting organization that is approved by the appropriate Secretary under clause (iii).

In taking action under subclause (I), the appropriate Secretary shall give deference to entities that are under contract with the Federal Government or with an applicable State authority to perform functions of the type performed by qualified external review entities.

(ii) PROCESS.—The appropriate Secretary shall not recognize or approve a process under clause (i)(I) unless the process applies standards (as promulgated in regulations) that ensure that a qualified external review entity—

(I) will carry out (and has carried out, in the case of recertification) the responsibilities of such an entity in accordance with this section, including meeting applicable deadlines;

(II) will meet (and has met, in the case of recertification) appropriate indicators of fiscal integrity;

(III) will maintain (and has maintained, in the case of recertification) appropriate confidentiality with respect to individually identifi-

able health information obtained in the course of conducting external review activities; and

(IV) in the case recertification, shall review the matters described in clause (iv).

(iii) APPROVAL OF QUALIFIED PRIVATE STANDARD-SETTING ORGANIZATIONS.—For purposes of clause (i)(II), the appropriate Secretary may approve a qualified private standard-setting organization if such Secretary finds that the organization only certifies (or recertifies) external review entities that meet at least the standards required for the certification (or recertification) of external review entities under clause (ii).

(iv) CONSIDERATIONS IN RECERTIFICATIONS.—In conducting recertifications of a qualified external review entity under this paragraph, the appropriate Secretary or organization conducting the recertification shall review compliance of the entity with the requirements for conducting ex-

ternal review activities under this section, including the following:

(I) Provision of information under subparagraph (D).

(II) Adherence to applicable deadlines (both by the entity and by independent medical reviewers it refers cases to).

(III) Compliance with limitations on compensation (with respect to both the entity and independent medical reviewers it refers cases to).

(IV) Compliance with applicable independence requirements.

(V) Compliance with the requirement of subsection (d)(1) that only medically reviewable decisions shall be the subject of independent medical review and with the requirement of subsection (d)(3) that independent medical reviewers may not require coverage for specifically excluded benefits.

(v) PERIOD OF CERTIFICATION OR RECERTIFICATION.—A certification or recer-

tification provided under this paragraph shall extend for a period not to exceed 2 years.

(vi) REVOCATION.—A certification or recertification under this paragraph may be revoked by the appropriate Secretary or by the organization providing such certification upon a showing of cause. The Secretary, or organization, shall revoke a certification or deny a recertification with respect to an entity if there is a showing that the entity has a pattern or practice of ordering coverage for benefits that are specifically excluded under the plan or coverage.

(vii) PETITION FOR DENIAL OR WITHDRAWAL.—An individual may petition the Secretary, or an organization providing the certification involves, for a denial of recertification or a withdrawal of a certification with respect to an entity under this subparagraph if there is a pattern or practice of such entity failing to meet a requirement of this section.

(viii) SUFFICIENT NUMBER OF ENTITIES.—The appropriate Secretary shall certify and recertify a number of external review entities which is sufficient to ensure the timely and efficient provision of review services.

(D) PROVISION OF INFORMATION.—

(i) IN GENERAL.—A qualified external review entity shall provide to the appropriate Secretary, in such manner and at such times as such Secretary may require, such information (relating to the denials which have been referred to the entity for the conduct of external review under this section) as such Secretary determines appropriate to assure compliance with the independence and other requirements of this section to monitor and assess the quality of its external review activities and lack of bias in making determinations. Such information shall include information described in clause (ii) but shall not include individually identifiable medical information.

(ii) INFORMATION TO BE INCLUDED.—The information described in this subclause with respect to an entity is as follows:

(I) The number and types of denials for which a request for review has been received by the entity.

(II) The disposition by the entity of such denials, including the number referred to a independent medical reviewer and the reasons for such dispositions (including the application of exclusions), on a plan or issuer-specific basis and on a health care specialty-specific basis.

(III) The length of time in making determinations with respect to such denials.

(IV) Updated information on the information required to be submitted as a condition of certification with respect to the entity's performance of external review activities.

(iii) INFORMATION TO BE PROVIDED TO CERTIFYING ORGANIZATION.—

(I) IN GENERAL.—In the case of a qualified external review entity which is certified (or recertified) under this subsection by a qualified private standard-setting organization, at the request of the organization, the entity shall provide the organization with the information provided to the appropriate Secretary under clause (i).

(II) ADDITIONAL INFORMATION.—Nothing in this subparagraph shall be construed as preventing such an organization from requiring additional information as a condition of certification or recertification of an entity.

(iv) USE OF INFORMATION.—Information provided under this subparagraph may be used by the appropriate Secretary and qualified private standard-setting organizations to conduct oversight of qualified external review entities, including recertification of such entities, and shall be made

available to the public in an appropriate manner.

(E) LIMITATION ON LIABILITY.—No qualified external review entity having a contract with a plan or issuer, and no person who is employed by any such entity or who furnishes professional services to such entity (including as an independent medical reviewer), shall be held by reason of the performance of any duty, function, or activity required or authorized pursuant to this section, to be civilly liable under any law of the United States or of any State (or political subdivision thereof) if there was no actual malice or gross misconduct in the performance of such duty, function, or activity.

(5) REPORT.—Not later than 12 months after the general effective date referred to in section 501, the General Accounting Office shall prepare and submit to the appropriate committees of Congress a report concerning—

(A) the information that is provided under paragraph (3)(D);

(B) the number of denials that have been upheld by independent medical reviewers and

the number of denials that have been reversed by such reviewers; and

(C) the extent to which independent medical reviewers are requiring coverage for benefits that are specifically excluded under the plan or coverage.

SEC. 105. HEALTH CARE CONSUMER ASSISTANCE FUND.

(a) GRANTS.—

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall establish a fund, to be known as the ''Health Care Consumer Assistance Fund'', to be used to award grants to eligible States to carry out consumer assistance activities (including programs established by States prior to the enactment of this Act) designed to provide information, assistance, and referrals to consumers of health insurance products.

(2) STATE ELIGIBILITY.—To be eligible to receive a grant under this subsection a State shall prepare and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including a State plan that describes—

(A) the manner in which the State will ensure that the health care consumer assistance

office (established under paragraph (4)) will educate and assist health care consumers in accessing needed care;

(B) the manner in which the State will coordinate and distinguish the services provided by the health care consumer assistance office with the services provided by Federal, State and local health-related ombudsman, information, protection and advocacy, insurance, and fraud and abuse programs;

(C) the manner in which the State will provide information, outreach, and services to underserved, minority populations with limited English proficiency and populations residing in rural areas;

(D) the manner in which the State will oversee the health care consumer assistance office, its activities, product materials and evaluate program effectiveness;

(E) the manner in which the State will ensure that funds made available under this section will be used to supplement, and not supplant, any other Federal, State, or local funds expended to provide services for programs de-

scribed under this section and those described in subparagraphs (C) and (D);

(F) the manner in which the State will ensure that health care consumer office personnel have the professional background and training to carry out the activities of the office; and

(G) the manner in which the State will ensure that consumers have direct access to consumer assistance personnel during regular business hours.

(3) AMOUNT OF GRANT.—

(A) IN GENERAL.—From amounts appropriated under subsection (b) for a fiscal year, the Secretary shall award a grant to a State in an amount that bears the same ratio to such amounts as the number of individuals within the State covered under a group health plan or under health insurance coverage offered by a health insurance issuer bears to the total number of individuals so covered in all States (as determined by the Secretary). Any amounts provided to a State under this subsection that are not used by the State shall be remitted to the Secretary and reallocated in accordance with this subparagraph.

(B) MINIMUM AMOUNT.—In no case shall the amount provided to a State under a grant under this subsection for a fiscal year be less than an amount equal to 0.5 percent of the amount appropriated for such fiscal year to carry out this section.

(C) NON-FEDERAL CONTRIBUTIONS.—A State will provide for the collection of non-Federal contributions for the operation of the office in an amount that is not less than 25 percent of the amount of Federal funds provided to the State under this section.

(4) PROVISION OF FUNDS FOR ESTABLISHMENT OF OFFICE.—

(A) IN GENERAL.—From amounts provided under a grant under this subsection, a State shall, directly or through a contract with an independent, nonprofit entity with demonstrated experience in serving the needs of health care consumers, provide for the establishment and operation of a State health care consumer assistance office.

(B) ELIGIBILITY OF ENTITY.—To be eligible to enter into a contract under subparagraph (A), an entity shall demonstrate that it has the

technical, organizational, and professional capacity to deliver the services described in subsection (b) to all public and private health insurance participants, beneficiaries, enrollees, or prospective enrollees.

(C) EXISTING STATE ENTITY.—Nothing in this section shall prevent the funding of an existing health care consumer assistance program that otherwise meets the requirements of this section.

(b) USE OF FUNDS.—

(1) BY STATE.—A State shall use amounts provided under a grant awarded under this section to carry out consumer assistance activities directly or by contract with an independent, non-profit organization. An eligible entity may use some reasonable amount of such grant to ensure the adequate training of personnel carrying out such activities. To receive amounts under this subsection, an eligible entity shall provide consumer assistance services, including—

(A) the operation of a toll-free telephone hotline to respond to consumer requests;

(B) the dissemination of appropriate educational materials on available health insurance

products and on how best to access health care and the rights and responsibilities of health care consumers;

(C) the provision of education on effective methods to promptly and efficiently resolve questions, problems, and grievances;

(D) the coordination of educational and outreach efforts with health plans, health care providers, payers, and governmental agencies;

(E) referrals to appropriate private and public entities to resolve questions, problems and grievances; and

(F) the provision of information and assistance, including acting as an authorized representative, regarding internal, external, or administrative grievances or appeals procedures in nonlitigative settings to appeal the denial, termination, or reduction of health care services, or the refusal to pay for such services, under a group health plan or health insurance coverage offered by a health insurance issuer.

(2) CONFIDENTIALITY AND ACCESS TO INFORMATION.—

(A) STATE ENTITY.—With respect to a State that directly establishes a health care con-

sumer assistance office, such office shall establish and implement procedures and protocols in accordance with applicable Federal and State laws.

(B) CONTRACT ENTITY.—With respect to a State that, through contract, establishes a health care consumer assistance office, such office shall establish and implement procedures and protocols, consistent with applicable Federal and State laws, to ensure the confidentiality of all information shared by a participant, beneficiary, enrollee, or their personal representative and their health care providers, group health plans, or health insurance insurers with the office and to ensure that no such information is used by the office, or released or disclosed to State agencies or outside persons or entities without the prior written authorization (in accordance with section 164.508 of title 45, Code of Federal Regulations) of the individual or personal representative. The office may, consistent with applicable Federal and State confidentiality laws, collect, use or disclose aggregate information that is not individually identifiable (as defined in section 164.501 of title 45,

Code of Federal Regulations). The office shall provide a written description of the policies and procedures of the office with respect to the manner in which health information may be used or disclosed to carry out consumer assistance activities. The office shall provide health care providers, group health plans, or health insurance issuers with a written authorization (in accordance with section 164.508 of title 45, Code of Federal Regulations) to allow the office to obtain medical information relevant to the matter before the office.

(3) AVAILABILITY OF SERVICES.—The health care consumer assistance office of a State shall not discriminate in the provision of information, referrals, and services regardless of the source of the individual's health insurance coverage or prospective coverage, including individuals covered under a group health plan or health insurance coverage offered by a health insurance issuer, the medicare or medicaid programs under title XVIII or XIX of the Social Security Act (42 U.S.C. 1395 and 1396 et seq.), or under any other Federal or State health care program.

(4) DESIGNATION OF RESPONSIBILITIES.—

(A) WITHIN EXISTING STATE ENTITY.—If the health care consumer assistance office of a State is located within an existing State regulatory agency or office of an elected State official, the State shall ensure that—

(i) there is a separate delineation of the funding, activities, and responsibilities of the office as compared to the other funding, activities, and responsibilities of the agency; and

(ii) the office establishes and implements procedures and protocols to ensure the confidentiality of all information shared by a participant, beneficiary, or enrollee or their personal representative and their health care providers, group health plans, or health insurance issuers with the office and to ensure that no information is disclosed to the State agency or office without the written authorization of the individual or their personal representative in accordance with paragraph (2).

(B) CONTRACT ENTITY.—In the case of an entity that enters into a contract with a State under subsection (a)(3), the entity shall provide

assurances that the entity has no conflict of interest in carrying out the activities of the office and that the entity is independent of group health plans, health insurance issuers, providers, payers, and regulators of health care.

(5) SUBCONTRACTS.—The health care consumer assistance office of a State may carry out activities and provide services through contracts entered into with 1 or more nonprofit entities so long as the office can demonstrate that all of the requirements of this section are complied with by the office.

(6) TERM.—A contract entered into under this subsection shall be for a term of 3 years.

(c) REPORT.—Not later than 1 year after the Secretary first awards grants under this section, and annually thereafter, the Secretary shall prepare and submit to the appropriate committees of Congress a report concerning the activities funded under this section and the effectiveness of such activities in resolving health care-related problems and grievances.

(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out this section.

Subtitle B—Access to Care

SEC. 111. CONSUMER CHOICE OPTION.

(a) IN GENERAL.—If—

(1) a health insurance issuer providing health insurance coverage in connection with a group health plan offers to enrollees health insurance coverage 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, or

(2) a group health plan offers to participants or beneficiaries health benefits which provide 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 plan to provide such services—

then the issuer or plan shall also offer or arrange to be offered to such enrollees, participants, or beneficiaries (at the time of enrollment and during an annual open season as provided under subsection (c)) the option of health insurance coverage or health benefits which provide for coverage of such services which are not furnished through

health care professionals and providers who are members of such a network unless such enrollees, participants, or beneficiaries 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 or group health plan 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, participant, or beneficiary unless it is paid by the health plan sponsor or group health plan through agreement with the health insurance issuer.

(c) OPEN SEASON.—An enrollee, participant, or beneficiary, may change to the offering provided under this section only during a time period determined by the health insurance issuer or group health plan. 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 and 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.

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

ance 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 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, with respect to an emergency medical condition—

(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.

(C) STABILIZE.—The term ''to stabilize'', with respect to an emergency medical condition (as defined in subparagraph (A)), has the meaning give in section 1867(e)(3) of the Social Security Act (42 U.S.C. 1395dd(e)(3)).

(b) REIMBURSEMENT FOR MAINTENANCE CARE AND POST-STABILIZATION CARE.—A group health plan, and health insurance coverage offered by a health insurance issuer, must provide reimbursement for maintenance care and post-stabilization care in accordance with the requirements of section 1852(d)(2) of the Social Security Act (42 U.S.C. 1395w–22(d)(2)). Such reimbursement shall be provided in a manner consistent with subsection (a)(1)(C).

(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. 114. TIMELY ACCESS TO SPECIALISTS.

(a) TIMELY ACCESS.—

(1) IN GENERAL.—A group health plan or health insurance issuer offering health insurance coverage shall ensure that participants, beneficiaries, and enrollees receive timely access to specialists who are appropriate to the condition of, and accessible to, the participant, beneficiary, or enrollee, when such specialty care is a covered benefit under the plan or coverage.

(2) RULE OF CONSTRUCTION.—Nothing in paragraph (1) shall be construed—

(A) to require the coverage under a group health plan or health insurance coverage of benefits or services;

(B) to prohibit a plan or issuer from including providers in the network only to the extent necessary to meet the needs of the plan's or issuer's participants, beneficiaries, or enrollees; or

(C) to override any State licensure or scope-of-practice law.

(3) ACCESS TO CERTAIN PROVIDERS.—

(A) IN GENERAL.—With respect to specialty care under this section, if a participating specialist is not available and qualified to provide such care to the participant, beneficiary, or enrollee, the plan or issuer shall provide for coverage of such care by a nonparticipating specialist.

(B) TREATMENT OF NONPARTICIPATING PROVIDERS.—If a participant, beneficiary, or enrollee receives care from a nonparticipating specialist pursuant to subparagraph (A), such specialty care shall be provided at no additional cost to the participant, beneficiary, or enrollee beyond what the participant, beneficiary, or enrollee would otherwise pay for such specialty care if provided by a participating specialist.

(b) REFERRALS.—

(1) AUTHORIZATION.—Subject to subsection (a)(1), a group health plan or health insurance issuer may require an authorization in order to obtain coverage for specialty services under this section. Any such authorization—

(A) shall be for an appropriate duration of time or number of referrals, including an au-

thorization for a standing referral where appropriate; and

(B) may not be refused solely because the authorization involves services of a nonparticipating specialist (described in subsection (a)(3)).

(2) REFERRALS FOR ONGOING SPECIAL CONDITIONS.—

(A) IN GENERAL.—Subject to subsection (a)(1), a group health plan or health insurance issuer shall permit a participant, beneficiary, or enrollee who has an ongoing special condition (as defined in subparagraph (B)) to receive a referral to a specialist for the treatment of such condition and such specialist may authorize such referrals, procedures, tests, and other medical services with respect to such condition, or coordinate the care for such condition, subject to the terms of a treatment plan (if any) referred to in subsection (c) with respect to the condition.

(B) ONGOING SPECIAL CONDITION DEFINED.—In this subsection, the term ''ongoing special condition'' means a condition or disease that—

(i) is life-threatening, degenerative, potentially disabling, or congenital; and

(ii) requires specialized medical care over a prolonged period of time.

(c) TREATMENT PLANS.—

(1) IN GENERAL.—A group health plan or health insurance issuer may require that the specialty care be provided—

(A) pursuant to a treatment plan, but only if the treatment plan—

(i) is developed by the specialist, in consultation with the case manager or primary care provider, and the participant, beneficiary, or enrollee, and

(ii) is approved by the plan or issuer in a timely manner, if the plan or issuer requires such approval; and

(B) in accordance with applicable quality assurance and utilization review standards of the plan or issuer.

(2) NOTIFICATION.—Nothing in paragraph (1) shall be construed as prohibiting a plan or issuer from requiring the specialist to provide the plan or issuer with regular updates on the specialty care

provided, as well as all other reasonably necessary medical information.

(d) SPECIALIST DEFINED.—For purposes of this section, the term ''specialist'' means, with respect to the condition of the participant, beneficiary, or enrollee, a health care professional, 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.

SEC. 115. PATIENT ACCESS TO OBSTETRICAL AND GYNECOLOGICAL CARE.

(a) GENERAL RIGHTS.—

(1) DIRECT ACCESS.—A group health plan, or health insurance issuer offering health insurance coverage, described in subsection (b) may not require authorization or referral by the plan, issuer, or any person (including a primary care provider described in subsection (b)(2)) in the case of a female participant, beneficiary, or enrollee who seeks coverage for obstetrical or gynecological care provided by a participating health care professional who specializes in obstetrics or gynecology.

(2) OBSTETRICAL AND GYNECOLOGICAL CARE.—A group health plan or health insurance issuer described in subsection (b) shall treat the pro-

vision of obstetrical and gynecological care, and the ordering of related obstetrical and gynecological items and services, pursuant to the direct access described under paragraph (1), by a participating health care professional who specializes in obstetrics or gynecology as the authorization of the primary care provider.

(b) APPLICATION OF SECTION.—A group health plan, or health insurance issuer offering health insurance coverage, described in this subsection is a group health plan or coverage that—

(1) provides coverage for obstetric or gynecologic care; and

(2) requires the designation by a participant, beneficiary, or enrollee of a participating primary care provider.

(c) CONSTRUCTION.—Nothing in subsection (a) shall be construed to—

(1) waive any exclusions of coverage under the terms and conditions 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.—In the case of a person who has a child who is a participant, beneficiary, or enrollee under a group health plan, or health insurance coverage offered by a health insurance issuer, if the plan or issuer requires or provides for the designation of a participating primary care provider for the child, the plan or issuer shall permit such person to designate a physician (allopathic or osteopathic) who specializes in pediatrics as the child's primary care provider if such provider participates in the network of the plan or issuer.

(b) CONSTRUCTION.—Nothing in subsection (a) shall be construed to waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of pediatric care.

SEC. 117. CONTINUITY OF CARE.

(a) TERMINATION OF PROVIDER.—

(1) IN GENERAL.—If—

(A) a contract between a group health plan, or a health insurance issuer offering health insurance coverage, and a treating health care provider is terminated (as defined in paragraph (e)(4)), or

(B) benefits or coverage provided by a health care provider are terminated because of a change in the terms of provider participation in such plan or coverage—

the plan or issuer shall meet the requirements of paragraph (3) with respect to each continuing care patient.

(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) REQUIREMENTS.—The requirements of this paragraph are that the plan or issuer—

(A) notify the continuing care patient involved, or arrange to have the patient notified

pursuant to subsection (d)(2), on a timely basis of the termination described in paragraph (1) (or paragraph (2), if applicable) and the right to elect continued transitional care from the provider under this section;

(B) provide the patient with an opportunity to notify the plan or issuer of the patient's need for transitional care; and

(C) subject to subsection (c), permit the patient to elect to continue to be covered with respect to the course of treatment by such provider with the provider's consent during a transitional period (as provided for under subsection (b)).

(4) CONTINUING CARE PATIENT.—For purposes of this section, the term ''continuing care patient'' means a participant, beneficiary, or enrollee who—

(A) is undergoing a course of treatment for a serious and complex condition from the provider at the time the plan or issuer receives or provides notice of provider, benefit, or coverage termination described in paragraph (1) (or paragraph (2), if applicable);

(B) is undergoing a course of institutional or inpatient care from the provider at the time of such notice;

(C) is scheduled to undergo non-elective surgery from the provider at the time of such notice;

(D) is pregnant and undergoing a course of treatment for the pregnancy from the provider at the time of such notice; or

(E) is or was determined to be terminally ill (as determined under section 1861(dd)(3)(A) of the Social Security Act) at the time of such notice, but only with respect to a provider that was treating the terminal illness before the date of such notice.

(b) TRANSITIONAL PERIODS.—

(1) SERIOUS AND COMPLEX CONDITIONS.—The transitional period under this subsection with respect to a continuing care patient described in subsection (a)(4)(A) shall extend for up to 90 days (as determined by the treating health care professional) from the date of the notice described in subsection (a)(3)(A).

(2) INSTITUTIONAL OR INPATIENT CARE.—The transitional period under this subsection for a con-

tinuing care patient described in subsection (a)(4)(B) shall extend until the earlier of—

(A) the expiration of the 90-day period beginning on the date on which the notice under subsection (a)(3)(A) is provided; or

(B) the date of discharge of the patient from such care or the termination of the period of institutionalization, or, if later, the date of completion of reasonable follow-up care.

(3) SCHEDULED NON-ELECTIVE SURGERY.—The transitional period under this subsection for a continuing care patient described in subsection (a)(4)(C) shall extend until the completion of the surgery involved and post-surgical follow-up care relating to the surgery and occurring within 90 days after the date of the surgery.

(4) PREGNANCY.—The transitional period under this subsection for a continuing care patient described in subsection (a)(4)(D) shall extend through the provision of post-partum care directly related to the delivery.

(5) TERMINAL ILLNESS.—The transitional period under this subsection for a continuing care patient described in subsection (a)(4)(E) shall extend for the remainder of the patient's life for care that

is 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 this section upon the provider agreeing to the following terms and conditions:

(1) The treating health care provider agrees to accept reimbursement from the plan or issuer and continuing care patient 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 coverage after the date of the termination of the contract with the group health plan or health insurance issuer) and not to impose cost-sharing with respect to the patient 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 treating health care 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 nec-

essary medical information related to the care provided.

(3) The treating health care 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) RULES OF CONSTRUCTION.—Nothing in this section shall be construed—

(1) to require the coverage of benefits which would not have been covered if the provider involved remained a participating provider; or

(2) with respect to the termination of a contract under subsection (a) to prevent a group health plan or health insurance issuer from requiring that the health care provider—

(A) notify participants, beneficiaries, or enrollees of their rights under this section; or

(B) provide the plan or issuer with the name of each participant, beneficiary, or enrollee who the provider believes is a continuing care patient.

(e) DEFINITIONS.—In this section:

(1) CONTRACT.—The term ''contract'' includes, with respect to a plan or issuer and a treating health care provider, a contract between such plan or issuer and an organized network of providers that includes the treating health care provider, and (in the case of such a contract) the contract between the treating health care provider and the organized network.

(2) HEALTH CARE PROVIDER.—The term ''health care provider'' or ''provider'' means—

(A) any individual who is engaged in the delivery of health care services in a State and who is required by State law or regulation to be licensed or certified by the State to engage in the delivery of such services in the State; and

(B) any entity that is engaged in the delivery of health care services in a State and that, if it is required by State law or regulation to be licensed or certified by the State to engage in the delivery of such services in the State, is so licensed.

(3) SERIOUS AND COMPLEX CONDITION.—The term ''serious and complex condition'' means, with respect to a participant, beneficiary, or enrollee under the plan or coverage—

(A) in the case of an acute illness, a condition that is serious enough to require specialized medical treatment to avoid the reasonable possibility of death or permanent harm; or

(B) in the case of a chronic illness or condition, is an ongoing special condition (as defined in section 114(b)(2)(B)).

(4) TERMINATED.—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 for failure to meet applicable quality standards or for fraud.

SEC. 118. ACCESS TO NEEDED PRESCRIPTION DRUGS.

(a) IN GENERAL.—To the extent that a group health plan, or health insurance coverage offered by a health insurance issuer, provides coverage for benefits with respect to prescription drugs, and limits such coverage to drugs included in a formulary, the plan or issuer shall—

(1) ensure the participation of physicians and pharmacists in developing and reviewing such formulary;

(2) provide for disclosure of the formulary to providers; and

(3) in accordance with the applicable quality assurance and utilization review standards of the plan

or issuer, provide for exceptions from the formulary limitation when a non-formulary alternative is medically necessary and appropriate and, in the case of such an exception, apply the same cost-sharing requirements that would have applied in the case of a drug covered under the formulary.

(b) COVERAGE OF APPROVED DRUGS AND MEDICAL DEVICES.—

(1) IN GENERAL.—A group health plan (or health insurance coverage offered in connection with such a plan) that provides any coverage of prescription drugs or medical devices shall not deny coverage of such a drug or device on the basis that the use is investigational, if the use—

(A) in the case of a prescription drug—

(i) is included in the labeling authorized by the application in effect for the drug pursuant to subsection (b) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act, without regard to any postmarketing requirements that may apply under such Act; or

(ii) is included in the labeling authorized by the application in effect for the drug under section 351 of the Public

Health Service Act, without regard to any postmarketing requirements that may apply pursuant to such section; or

(B) in the case of a medical device, is included in the labeling authorized by a regulation under subsection (d) or (3) of section 513 of the Federal Food, Drug, and Cosmetic Act, an order under subsection (f) of such section, or an application approved under section 515 of such Act, without regard to any postmarketing requirements that may apply under such Act.

(2) CONSTRUCTION.—Nothing in this subsection shall be construed as requiring a group health plan (or health insurance coverage offered in connection with such a plan) to provide any coverage of prescription drugs or medical devices.

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 appropriate 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—

(A) approved and funded (which may include funding through in-kind contributions) by one or more of the following:

(i) the National Institutes of Health;

(ii) a cooperative group or center of the National Institutes of Health, such as a qualified nongovernmental research entity to which the National Cancer Institute has awarded a center support grant;

(iii) either of the following if the conditions described in paragraph (2) are met—

(I) the Department of Veterans Affairs;

(II) the Department of Defense; or

(B) approved by the Food and Drug Administration.

(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 appropriate 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 ethical 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.

SEC. 120. REQUIRED COVERAGE FOR MINIMUM HOSPITAL STAY FOR MASTECTOMIES AND LYMPH NODE DISSECTIONS FOR THE TREATMENT OF BREAST CANCER AND COVERAGE FOR SECONDARY CONSULTATIONS.

(a) INPATIENT CARE.—

(1) IN GENERAL.—A group health plan, and a health insurance issuer providing health insurance coverage, that provides medical and surgical benefits shall ensure that inpatient coverage with respect to the treatment of breast cancer is provided for a period of time as is determined by the attending physician, in consultation with the patient, to be medically necessary and appropriate following—

(A) a mastectomy;

(B) a lumpectomy; or

(C) a lymph node dissection for the treatment of breast cancer.

(2) EXCEPTION.—Nothing in this section shall be construed as requiring the provision of inpatient coverage if the attending physician and patient determine that a shorter period of hospital stay is medically appropriate.

(b) PROHIBITION ON CERTAIN MODIFICATIONS.—In implementing the requirements of this section, a group health plan, and a health insurance issuer providing health insurance coverage, may not modify the terms and conditions of coverage based on the determination by a participant, beneficiary, or enrollee to request less than the minimum coverage required under subsection (a).

(c) SECONDARY CONSULTATIONS.—

(1) IN GENERAL.—A group health plan, and a health insurance issuer providing health insurance coverage, that provides coverage with respect to medical and surgical services provided in relation to the diagnosis and treatment of cancer shall ensure that full coverage is provided for secondary consultations by specialists in the appropriate medical fields (including pathology, radiology, and oncology) to confirm or refute such diagnosis. Such plan or issuer shall ensure that full coverage is provided for such

secondary consultation whether such consultation is based on a positive or negative initial diagnosis. In any case in which the attending physician certifies in writing that services necessary for such a secondary consultation are not sufficiently available from specialists operating under the plan or coverage with respect to whose services coverage is otherwise provided under such plan or by such issuer, such plan or issuer shall ensure that coverage is provided with respect to the services necessary for the secondary consultation with any other specialist selected by the attending physician for such purpose at no additional cost to the individual beyond that which the individual would have paid if the specialist was participating in the network of the plan or issuer.

(2) EXCEPTION.—Nothing in paragraph (1) shall be construed as requiring the provision of secondary consultations where the patient determines not to seek such a consultation.

(d) PROHIBITION ON PENALTIES OR INCENTIVES.—A group health plan, and a health insurance issuer providing health insurance coverage, may not—

(1) penalize or otherwise reduce or limit the reimbursement of a provider or specialist because the

provider or specialist provided care to a participant, beneficiary, or enrollee in accordance with this section;

(2) provide financial or other incentives to a physician or specialist to induce the physician or specialist to keep the length of inpatient stays of patients following a mastectomy, lumpectomy, or a lymph node dissection for the treatment of breast cancer below certain limits or to limit referrals for secondary consultations; or

(3) provide financial or other incentives to a physician or specialist to induce the physician or specialist to refrain from referring a participant, beneficiary, or enrollee for a secondary consultation that would otherwise be covered by the plan or coverage involved under subsection (c).

Subtitle C—Access to Information

SEC. 121. PATIENT ACCESS TO INFORMATION.

(a) REQUIREMENT.—

(1) DISCLOSURE.—

(A) IN GENERAL.—A group health plan, and a health insurance issuer that provides coverage in connection with health insurance coverage, shall provide for the disclosure to participants, beneficiaries, and enrollees—

(i) of the information described in subsection (b) at the time of the initial enrollment of the participant, beneficiary, or enrollee under the plan or coverage;

(ii) of such information on an annual basis—

(I) in conjunction with the election period of the plan or coverage if the plan or coverage has such an election period; or

(II) in the case of a plan or coverage that does not have an election period, in conjunction with the beginning of the plan or coverage year; and

(iii) of information relating to any material reduction to the benefits or information described in such subsection or subsection (c), in the form of a notice provided not later than 30 days before the date on which the reduction takes effect.

(B) PARTICIPANTS, BENEFICIARIES, AND ENROLLEES.—The disclosure required under subparagraph (A) shall be provided—

(i) jointly to each participant, beneficiary, and enrollee who reside at the same address; or

(ii) in the case of a beneficiary or enrollee who does not reside at the same address as the participant or another enrollee, separately to the participant or other enrollees and such beneficiary or enrollee.

(2) PROVISION OF INFORMATION.—Information shall be provided to participants, beneficiaries, and enrollees under this section at the last known address maintained by the plan or issuer with respect to such participants, beneficiaries, or enrollees, to the extent that such information is provided to participants, beneficiaries, or enrollees via the United States Postal Service or other private delivery service.

(b) REQUIRED INFORMATION.—The informational materials to be distributed under this section shall include for each option available under the group health plan or health insurance coverage the following:

(1) BENEFITS.—A description of the covered benefits, including—

(A) any in- and out-of-network benefits;

(B) specific preventive services covered under the plan or coverage if such services are covered;

(C) any specific exclusions or express limitations of benefits described in section 104(d)(3)(C);

(D) any other benefit limitations, including any annual or lifetime benefit limits and any monetary limits or limits on the number of visits, days, or services, and any specific coverage exclusions; and

(E) any definition of medical necessity used in making coverage determinations by the plan, issuer, or claims administrator.

(2) COST SHARING.—A description of any cost-sharing requirements, including—

(A) any premiums, deductibles, coinsurance, copayment amounts, and liability for balance billing, for which the participant, beneficiary, or enrollee will be responsible under each option available under the plan;

(B) any maximum out-of-pocket expense for which the participant, beneficiary, or enrollee may be liable;

(C) any cost-sharing requirements for out-of-network benefits or services received from nonparticipating providers; and

(D) any additional cost-sharing or charges for benefits and services that are furnished without meeting applicable plan or coverage requirements, such as prior authorization or precertification.

(3) DISENROLLMENT.—Information relating to the disenrollment of a participant, beneficiary, or enrollee.

(4) SERVICE AREA.—A description of the plan or issuer's service area, including the provision of any out-of-area coverage.

(5) PARTICIPATING PROVIDERS.—A directory of participating providers (to the extent a plan or issuer provides coverage through a network of providers) that includes, at a minimum, the name, address, and telephone number of each participating provider, and information about how to inquire whether a participating provider is currently accepting new patients.

(6) CHOICE OF PRIMARY CARE PROVIDER.—A description of any requirements and procedures to be used by participants, beneficiaries, and enrollees

in selecting, accessing, or changing their primary care provider, including providers both within and outside of the network (if the plan or issuer permits out-of-network services), and the right to select a pediatrician as a primary care provider under section 116 for a participant, beneficiary, or enrollee who is a child if such section applies.

(7) PREAUTHORIZATION REQUIREMENTS.—A description of the requirements and procedures to be used to obtain preauthorization for health services, if such preauthorization is required.

(8) EXPERIMENTAL AND INVESTIGATIONAL TREATMENTS.—A description of the process for determining whether a particular item, service, or treatment is considered experimental or investigational, and the circumstances under which such treatments are covered by the plan or issuer.

(9) SPECIALTY CARE.—A description of the requirements and procedures to be used by participants, beneficiaries, and enrollees in accessing specialty care and obtaining referrals to participating and nonparticipating specialists, including any limitations on choice of health care professionals referred to in section 112(b)(2) and the right to timely

access to specialists care under section 114 if such section applies.

(10) CLINICAL TRIALS.—A description of the circumstances and conditions under which participation in clinical trials is covered under the terms and conditions of the plan or coverage, and the right to obtain coverage for approved clinical trials under section 119 if such section applies.

(11) PRESCRIPTION DRUGS.—To the extent the plan or issuer provides coverage for prescription drugs, a statement of whether such coverage is limited to drugs included in a formulary, a description of any provisions and cost-sharing required for obtaining on- and off-formulary medications, and a description of the rights of participants, beneficiaries, and enrollees in obtaining access to access to prescription drugs under section 118 if such section applies.

(12) EMERGENCY SERVICES.—A summary of the rules and procedures for accessing emergency services, including the right of a participant, beneficiary, or enrollee to obtain emergency services under the prudent layperson standard under section 113, if such section applies, and any educational in-

formation that the plan or issuer may provide regarding the appropriate use of emergency services.

(13) CLAIMS AND APPEALS.—A description of the plan or issuer's rules and procedures pertaining to claims and appeals, a description of the rights (including deadlines for exercising rights) of participants, beneficiaries, and enrollees under subtitle A in obtaining covered benefits, filing a claim for benefits, and appealing coverage decisions internally and externally (including telephone numbers and mailing addresses of the appropriate authority), and a description of any additional legal rights and remedies available under section 502 of the Employee Retirement Income Security Act of 1974 and applicable State law.

(14) ADVANCE DIRECTIVES AND ORGAN DONATION.—A description of procedures for advance directives and organ donation decisions if the plan or issuer maintains such procedures.

(15) INFORMATION ON PLANS AND ISSUERS.—The name, mailing address, and telephone number or numbers of the plan administrator and the issuer to be used by participants, beneficiaries, and enrollees seeking information about plan or coverage benefits and services, payment of a claim, or authoriza-

tion for services and treatment. Notice of whether the benefits under the plan or coverage are provided under a contract or policy of insurance issued by an issuer, or whether benefits are provided directly by the plan sponsor who bears the insurance risk.

(16) TRANSLATION SERVICES.—A summary description of any translation or interpretation services (including the availability of printed information in languages other than English, audio tapes, or information in Braille) that are available for non-English speakers and participants, beneficiaries, and enrollees with communication disabilities and a description of how to access these items or services.

(17) ACCREDITATION INFORMATION.—Any information that is made public by accrediting organizations in the process of accreditation if the plan or issuer is accredited, or any additional quality indicators (such as the results of enrollee satisfaction surveys) that the plan or issuer makes public or makes available to participants, beneficiaries, and enrollees.

(18) NOTICE OF REQUIREMENTS.—A description of any rights of participants, beneficiaries, and enrollees that are established by the Bipartisan Patient Protection Act (excluding those described in paragraphs (1) through (17)) if such sections apply.

The description required under this paragraph may be combined with the notices of the type described in sections 711(d), 713(b), or 606(a)(1) of the Employee Retirement Income Security Act of 1974 and with any other notice provision that the appropriate Secretary determines may be combined, so long as such combination does not result in any reduction in the information that would otherwise be provided to the recipient.

(19) AVAILABILITY OF ADDITIONAL INFORMATION.—A statement that the information described in subsection (c), and instructions on obtaining such information (including telephone numbers and, if available, Internet websites), shall be made available upon request.

(20) DESIGNATED DECISIONMAKERS.—A description of the participants and beneficiaries with respect to whom each designated decisionmaker under the plan has assumed liability under section 502(o) of the Employee Retirement Income Security Act of 1974 and the name and address of each such decisionmaker.

(c) ADDITIONAL INFORMATION.—The informational materials to be provided upon the request of a participant, beneficiary, or enrollee shall include for each option avail-

able under a group health plan or health insurance coverage the following:

(1) STATUS OF PROVIDERS.—The State licensure status of the plan or issuer's participating health care professionals and participating health care facilities, and, if available, the education, training, specialty qualifications or certifications of such professionals.

(2) COMPENSATION METHODS.—A summary description by category of the applicable methods (such as capitation, fee-for-service, salary, bundled payments, per diem, or a combination thereof) used for compensating prospective or treating health care professionals (including primary care providers and specialists) and facilities in connection with the provision of health care under the plan or coverage.

(3) PRESCRIPTION DRUGS.—Information about whether a specific prescription medication is included in the formulary of the plan or issuer, if the plan or issuer uses a defined formulary.

(4) UTILIZATION REVIEW ACTIVITIES.—A description of procedures used and requirements (including circumstances, timeframes, and appeals rights) under any utilization review program under

sections 101 and 102, including any drug formulary program under section 118.

(5) EXTERNAL APPEALS INFORMATION.—Aggregate information on the number and outcomes of external medical reviews, relative to the sample size (such as the number of covered lives) under the plan or under the coverage of the issuer.

(d) MANNER OF DISCLOSURE.—The information described in this section shall be disclosed in an accessible medium and format that is calculated to be understood by a participant or enrollee.

(e) RULES OF CONSTRUCTION.—Nothing in this section shall be construed to prohibit a group health plan, or a health insurance issuer in connection with health insurance coverage, from—

(1) distributing any other additional information determined by the plan or issuer to be important or necessary in assisting participants, beneficiaries, and enrollees in the selection of a health plan or health insurance coverage; and

(2) complying with the provisions of this section by providing information in brochures, through the Internet or other electronic media, or through other similar means, so long as—

(A) the disclosure of such information in such form is in accordance with requirements as the appropriate Secretary may impose, and

(B) in connection with any such disclosure of information through the Internet or other electronic media—

(i) the recipient has affirmatively consented to the disclosure of such information in such form,

(ii) the recipient is capable of accessing the information so disclosed on the recipient's individual workstation or at the recipient's home,

(iii) the recipient retains an ongoing right to receive paper disclosure of such information and receives, in advance of any attempt at disclosure of such information to him or her through the Internet or other electronic media, notice in printed form of such ongoing right and of the proper software required to view information so disclosed, and

(iv) the plan administrator appropriately ensures that the intended recipient is receiving the information so disclosed

and provides the information in printed form if the information is not received.

SEC. 122. GENETIC INFORMATION.

(a) DEFINITIONS.—In this section:

(1) FAMILY MEMBER.—The term ''family member'' means with respect to an individual—

(A) the spouse of the individual;

(B) a dependent child of the individual, including a child who is born to or placed for adoption with the individual; and

(C) all other individuals related by blood to the individual or the spouse or child described in subparagraph (A) or (B).

(2) GENETIC INFORMATION.—The term ''genetic information'' means information about genes, gene products, or inherited characteristics that may derive from an individual or a family member of such individual (including information about a request for or the receipt of genetic services by such individual or a family member of such individual).

(3) GENETIC SERVICES.—The term ''genetic services'' means health services, including genetic tests, provided to obtain, assess, or interpret genetic information for diagnostic and therapeutic purposes, and for genetic education and counseling.

(4) GENETIC TEST.—The term ''genetic test'' means the analysis of human DNA, RNA, chromosomes, proteins, and certain metabolites, including analysis of genotypes, mutations, phenotypes, or karyotypes, for the purpose of predicting risk of disease in asymptomatic or undiagnosed individuals. Such term does not include a physical test, such as a chemical, blood, or urine analysis of an individual, including a cholesterol test, or a physical exam of the individual, in order to detect symptoms, clinical signs, or a diagnosis of disease.

(5) GROUP HEALTH PLAN, HEALTH INSURANCE ISSUER.—The terms ''group health plan'' and ''health insurance issuer'' include a third party administrator or other person acting for or on behalf of such plan or issuer.

(6) PREDICTIVE GENETIC INFORMATION.—

(A) IN GENERAL.—The term ''predictive genetic information'' means—

(i) information about an individual's genetic tests;

(ii) information about genetic tests of family members of the individual; or

(iii) information about the occurrence of a disease or disorder in family members.

(B) LIMITATIONS.—The term ''predictive genetic information'' shall not include—

(i) information about the sex or age of the individual;

(ii) information about chemical, blood, or urine analyses of the individual, including cholesterol tests, unless these analyses are genetic tests, as defined in paragraph (4); or

(iii) information about physical exams of the individual, and other information relevant to determining the current health status of the individual.

(b) NONDISCRIMINATION.—

(1) NO ENROLLMENT RESTRICTION FOR GENETIC SERVICES.—A group health plan, and a health insurance issuer offering health insurance coverage, shall not establish rules for eligibility (including continued eligibility) of any individual to enroll under the terms of the plan or coverage based on genetic information (or information about a request for or the receipt of genetic services by such individual or a family member of such individual) in relation to the individual or a dependent of the individual.

(2) NO DISCRIMINATION IN RATE BASED ON PREDICTIVE GENETIC INFORMATION.—A group health plan, and a health insurance issuer offering health insurance coverage, shall not deny eligibility or adjust premium or contribution rates on the basis of predictive genetic information concerning an individual (or information about a request for or the receipt of genetic services by such individual or a family member of such individual).

(c) COLLECTION OF PREDICTIVE GENETIC INFORMATION.—

(1) LIMITATION ON REQUESTING OR REQUIRING PREDICTIVE GENETIC INFORMATION.—Except as provided in paragraph (2), a group health plan, or a health insurance issuer offering health insurance coverage, shall not request or require predictive genetic information concerning an individual or a family member of the individual (including information about a request for or the receipt of genetic services by such individual or a family member of such individual).

(2) INFORMATION NEEDED FOR DIAGNOSIS, TREATMENT, OR PAYMENT.—

(A) IN GENERAL.—Notwithstanding paragraph (1), a group health plan, or a health in-

surance issuer offering health insurance coverage, that provides health care items and services to an individual or dependent may request (but may not require) that such individual or dependent disclose, or authorize the collection or disclosure of, predictive genetic information for purposes of diagnosis, treatment, or payment relating to the provision of health care items and services to such individual or dependent.

(B) NOTICE OF CONFIDENTIALITY PRACTICES AND DESCRIPTION OF SAFEGUARDS.—As a part of a request under subparagraph (A), the group health plan, or a health insurance issuer offering health insurance coverage, shall provide to the individual or dependent a description of the procedures in place to safeguard the confidentiality, as described in subsection (d), of such predictive genetic information.

(d) CONFIDENTIALITY WITH RESPECT TO PREDICTIVE GENETIC INFORMATION.—

(1) NOTICE OF CONFIDENTIALITY PRACTICES.—A group health plan, or a health insurance issuer offering health insurance coverage, shall post

or provide, in writing and in a clear and conspicuous manner, notice of the plan or issuer's confidentiality practices, that shall include—

(A) a description of an individual's rights with respect to predictive genetic information;

(B) the procedures established by the plan or issuer for the exercise of the individual's rights; and

(C) a description of the right to obtain a copy of the notice of the confidentiality practices required under this subsection.

(2) ESTABLISHMENT OF SAFEGUARDS.—A group health plan, or a health insurance issuer offering health insurance coverage, shall establish and maintain appropriate administrative, technical, and physical safeguards to protect the confidentiality, security, accuracy, and integrity of predictive genetic information created, received, obtained, maintained, used, transmitted, or disposed of by such plan or issuer.

(3) COMPLIANCE WITH CERTAIN STANDARDS.—With respect to the establishment and maintenance of safeguards under this subsection or subsection (c)(2)(B), a group health plan, or a health insurance issuer offering health insurance coverage, shall be

deemed to be in compliance with such subsections if such plan or issuer is in compliance with the standards promulgated by the Secretary of Health and Human Services under—

(A) part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.); or

(B) section 264(c) of Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note).

(e) SPECIAL RULE IN CASE OF GENETIC INFORMATION.—With respect to health insurance coverage offered by a health insurance issuer, the provisions of this section relating to genetic information (including information about a request for or the receipt of genetic services by an individual or a family member of such individual) shall not be construed to supersede any provision of State law that establishes, implements, or continues in effect a standard, requirement, or remedy that more completely—

(1) protects the confidentiality of genetic information (including information about a request for or the receipt of genetic services by an individual or a family member of such individual) or the privacy of an individual or a family member of the individual with respect to genetic information (including information about a request for or the receipt of genetic

services by the individual or a family member of such individual); or

(2) prohibits discrimination on the basis of genetic information than does this section.

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 with respect to 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 a particular benefit or service 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 section 1842(c)(2) of the Social Security Act (42 U.S.C. 1395u(c)(2)).

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 es-

tablished 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) 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.

(2) 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.

(3) 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, except that such term includes a employee welfare benefit plan treated as a group health plan under section 732(d) of such Act or defined as such a plan under section 607(1) of such Act.

(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 ''non-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, 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) 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.

(10) TERMS AND CONDITIONS.—The term ''terms and conditions'' includes, with respect to a group health plan or health insurance coverage, requirements imposed under this title with respect to the plan or coverage.

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 Income Security Act of 1974 with respect to group health plans.

(3) CONSTRUCTION.—In applying this section, a State law that provides for equal access to, and availability of, all categories of licensed health care providers and services shall not be treated as preventing the application of any requirement of this title.

(b) APPLICATION OF SUBSTANTIALLY COMPLIANT STATE LAWS.—

(1) IN GENERAL.—In the case of a State law that imposes, with respect to health insurance coverage offered by a health insurance issuer and with respect to a group health plan that is a non-Federal governmental plan, a requirement that substantially complies (within the meaning of subsection (c)) with a patient protection requirement (as defined in paragraph (3)) and does not prevent the application of other requirements under this Act (except in the case of other substantially compliant requirements), in applying the requirements of this title under section 2707 and 2753 (as applicable) of the Public Health Service Act (as added by title II), subject to subsection (a)(2)—

(A) the State law shall not be treated as being superseded under subsection (a); and

(B) the State law shall apply instead of the patient protection requirement otherwise applicable with respect to health insurance coverage and non-Federal governmental plans.

(2) LIMITATION.—In the case of a group health plan covered under title I of the Employee Retirement Income Security Act of 1974, paragraph (1)

shall be construed to apply only with respect to the health insurance coverage (if any) offered in connection with the plan.

(3) DEFINITIONS.—In this section:

(A) PATIENT PROTECTION REQUIREMENT.—The term ''patient protection requirement'' means a requirement under this title, and includes (as a single requirement) a group or related set of requirements under a section or similar unit under this title.

(B) SUBSTANTIALLY COMPLIANT.—The terms ''substantially compliant'', substantially complies'', or ''substantial compliance'' with respect to a State law, mean that the State law has the same or similar features as the patient protection requirements and has a similar effect.

(c) DETERMINATIONS OF SUBSTANTIAL COMPLIANCE.—

(1) CERTIFICATION BY STATES.—A State may submit to the Secretary a certification that a State law provides for patient protections that are at least substantially compliant with one or more patient protection requirements. Such certification shall be accompanied by such information as may be re-

quired to permit the Secretary to make the determination described in paragraph (2)(A).

(2) REVIEW.—

(A) IN GENERAL.—The Secretary shall promptly review a certification submitted under paragraph (1) with respect to a State law to determine if the State law substantially complies with the patient protection requirement (or requirements) to which the law relates.

(B) APPROVAL DEADLINES.—

(i) INITIAL REVIEW.—Such a certification is considered approved unless the Secretary notifies the State in writing, within 90 days after the date of receipt of the certification, that the certification is disapproved (and the reasons for disapproval) or that specified additional information is needed to make the determination described in subparagraph (A).

(ii) ADDITIONAL INFORMATION.—With respect to a State that has been notified by the Secretary under clause (i) that specified additional information is needed to make the determination described in subparagraph (A), the Secretary shall

make the determination within 60 days after the date on which such specified additional information is received by the Secretary.

(3) APPROVAL.—

(A) IN GENERAL.—The Secretary shall approve a certification under paragraph (1) unless—

(i) the State fails to provide sufficient information to enable the Secretary to make a determination under paragraph (2)(A); or

(ii) the Secretary determines that the State law involved does not provide for patient protections that substantially comply with the patient protection requirement (or requirements) to which the law relates.

(B) STATE CHALLENGE.—A State that has a certification disapproved by the Secretary under subparagraph (A) may challenge such disapproval in the appropriate United States district court.

(C) DEFERENCE TO STATES.—With respect to a certification submitted under paragraph (1), the Secretary shall give deference to

the State's interpretation of the State law involved and the compliance of the law with a patient protection requirement.

(D) PUBLIC NOTIFICATION.—The Secretary shall—

(i) provide a State with a notice of the determination to approve or disapprove a certification under this paragraph;

(ii) promptly publish in the Federal Register a notice that a State has submitted a certification under paragraph (1);

(iii) promptly publish in the Federal Register the notice described in clause (i) with respect to the State; and

(iv) annually publish the status of all States with respect to certifications.

(4) CONSTRUCTION.—Nothing in this subsection shall be construed as preventing the certification (and approval of certification) of a State law under this subsection solely because it provides for greater protections for patients than those protections otherwise required to establish substantial compliance.

(5) PETITIONS.—

(A) PETITION PROCESS.—Effective on the date on which the provisions of this Act become effective, as provided for in section 501, a group health plan, health insurance issuer, participant, beneficiary, or enrollee may submit a petition to the Secretary for an advisory opinion as to whether or not a standard or requirement under a State law applicable to the plan, issuer, participant, beneficiary, or enrollee that is not the subject of a certification under this subsection, is superseded under subsection (a)(1) because such standard or requirement prevents the application of a requirement of this title.

(B) OPINION.—The Secretary shall issue an advisory opinion with respect to a petition submitted under subparagraph (A) within the 60-day period beginning on the date on which such petition is submitted.

(d) 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 under the terms of such a plan or coverage, other than those provided under the terms and conditions 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 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 that agrees 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. 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 section 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.

SEC. 156. INCORPORATION INTO PLAN OR COVERAGE DOCUMENTS.

The requirements of this title with respect to a group health plan or health insurance coverage are deemed to be incorporated into, and made a part of, such plan or the policy, certificate, or contract providing such coverage and are enforceable under law as if directly included in the documentation of such plan or such policy, certificate, or contract.

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.

''Each group health plan shall comply with patient protection requirements under title I of the Bipartisan Patient Protection Act, 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) 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.

''Each health insurance issuer shall comply with patient protection requirements under title I of the Bipartisan Patient Protection Act with respect to individual health insurance coverage it offers, and such requirements shall be deemed to be incorporated into this subsection.''.

SEC. 203. COOPERATION BETWEEN FEDERAL AND STATE AUTHORITIES.

Part C of title XXVII of the Public Health Service Act (42 U.S.C. 300gg–91 et seq.) is amended by adding at the end the following:

"SEC. 2793. COOPERATION BETWEEN FEDERAL AND STATE AUTHORITIES.

''(a) AGREEMENT WITH STATES.—A State may enter into an agreement with the Secretary for the delegation to the State of some or all of the Secretary's authority under this title to enforce the requirements applicable under title I of the Bipartisan Patient Protection Act with respect to health insurance coverage offered by a health insurance issuer and with respect to a group health plan that is a non-Federal governmental plan.

''(b) DELEGATIONS.—Any department, agency, or instrumentality of a State to which authority is delegated pursuant to an agreement entered into under this section may, if authorized under State law and to the extent consistent with such agreement, exercise the powers of the Secretary under this title which relate to such authority.''.

SEC. 204. ELIMINATION OF OPTION OF NON-FEDERAL GOVERNMENTAL PLANS TO BE EXCEPTED FROM REQUIREMENTS CONCERNING GENETIC INFORMATION.

Section 2721(b)(2) of the Public Health Service Act (42 U.S. C. 300gg–21(b)(2)) is amended—

(1) in subparagraph (A), by striking ''If the plan sponsor'' and inserting ''Except as provided in subparagraph (D), if the plan sponsor''; and

(2) by adding at the end the following:

''(D) ELECTION NOT APPLICABLE TO REQUIREMENTS CONCERNING GENETIC INFORMATION.—The election described in subparagraph (A) shall not be available with respect to the provisions of subsections (b), (c), and (d) of section 122 of the Bipartisan Patient Protection Act and the provisions of section 2702(b) to the extent that the subsections and section apply to genetic information (or information

about a request for or the receipt of genetic services by an individual or a family member of such individual).''.

TITLE III—APPLICATION OF PATIENT PROTECTION STANDARDS TO FEDERAL HEALTH CARE PROGRAMS

SEC. 301. APPLICATION OF PATIENT PROTECTION STANDARDS TO FEDERAL HEALTH CARE PROGRAMS.

(a) APPLICATION OF STANDARDS.—

(1) IN GENERAL.—Each Federal health care program shall comply with the patient protection requirements under title I, and such requirements shall be deemed to be incorporated into this section.

(2) CAUSE OF ACTION RELATING TO PROVISION OF HEALTH BENEFITS.—Any individual who receives a health care item or service under a Federal health care program shall have a cause of action against the Federal Government under sections 502(n) and 514(d) of the Employee Retirement Income Security Act of 1974, and the provisions of such sections shall be deemed to be incorporated into this section.

(3) RULES OF CONSTRUCTION.—For purposes of this subsection—

(A) each Federal health care program shall be deemed to be a group health plan;

(B) the Federal Government shall be deemed to be the plan sponsor of each Federal health care program; and

(C) each individual eligible for benefits under a Federal health care program shall be deemed to be a participant, beneficiary, or enrollee under that program.

(b) FEDERAL HEALTH CARE PROGRAM DEFINED.—In this section, the term ''Federal health care program'' has the meaning given that term under section 1128B(f) of the Social Security Act (42 U.S.C. 1320a–7b) except that, for purposes of this section, such term includes the Federal employees health benefits program established under chapter 89 of title 5, United States Code.

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

SEC. 401. 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 Patient Protection Act (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 pro-

vides 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 Patient Protection Act 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 111 (relating to consumer choice option).

"(B) Section 112 (relating to choice of health care professional).

"(C) Section 113 (relating to access to emergency care).

"(D) Section 114 (relating to timely access to specialists).

"(E) Section 115 (relating to patient access to obstetrical and gynecological care).

"(F) Section 116 (relating to access to pediatric care).

"(G) Section 117 (relating to continuity of care), but only insofar as a replacement issuer assumes the obligation for continuity of care.

''(H) Section 118 (relating to access to needed prescription drugs).

''(I) Section 119 (relating to coverage for individuals participating in approved clinical trials).

''(J) Section 120 (relating to required coverage for minimum hospital stay for mastectomies and lymph node dissections for the treatment of breast cancer and coverage for secondary consultations).

''(K) Section 134 (relating to payment of claims).

''(2) INFORMATION.—With respect to information required to be provided or made available under section 121 of the Bipartisan Patient Protection Act, 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) INTERNAL APPEALS.—With respect to the internal appeals process required to be established under section 103 of such Act, 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 104 of such Act, 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 of the Bipartisan Patient Protection Act, 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) TREATMENT OF SUBSTANTIALLY COMPLIANT STATE LAWS.—For purposes of applying this subsection, any reference in this subsection to a requirement in a section or other provision in the Bipartisan Patient Protection Act with respect to a health insurance issuer is deemed to include a reference to a requirement under a State law that substantially complies (as determined under section

152(c) of such Act) with the requirement in such section or other provisions.

''(8) APPLICATION TO CERTAIN PROHIBITIONS AGAINST RETALIATION.—With respect to compliance with the requirements of section 135(b)(1) of the Bipartisan Patient Protection Act, 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 Patient Protection Act 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 shall issue regulations to coordinate the requirements on group health plans and health insurance issuers under this section with the requirements imposed under the other provisions of this title. In order to reduce duplication and clarify the rights of participants and beneficiaries with respect to information that is required to be provided, such regulations shall coordinate the information disclosure requirements under section 121 of the Bipartisan Patient Protection Act with the reporting and disclosure requirements imposed under part 1, so long as such coordination does not result in any reduction in the information that would otherwise be provided to participants and beneficiaries.''.

(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 Patient Protection Act, and compliance with regulations promulgated by the Secretary, 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. 402. AVAILABILITY OF CIVIL REMEDIES.

(a) AVAILABILITY OF FEDERAL CIVIL REMEDIES IN CASES NOT INVOLVING MEDICALLY REVIEWABLE DECISIONS.—

(1) 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 subsections:

''(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, issuer, or plan sponsor upon consideration of a claim

for benefits of a participant or beneficiary under section 102 of the Bipartisan Patient Protection Act of 2004 (relating to procedures for initial claims for benefits and prior authorization determinations) or upon review of a denial of such a claim under section 103 of such Act (relating to internal appeal of a denial of a claim for benefits), fails to exercise ordinary care in making a decision—

''(i) regarding whether an item or service is covered under the terms and conditions of the plan or coverage,

''(ii) regarding whether an individual is a participant or beneficiary who is enrolled under the terms and conditions of the plan or coverage (including the applicability of any waiting period under the plan or coverage), or

''(iii) as to the application of cost-sharing requirements or the application of a specific exclusion or express limitation on the amount, duration, or scope of coverage of items or services under the terms and conditions of the plan or coverage, and

"(B) such failure is a proximate cause of personal injury to, or the death of, the participant or beneficiary—

such plan, plan sponsor or issuer shall be liable to the participant or beneficiary (or the estate of such participant or beneficiary) for economic and non-economic damages (but not exemplary or punitive damages) in connection with such personal injury or death.

"(2) CAUSE OF ACTION MUST NOT INVOLVE MEDICALLY REVIEWABLE DECISION.—

"(A) IN GENERAL.—A cause of action is established under paragraph (1)(A) only if the decision referred to in paragraph (1)(A) does not include a medically reviewable decision.

"(B) MEDICALLY REVIEWABLE DECISION.—For purposes of this subsection, the term 'medically reviewable decision' means a denial of a claim for benefits under the plan which is described in section 104(d)(2) of the Bipartisan Patient Protection Act of 2004 (relating to medically reviewable decisions).

"(3) LIMITATION REGARDING CERTAIN TYPES OF ACTIONS SAVED FROM PREEMPTION OF STATE LAW.—A cause of action is not established under

paragraph (1)(A) in connection with a failure described in paragraph (1)(A) to the extent that a cause of action under State law (as defined in section 514(c)) for such failure would not be preempted under section 514.

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

''(A) ORDINARY CARE.—The term 'ordinary care' means, with respect to a determination on a claim for benefits, that degree of care, skill, and diligence that a reasonable and prudent individual would exercise in making a fair determination on a claim for benefits of like kind to the claims involved.

''(B) PERSONAL INJURY.—The term 'personal injury' means a physical injury and includes an injury arising out of the treatment (or failure to treat) a mental illness or disease.

''(C) CLAIM FOR BENEFITS; DENIAL.—The terms 'claim for benefits' and 'denial of a claim for benefits' have the meanings provided such terms in section 102(e) of the Bipartisan Patient Protection Act of 2004.

''(D) TERMS AND CONDITIONS.—The term 'terms and conditions' includes, with respect to

a group health plan or health insurance coverage, requirements imposed under title I of the Bipartisan Patient Protection Act of 2004.

''(E) GROUP HEALTH PLAN AND OTHER RELATED TERMS.—The provisions of sections 732(d) and 733 apply for purposes of this subsection in the same manner as they apply for purposes of part 7, except that the term 'group health plan' includes a group health plan (as defined in section 607(1)).

''(5) EXCLUSION OF EMPLOYERS AND OTHER PLAN SPONSORS.—

''(A) CAUSES OF ACTION AGAINST EMPLOYERS AND PLAN SPONSORS PRECLUDED.—Subject to subparagraph (B), paragraph (1)(A) does not authorize a cause of action against an employer or other plan sponsor maintaining the plan (or against an employee of such an employer or sponsor acting within the scope of employment).

''(B) CERTAIN CAUSES OF ACTION PERMITTED.—Notwithstanding subparagraph (A), a cause of action may arise against an employer or other plan sponsor (or against an employee of such an employer or sponsor acting within

the scope of employment) under paragraph (1)(A), to the extent there was direct participation by the employer or other plan sponsor (or employee) in the decision of the plan under section 102 of the Bipartisan Patient Protection Act of 2004 upon consideration of a claim for benefits or under section 103 of such Act upon review of a denial of a claim for benefits.

''(C) DIRECT PARTICIPATION.—

''(i) IN GENERAL.—For purposes of subparagraph (B), the term 'direct participation' means, in connection with a decision described in paragraph (1)(A), the actual making of such decision or the actual exercise of control in making such decision.

''(ii) RULES OF CONSTRUCTION.—For purposes of clause (i), the employer or plan sponsor (or employee) shall not be construed to be engaged in direct participation because of any form of decisionmaking or other conduct that is merely collateral or precedent to the decision described in paragraph (1)(A) on a particular claim for benefits of a 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 process of creating, continuing, modifying, or terminating the plan or any benefit under the plan, if such process was not substantially focused solely on the particular situation of the participant or beneficiary referred to in paragraph (1)(A); and

''(IV) any participation by the employer or other plan sponsor (or employee) in the design of any benefit

under the plan, including the amount of copayment and limits connected with such benefit.

''(iii) IRRELEVANCE OF CERTAIN COLLATERAL EFFORTS MADE BY EMPLOYER OR PLAN SPONSOR.—For purposes of this subparagraph, an employer or plan sponsor shall not be treated as engaged in direct participation in a decision with respect to any claim for benefits or denial thereof in the case of any particular participant or beneficiary solely by reason of—

''(I) any efforts that may have been made by the employer or plan sponsor to advocate for authorization of coverage for that or any other participant or beneficiary (or any group of participants or beneficiaries), or

''(II) any provision that may have been made by the employer or plan sponsor for benefits which are not covered under the terms and conditions of the plan for that or any other participant or beneficiary (or

any group of participants or beneficiaries).

''(D) APPLICATION TO CERTAIN PLANS.—

''(i) IN GENERAL.—Notwithstanding any other provision of this subsection, no group health plan described in clause (ii) shall be liable under paragraph (1) for the performance of, or the failure to perform, any non-medically reviewable duty under the plan.

''(ii) DEFINITION.—A group health plan described in this clause is—

''(I) a group health plan that is self-insured and self administered by an employer (including an employee of such an employer acting within the scope of employment); or

''(II) a multiemployer plan as defined in section 3(37)(A) (including an employee of a contributing employer or of the plan, or a fiduciary of the plan, acting within the scope of employment or fiduciary responsibility) that is self-insured and self-administered.

''(6) EXCLUSION OF PHYSICIANS AND OTHER HEALTH CARE PROFESSIONALS.—

''(A) IN GENERAL.—No treating physician or other treating health care professional of the participant or beneficiary, and no person acting under the direction of such a physician or health care professional, shall be liable under paragraph (1) for the performance of, or the failure to perform, any non-medically reviewable duty of the plan, the plan sponsor, or any health insurance issuer offering health insurance coverage in connection with the plan.

''(B) DEFINITIONS.—For purposes of subparagraph (A)—

''(i) 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.

''(ii) NON-MEDICALLY REVIEWABLE DUTY.—The term 'non-medically reviewable duty' means a duty the discharge of

which does not include the making of a medically reviewable decision.

''(7) EXCLUSION OF HOSPITALS.—No treating hospital of the participant or beneficiary shall be liable under paragraph (1) for the performance of, or the failure to perform, any non-medically reviewable duty (as defined in paragraph (6)(B)(ii)) of the plan, the plan sponsor, or any health insurance issuer offering health insurance coverage in connection with the plan.

''(8) RULE OF CONSTRUCTION RELATING TO EXCLUSION FROM LIABILITY OF PHYSICIANS, HEALTH CARE PROFESSIONALS, AND HOSPITALS.—Nothing in paragraph (6) or (7) shall be construed to limit the liability (whether direct or vicarious) of the plan, the plan sponsor, or any health insurance issuer offering health insurance coverage in connection with the plan.

''(9) REQUIREMENT OF EXHAUSTION.—

''(A) IN GENERAL.—A cause of action may not be brought under paragraph (1) in connection with any denial of a claim for benefits of any individual until all administrative processes under sections 102 and 103 of the Bipartisan

Patient Protection Act of 2004 (if applicable) have been exhausted.

''(B) EXCEPTION FOR NEEDED CARE.—A participant or beneficiary may seek relief exclusively in Federal court under subsection 502(a)(1)(B) prior to the exhaustion of administrative remedies under sections 102, 103, or 104 of the Bipartisan Patient Protection Act (as required under subparagraph (A)) if it is demonstrated to the court that the exhaustion of such remedies would cause irreparable harm to the health of the participant or beneficiary. Notwithstanding the awarding of relief under subsection 502(a)(1)(B) pursuant to this subparagraph, no relief shall be available as a result of, or arising under, paragraph (1)(A) or paragraph (10)(B), with respect to a participant or beneficiary, unless the requirements of subparagraph (A) are met.

''(C) RECEIPT OF BENEFITS DURING APPEALS PROCESS.—Receipt by the participant or beneficiary of the benefits involved in the claim for benefits during the pendency of any administrative processes referred to in subparagraph

(A) or of any action commenced under this subsection—

''(i) shall not preclude continuation of all such administrative processes to their conclusion if so moved by any party, and

''(ii) shall not preclude any liability under subsection (a)(1)(C) and this subsection in connection with such claim.

The court in any action commenced under this subsection shall take into account any receipt of benefits during such administrative processes or such action in determining the amount of the damages awarded.

''(D) ADMISSIBLE.—Any determination made by a reviewer in an administrative proceeding under section 103 of the Bipartisan Patient Protection Act of 2004 shall be admissible in any Federal court proceeding and shall be presented to the trier of fact.

''(10) STATUTORY DAMAGES.—

''(A) IN GENERAL.—The remedies set forth in this subsection (n) shall be the exclusive remedies for causes of action brought under this subsection.

"(B) ASSESSMENT OF CIVIL PENALTIES.—In addition to the remedies provided for in paragraph (1) (relating to the failure to provide contract benefits in accordance with the plan), a civil assessment, in an amount not to exceed $5,000,000, payable to the claimant may be awarded in any action under such paragraph if the claimant establishes by clear and convincing evidence that the alleged conduct carried out by the defendant demonstrated bad faith and flagrant disregard for the rights of the participant or beneficiary under the plan and was a proximate cause of the personal injury or death that is the subject of the claim.

"(11) LIMITATION ON ATTORNEYS' FEES.—

"(A) IN GENERAL.—Notwithstanding any other provision of law, or any arrangement, agreement, or contract regarding an attorney's fee, the amount of an attorney's contingency fee allowable for a cause of action brought pursuant to this subsection shall not exceed ⅓ of the total amount of the plaintiff's recovery (not including the reimbursement of actual out-of-pocket expenses of the attorney).

"(B) DETERMINATION BY DISTRICT COURT.—The last Federal district court in which the action was pending upon the final disposition, including all appeals, of the action shall have jurisdiction to review the attorney's fee to ensure that the fee is a reasonable one.

"(12) LIMITATION OF ACTION.—Paragraph (1) shall not apply in connection with any action commenced after 3 years after the later of—

"(A) the date on which the plaintiff first knew, or reasonably should have known, of the personal injury or death resulting from the failure described in paragraph (1), or

"(B) the date as of which the requirements of paragraph (9) are first met.

"(13) TOLLING PROVISION.—The statute of limitations for any cause of action arising under State law relating to a denial of a claim for benefits that is the subject of an action brought in Federal court under this subsection shall be tolled until such time as the Federal court makes a final disposition, including all appeals, of whether such claim should properly be within the jurisdiction of the Federal court. The tolling period shall be determined by the

applicable Federal or State law, whichever period is greater.

''(14) PURCHASE OF INSURANCE TO COVER LIABILITY.—Nothing in section 410 shall be construed to preclude the purchase by a group health plan of insurance to cover any liability or losses arising under a cause of action under subsection (a)(1)(C) and this subsection.

''(15) EXCLUSION OF DIRECTED RECORDKEEPERS.—

''(A) IN GENERAL.—Subject to subparagraph (C), paragraph (1) shall not apply with respect to a directed recordkeeper in connection with a group health plan.

''(B) DIRECTED RECORDKEEPER.—For purposes of this paragraph, the term 'directed recordkeeper' means, in connection with a group health plan, a person engaged in directed recordkeeping activities pursuant to the specific instructions of the plan or the employer or other plan sponsor, including the distribution of enrollment information and distribution of disclosure materials under this Act or title I of the Bipartisan Patient Protection Act of 2004 and

whose duties do not include making decisions on claims for benefits.

''(C) LIMITATION.—Subparagraph (A) does not apply in connection with any directed recordkeeper to the extent that the directed recordkeeper fails to follow the specific instruction of the plan or the employer or other plan sponsor.

''(16) EXCLUSION OF HEALTH INSURANCE AGENTS.—Paragraph (1) does not apply with respect to a person whose sole involvement with the group health plan is providing advice or administrative services to the employer or other plan sponsor relating to the selection of health insurance coverage offered in connection with the plan.

''(17) NO EFFECT ON STATE LAW.—No provision of State law (as defined in section 514(c)(1)) shall be treated as superseded or otherwise altered, amended, modified, invalidated, or impaired by reason of the provisions of subsection (a)(1)(C) and this subsection.

''(18) RELIEF FROM LIABILITY FOR EMPLOYER OR OTHER PLAN SPONSOR BY MEANS OF DESIGNATED DECISIONMAKER.—

''(A) IN GENERAL.—Notwithstanding the direct participation (as defined in paragraph (5)(C)(i)) of an employer or plan sponsor, in any case in which there is deemed to be a designated decisionmaker under subparagraph (B) that meets the requirements of subsection (o)(1) for an employer or other plan sponsor—

''(i) all liability of such employer or plan sponsor (and any employee thereof acting within the scope of employment) under this subsection in connection with any participant or beneficiary shall be transferred to, and assumed by, the designated decisionmaker, and

''(ii) with respect to such liability, the designated decisionmaker shall be substituted for the employer or plan sponsor (or employee) in the action and may not raise any defense that the employer or plan sponsor (or employee) could not raise if such a decisionmaker were not so deemed.

''(B) AUTOMATIC DESIGNATION.—A health insurance issuer shall be deemed to be a designated decisionmaker for purposes of subparagraph (A) with respect to the participants and

beneficiaries of an employer or plan sponsor, whether or not the employer or plan sponsor makes such a designation, and shall be deemed to have assumed unconditionally all liability of the employer or plan sponsor under such designation in accordance with subsection (o), unless the employer or plan sponsor affirmatively enters into a contract to prevent the service of the designated decisionmaker.

''(19) PREVIOUSLY PROVIDED SERVICES.—

''(A) IN GENERAL.—Except as provided in this paragraph, a cause of action shall not arise under paragraph (1) where the denial involved relates to an item or service that has already been fully provided to the participant or beneficiary under the plan or coverage and the claim relates solely to the subsequent denial of payment for the provision of such item or service.

''(B) EXCEPTION.—Nothing in subparagraph (A) shall be construed to—

''(i) prohibit a cause of action under paragraph (1) where the nonpayment involved results in the participant or beneficiary being unable to receive further items or services that are directly related

to the item or service involved in the denial referred to in subparagraph (A) or that are part of a continuing treatment or series of procedures;

''(ii) prohibit a cause of action under paragraph (1) relating to quality of care; or

''(iii) limit liability that otherwise would arise from the provision of the item or services or the performance of a medical procedure.

''(20) EXEMPTION FROM PERSONAL LIABILITY FOR INDIVIDUAL MEMBERS OF BOARDS OF DIRECTORS, JOINT BOARDS OF TRUSTEES, ETC.—Any individual who is—

''(A) a member of a board of directors of an employer or plan sponsor; or

''(B) a member of an association, committee, employee organization, joint board of trustees, or other similar group of representatives of the entities that are the plan sponsor of plan maintained by two or more employers and one or more employee organizations;

shall not be personally liable under this subsection for conduct that is within the scope of employment

of the individuals unless the individual acts in a fraudulent manner for personal enrichment.

''(o) REQUIREMENTS FOR DESIGNATED DECISION-MAKERS OF GROUP HEALTH

''(1) IN GENERAL.—For purposes of subsection (n)(18) and section 514(d)(9), a designated decision-maker meets the requirements of this paragraph with respect to any participant or beneficiary if—

''(A) such designation is in such form as may be prescribed in regulations of the Secretary,

''(B) the designated decisionmaker—

''(i) meets the requirements of paragraph (2),

''(ii) assumes unconditionally all liability of the employer or plan sponsor involved (and any employee thereof acting within the scope of employment) either arising under subsection (n) or arising in a cause of action permitted under section 514(d) in connection with actions (and failures to act) of the employer or plan sponsor (or employee) occurring during the period in which the designation under subsection (n)(18) or section 514(d)(9) is in

effect relating to such participant and beneficiary,

''(iii) agrees to be substituted for the employer or plan sponsor (or employee) in the action and not to raise any defense with respect to such liability that the employer or plan sponsor (or employee) may not raise, and

''(iv) where paragraph (2)(B) applies, assumes unconditionally the exclusive authority under the group health plan to make medically reviewable decisions under the plan with respect to such participant or beneficiary, and

''(C) the designated decisionmaker and the participants and beneficiaries for whom the decisionmaker has assumed liability are identified in the written instrument required under section 402(a) and as required under section 121(b)(19) of the Bipartisan Patient Protection Act.

Any liability assumed by a designated decisionmaker pursuant to this subsection shall be in addition to any liability that it may otherwise have under applicable law.

''(2) QUALIFICATIONS FOR DESIGNATED DECISIONMAKERS.—

''(A) IN GENERAL.—Subject to subparagraph (B), an entity is qualified under this paragraph to serve as a designated decisionmaker with respect to a group health plan if the entity has the ability to assume the liability described in paragraph (1) with respect to participants and beneficiaries under such plan, including requirements relating to the financial obligation for timely satisfying the assumed liability, and maintains with the plan sponsor and the Secretary certification of such ability. Such certification shall be provided to the plan sponsor or named fiduciary and to the Secretary upon designation under subsection (n)(18)(B) or section 517(d)(9)(B) and not less frequently than annually thereafter, or if such designation constitutes a multiyear arrangement, in conjunction with the renewal of the arrangement.

''(B) SPECIAL QUALIFICATION IN THE CASE OF CERTAIN REVIEWABLE DECISIONS.—In the case of a group health plan that provides benefits consisting of medical care to a participant or beneficiary only through health insur-

ance coverage offered by a single health insurance issue, such issuer is the only entity that may be qualified under this paragraph to serve as a designated decisionmaker with respect to such participant or beneficiary, and shall serve as the designated decisionmaker unless the employer or other plan sponsor acts affirmatively to prevent such service.

''(3) REQUIREMENTS RELATING TO FINANCIAL OBLIGATIONS.—For purposes of paragraph (2)(A), the requirements relating to the financial obligation of an entity for liability shall include—

''(A) coverage of such entity under an insurance policy or other arrangement, secured and maintained by such entity, to effectively insure such entity against losses arising from professional liability claims, including those arising from its service as a designated decisionmaker under this part; or

''(B) evidence of minimum capital and surplus levels that are maintained by such entity to cover any losses as a result of liability arising from its service as a designated decisionmaker under this part.

The appropriate amounts of liability insurance and minimum capital and surplus levels for purposes of subparagraphs (A) and (B) shall be determined by an actuary using sound actuarial principles and accounting practices pursuant to established guidelines of the American Academy of Actuaries and in accordance with such regulations as the Secretary may prescribe and shall be maintained throughout the term for which the designation is in effect. The provisions of this paragraph shall not apply in the case of a designated decisionmaker that is a group health plan, plan sponsor, or health insurance issuer and that is regulated under Federal law or a State financial solvency law.

''(4) LIMITATION ON APPOINTMENT OF TREATING PHYSICIANS.—A treating physician who directly delivered the care, treatment, or provided the patient service that is the subject of a cause of action by a participant or beneficiary under subsection (n) or section 514(d) may not be designated as a designated decisionmaker under this subsection with respect to such participant or beneficiary.''.

(2) CONFORMING AMENDMENT.—Section 502(a)(1) of such Act (29 U.S.C. 1132(a)(1)) is amended—

(A) by striking ''or'' at the end of subparagraph (A);

(B) in subparagraph (B), by striking ''plan;'' and inserting ''plan, or''; and

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

''(C) for the relief provided for in subsection (n) of this section.''.

(b) RULES RELATING TO ERISA PREEMPTION.—Section 514 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1144) is amended—

(1) by redesignating subsection (d) as subsection (f); and

(2) by inserting after subsection (c) the following new subsections:

''(d) PREEMPTION NOT TO APPLY TO CAUSES OF ACTION UNDER STATE LAW INVOLVING MEDICALLY REVIEWABLE DECISION.—

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

''(A) IN GENERAL.—Except as provided in this subsection, nothing in this title (including section 502) shall be construed to supersede or otherwise alter, amend, modify, invalidate, or impair any cause of action under State law of

a participant or beneficiary under a group health plan (or the estate of such a participant or beneficiary) to recover damages resulting from personal injury or for wrongful death against any person if such cause of action arises by reason of a medically reviewable decision.

''(B) MEDICALLY REVIEWABLE DECISION.—For purposes of subparagraph (A), the term 'medically reviewable decision' means a denial of a claim for benefits under the plan which is described in section 104(d)(2) of the Bipartisan Patient Protection Act of 2004 (relating to medically reviewable decisions).

''(C) LIMITATION ON PUNITIVE DAMAGES.—

''(i) IN GENERAL.—Except as provided in clauses (ii) and (iii), with respect to a cause of action described in subparagraph (A) brought with respect to a participant or beneficiary, State law is superseded insofar as it provides any punitive, exemplary, or similar damages if, as of the time of the personal injury or death, all the requirements of the following sections

of the Bipartisan Patient Protection Act of 2004 were satisfied with respect to the participant or beneficiary:

"(I) Section 102 (relating to procedures for initial claims for benefits and prior authorization determinations).

"(II) Section 103 of such Act (relating to internal appeals of claims denials).

"(III) Section 104 of such Act (relating to independent external appeals procedures).

"(ii) EXCEPTION FOR CERTAIN ACTIONS FOR WRONGFUL DEATH.—Clause (i) shall not apply with respect to an action for wrongful death if the applicable State law provides (or has been construed to provide) for damages in such an action which are only punitive or exemplary in nature.

"(iii) EXCEPTION FOR WILLFUL OR WANTON DISREGARD FOR THE RIGHTS OR SAFETY OF OTHERS.—Clause (i) shall not apply with respect to any cause of action described in subparagraph (A) if, in such

action, the plaintiff establishes by clear and convincing evidence that conduct carried out by the defendant with willful or wanton disregard for the rights or safety of others was a proximate cause of the personal injury or wrongful death that is the subject of the action.

''(2) DEFINITIONS.—For purposes of this subsection and subsection (e)—

''(A) GROUP HEALTH PLAN AND OTHER RELATED TERMS.—The provisions of sections 732(d) and 733 apply for purposes of this subsection in the same manner as they apply for purposes of part 7, except that the term 'group health plan' includes a group health plan (as defined in section 607(1)).

''(B) PERSONAL INJURY.—The term 'personal injury' means a physical injury and includes an injury arising out of the treatment (or failure to treat) a mental illness or disease.

''(C) CLAIM FOR BENEFIT; DENIAL.—The terms 'claim for benefits' and 'denial of a claim for benefits' shall have the meaning provided such terms under section 102(e) of the Bipartisan Patient Protection Act of 2004.

''(3) EXCLUSION OF EMPLOYERS AND OTHER PLAN SPONSORS.—

''(A) CAUSES OF ACTION AGAINST EMPLOYERS AND PLAN SPONSORS PRECLUDED.—Subject to subparagraph (B), paragraph (1) does not apply with respect to—

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

''(ii) a right of recovery, indemnity, or contribution 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 to which paragraph (1) applies.

''(B) CERTAIN CAUSES OF ACTION PERMITTED.—Notwithstanding subparagraph (A), paragraph (1) applies with respect to any cause of action that is brought by a participant or beneficiary under a group health plan (or the estate of such a participant or beneficiary) to recover damages resulting from personal injury or for wrongful death against any employer or

other plan sponsor maintaining the plan (or against an employee of such an employer or sponsor acting within the scope of employment) if such cause of action arises by reason of a medically reviewable decision, to the extent that there was direct participation by the employer or other plan sponsor (or employee) in the decision.

''(C) DIRECT PARTICIPATION.—

''(i) DIRECT PARTICIPATION IN DECISIONS.—For purposes of subparagraph (B), the term 'direct participation' means, in connection with a decision described in subparagraph (B), the actual making of such decision or the actual exercise of control in making such decision or in the conduct constituting the failure.

''(ii) RULES OF CONSTRUCTION.—For purposes of clause (i), the employer or plan sponsor (or employee) shall not be construed to be engaged in direct participation because of any form of decisionmaking or other conduct that is merely collateral or precedent to the decision described in subparagraph (B) on a particular claim for

benefits of a particular 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 process of creating, continuing, modifying, or terminating the plan or any benefit under the plan, if such process was not substantially focused solely on the particular situation of the participant or beneficiary referred to in paragraph (1)(A); and

''(IV) any participation by the employer or other plan sponsor (or employee) in the design of any benefit under the plan, including the amount of copayment and limits connected with such benefit.

''(iii) IRRELEVANCE OF CERTAIN COLLATERAL EFFORTS MADE BY EMPLOYER OR PLAN SPONSOR.—For purposes of this subparagraph, an employer or plan sponsor shall not be treated as engaged in direct participation in a decision with respect to any claim for benefits or denial thereof in the case of any particular participant or beneficiary solely by reason of—

''(I) any efforts that may have been made by the employer or plan sponsor to advocate for authorization of coverage for that or any other participant or beneficiary (or any group of participants or beneficiaries), or

''(II) any provision that may have been made by the employer or plan sponsor for benefits which are not covered under the terms and con-

ditions of the plan for that or any other participant or beneficiary (or any group of participants or beneficiaries).

''(4) REQUIREMENT OF EXHAUSTION.—

''(A) IN GENERAL.—Except as provided in subparagraph (D), a cause of action may not be brought under paragraph (1) in connection with any denial of a claim for benefits of any individual until all administrative processes under sections 102, 103, and 104 of the Bipartisan Patient Protection Act of 2004 (if applicable) have been exhausted.

''(B) LATE MANIFESTATION OF INJURY.—

''(i) IN GENERAL.—A participant or beneficiary shall not be precluded from pursuing a review under section 104 of the Bipartisan Patient Protection Act regarding an injury that such participant or beneficiary has experienced if the external review entity first determines that the injury of such participant or beneficiary is a late manifestation of an earlier injury.

''(ii) DEFINITION.—In this subparagraph, the term 'late manifestation of an

earlier injury' means an injury sustained by the participant or beneficiary which was not known, and should not have been known, by such participant or beneficiary by the latest date that the requirements of subparagraph (A) should have been met regarding the claim for benefits which was denied.

''(C) EXCEPTION FOR NEEDED CARE.—A participant or beneficiary may seek relief exclusively in Federal court under subsection 502(a)(1)(B) prior to the exhaustion of administrative remedies under sections 102, 103, or 104 of the Bipartisan Patient Protection Act (as required under subparagraph (A)) if it is demonstrated to the court that the exhaustion of such remedies would cause irreparable harm to the health of the participant or beneficiary. Notwithstanding the awarding of relief under subsection 502(a)(1)(B) pursuant to this subparagraph, no relief shall be available as a result of, or arising under, paragraph (1)(A) unless the requirements of subparagraph (A) are met.

''(D) FAILURE TO REVIEW.—

"(i) IN GENERAL.—If the external review entity fails to make a determination within the time required under section 104(e)(1)(A)(i), a participant or beneficiary may bring an action under section 514(d) after 10 additional days after the date on which such time period has expired and the filing of such action shall not affect the duty of the independent medical reviewer (or reviewers) to make a determination pursuant to section 104(e)(1)(A)(i).

"(ii) EXPEDITED DETERMINATION.—If the external review entity fails to make a determination within the time required under section 104(e)(1)(A)(ii), a participant or beneficiary may bring an action under this subsection and the filing of such an action shall not affect the duty of the independent medical reviewer (or reviewers) to make a determination pursuant to section 104(e)(1)(A)(ii).

"(E) RECEIPT OF BENEFITS DURING APPEALS PROCESS.—Receipt by the participant or beneficiary of the benefits involved in the claim

for benefits during the pendency of any administrative processes referred to in subparagraph (A) or of any action commenced under this subsection—

''(i) shall not preclude continuation of all such administrative processes to their conclusion if so moved by any party, and

''(ii) shall not preclude any liability under subsection (a)(1)(C) and this subsection in connection with such claim.

''(F) ADMISSIBLE.—Any determination made by a reviewer in an administrative proceeding under section 104 of the Bipartisan Patient Protection Act of 2004 shall be admissible in any Federal or State court proceeding and shall be presented to the trier of fact.

''(5) TOLLING PROVISION.—The statute of limitations for any cause of action arising under section 502(n) relating to a denial of a claim for benefits that is the subject of an action brought in State court shall be tolled until such time as the State court makes a final disposition, including all appeals, of whether such claim should properly be within the jurisdiction of the State court. The tolling

period shall be determined by the applicable Federal or State law, whichever period is greater.

''(6) EXCLUSION OF DIRECTED RECORDKEEPERS.—

''(A) IN GENERAL.—Subject to subparagraph (C), paragraph (1) shall not apply with respect to a directed recordkeeper in connection with a group health plan.

''(B) DIRECTED RECORDKEEPER.—For purposes of this paragraph, the term 'directed recordkeeper' means, in connection with a group health plan, a person engaged in directed recordkeeping activities pursuant to the specific instructions of the plan or the employer or other plan sponsor, including the distribution of enrollment information and distribution of disclosure materials under this Act or title I of the Bipartisan Patient Protection Act of 2004 and whose duties do not include making decisions on claims for benefits.

''(C) LIMITATION.—Subparagraph (A) does not apply in connection with any directed recordkeeper to the extent that the directed recordkeeper fails to follow the specific instruction

of the plan or the employer or other plan sponsor.

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

''(A) saving from preemption a cause of action under State law for the failure to provide a benefit for an item or service which is specifically excluded under the group health plan involved, except to the extent that—

''(i) the application or interpretation of the exclusion involves a determination described in section 104(d)(2) of the Bipartisan Patient Protection Act of 2004, or

''(ii) the provision of the benefit for the item or service is required under Federal law or under applicable State law consistent with subsection (b)(2)(B);

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

''(C) affecting a cause of action or remedy under State law in connection with the provision or arrangement of excepted benefits (as de-

fined in section 733(c)), other than those described in section 733(c)(2)(A); or

''(D) affecting a cause of action under State law other than a cause of action described in paragraph (1)(A).

''(8) PURCHASE OF INSURANCE TO COVER LIABILITY.—Nothing in section 410 shall be construed to preclude the purchase by a group health plan of insurance to cover any liability or losses arising under a cause of action described in paragraph (1)(A).

''(9) RELIEF FROM LIABILITY FOR EMPLOYER OR OTHER PLAN SPONSOR BY MEANS OF DESIGNATED DECISIONMAKER.—

''(A) IN GENERAL.—Paragraph (1) shall not apply with respect to any cause of action described in paragraph (1)(A) under State law insofar as such cause of action provides for liability of an employer or plan sponsor (or an employee thereof acting within the scope of employment) with respect to a participant or beneficiary, if with respect to the employer or plan sponsor there is deemed to be a designated decisionmaker that meets the requirements of section 502(o)(1) with respect to such participant

or beneficiary. Such paragraph (1) shall apply with respect to any cause of action described in paragraph (1)(A) under State law against the designated decisionmaker of such employer or other plan sponsor with respect to the participant or beneficiary.

''(B) AUTOMATIC DESIGNATION.—A health insurance issuer shall be deemed to be a designated decisionmaker for purposes of subparagraph (A) with respect to the participants and beneficiaries of an employer or plan sponsor, whether or not the employer or plan sponsor makes such a designation, and shall be deemed to have assumed unconditionally all liability of the employer or plan sponsor under such designation in accordance with subsection (o), unless the employer or plan sponsor affirmatively enters into a contract to prevent the service of the designated decisionmaker.

''(10) PREVIOUSLY PROVIDED SERVICES.—

''(A) IN GENERAL.—Except as provided in this paragraph, a cause of action shall not arise under paragraph (1) where the denial involved relates to an item or service that has already been fully provided to the participant or bene-

ficiary under the plan or coverage and the claim relates solely to the subsequent denial of payment for the provision of such item or service.

"(B) EXCEPTION.—Nothing in subparagraph (A) shall be construed to—

"(i) prohibit a cause of action under paragraph (1) where the nonpayment involved results in the participant or beneficiary being unable to receive further items or services that are directly related to the item or service involved in the denial referred to in subparagraph (A) or that are part of a continuing treatment or series of procedures;

"(ii) prohibit a cause of action under paragraph (1) relating to quality of care; or

"(iii) limit liability that otherwise would arise from the provision of the item or services or the performance of a medical procedure.

"(11) EXEMPTION FROM PERSONAL LIABILITY FOR INDIVIDUAL MEMBERS OF BOARDS OF DIRECTORS, JOINT BOARDS OF TRUSTEES, ETC.—Any individual who is—

"(A) a member of a board of directors of an employer or plan sponsor; or

"(B) a member of an association, committee, employee organization, joint board of trustees, or other similar group of representatives of the entities that are the plan sponsor of plan maintained by two or more employers and one or more employee organizations—

shall not be personally liable under this subsection for conduct that is within the scope of employment of the individuals unless the individual acts in a fraudulent manner for personal enrichment.

"(12) CHOICE OF LAW.—A cause of action brought under paragraph (1) shall be governed by the law (including choice of law rules) of the State in which the plaintiff resides.

"(13) LIMITATION ON ATTORNEYS' FEES.—

"(A) IN GENERAL.—Notwithstanding any other provision of law, or any arrangement, agreement, or contract regarding an attorney's fee, the amount of an attorney's contingency fee allowable for a cause of action brought under paragraph (1) shall not exceed ⅓ of the total amount of the plaintiff's recovery (not including

the reimbursement of actual out-of-pocket expenses of the attorney).

''(B) DETERMINATION BY COURT.—The last court in which the action was pending upon the final disposition, including all appeals, of the action may review the attorney's fee to ensure that the fee is a reasonable one.

''(C) NO PREEMPTION OF STATE LAW.—Subparagraph (A) shall not apply with respect to a cause of action under paragraph (1) that is brought in a State that has a law or framework of laws with respect to the amount of an attorney's contingency fee that may be incurred for the representation of a participant or beneficiary (or the estate of such participant or beneficiary) who brings such a cause of action.

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

''(1) affecting any State law relating to the practice of medicine or the provision of, or the failure to provide, medical care, or affecting any action (whether the liability is direct or vicarious) based upon such a State law,

''(2) superseding any State law permitted under section 152(b)(1)(A) of the Bipartisan Patient Protection Act of 2004, or

''(3) affecting any applicable State law with respect to limitations on monetary damages.''.

(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 that is 6 months after the date of enactment of this Act.

SEC. 403. LIMITATION ON CERTAIN CLASS ACTION LITIGATION.

Section 502 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1132), as amended by section 402, is further amended by adding at the end the following:

''(p) LIMITATION ON CLASS ACTION LITIGATION.—

''(1) IN GENERAL.—Any claim or cause of action that is maintained under this section in connection with a group health plan, or health insurance coverage issued in connection with a group health plan, as a class action, derivative action, or as an action on behalf of any group of 2 or more claimants, may be maintained only if the class, the derivative claimant, or the group of claimants is limited to the participants or beneficiaries of a group health plan

established by only 1 plan sponsor. No action maintained by such class, such derivative claimant, or such group of claimants may be joined in the same proceeding with any action maintained by another class, derivative claimant, or group of claimants or consolidated for any purpose with any other proceeding. In this paragraph, the terms 'group health plan' and 'health insurance coverage' have the meanings given such terms in section 733.

''(2) EFFECTIVE DATE.—This subsection shall apply to all civil actions that are filed on or after the date that is 6 months after the date of enactment of the Bipartisan Patient Protection Act of 2004.''.

SEC. 404. LIMITATIONS ON ACTIONS.

Section 502 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1132) (as amended by section 402(a)) is amended further by adding at the end the following new subsection:

''(q) LIMITATIONS ON ACTIONS RELATING TO GROUP HEALTH PLANS.—

''(1) IN GENERAL.—Except as provided in paragraph (2), 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 sub-

title D of title I of the Bipartisan Patient Protection Act (as incorporated under section 714).

''(2) CERTAIN ACTIONS ALLOWABLE.—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, 118(a)(3), 119, or 120 of the Bipartisan Patient Protection Act (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) OTHER PROVISIONS UNAFFECTED.—Nothing in this subsection shall be construed as affecting subsections (a)(1)(C) and (n) or section 514(d).

''(4) ENFORCEMENT BY SECRETARY UNAFFECTED.—Nothing in this subsection shall be construed as affecting any action brought by the Secretary.''.

SEC. 405. COOPERATION BETWEEN FEDERAL AND STATE AUTHORITIES.

Subpart C of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1191 et seq.) is amended by adding at the end the following new section:

''SEC. 735. COOPERATION BETWEEN FEDERAL AND STATE AUTHORITIES.

''(a) AGREEMENT WITH STATES.—A State may enter into an agreement with the Secretary for the delegation to the State of some or all of the Secretary's authority under this title to enforce the requirements applicable under title I of the Bipartisan Patient Protection Act with respect to health insurance coverage offered by a health insurance issuer and with respect to a group health plan that is a non-Federal governmental plan.

''(b) DELEGATIONS.—Any department, agency, or instrumentality of a State to which authority is delegated pursuant to an agreement entered into under this section may, if authorized under State law and to the extent con-

sistent with such agreement, exercise the powers of the Secretary under this title which relate to such authority.''.

SEC. 406. SENSE OF THE SENATE CONCERNING THE IMPORTANCE OF CERTAIN UNPAID SERVICES.

It is the sense of the Senate that the court should consider the loss of a nonwage earning spouse or parent as an economic loss for the purposes of this section. Furthermore, the court should define the compensation for the loss not as minimum services, but, rather, in terms that fully compensate for the true and whole replacement cost to the family.

TITLE V—EFFECTIVE DATES; COORDINATION IN IMPLEMENTATION

SEC. 501. EFFECTIVE DATES.

(a) GROUP HEALTH COVERAGE.—

(1) IN GENERAL.—Subject to paragraph (2) and subsection (d), the amendments made by sections 201(a), 401, and 403 (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 the date that is 6 months after the date of enactment of this Act (in

this section referred to as the ''general effective date'').

(2) TREATMENT OF 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 sections 201(a), 401, and 403 (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 (excluding any extension thereof agreed to after the date of the enactment of this Act); or

(B) the general effective date—

but shall apply not later than 1 year after 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.—Subject to subsection (d), 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.

(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 nonmedical 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.

(d) TRANSITION FOR NOTICE REQUIREMENT.—The disclosure of information required under section 121 of this Act shall first be provided pursuant to—

(1) subsection (a) with respect to a group health plan that is maintained as of the general effective date, not later than 30 days before the beginning of the first plan year to which title I applies

in connection with the plan under such subsection; or

(2) subsection (b) with respect to a individual health insurance coverage that is in effect as of the general effective date, not later than 30 days before the first date as of which title I applies to the coverage under such subsection.

SEC. 502. COORDINATION IN IMPLEMENTATION.

The Secretary of Labor and the Secretary of Health and Human Services 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.

SEC. 503. SEVERABILITY.

If any provision of this Act, an amendment made by this Act, or the application of such provision or amendment to any person or circumstance is held to be unconstitutional, the remainder of this Act, the amendments made by this Act, and the application of the provisions of such to any person or circumstance shall not be affected thereby.

TITLE VI—MISCELLANEOUS PROVISIONS

SEC. 601. NO IMPACT ON SOCIAL SECURITY TRUST FUND.

(a) IN GENERAL.—Nothing in this Act (or an amendment made by this Act) shall be construed to alter or amend the Social Security Act (or any regulation promulgated under that Act).

(b) TRANSFERS.—

(1) ESTIMATE OF SECRETARY.—The Secretary of the Treasury shall annually estimate the impact that the enactment of this Act has on the income and balances of the trust funds established under section 201 of the Social Security Act (42 U.S.C. 401).

(2) TRANSFER OF FUNDS.—If, under paragraph (1), the Secretary of the Treasury estimates that the enactment of this Act has a negative impact on the income and balances of the trust funds estab-

lished under section 201 of the Social Security Act (42 U.S.C. 401), the Secretary shall transfer, not less frequently than quarterly, from the general revenues of the Federal Government an amount sufficient so as to ensure that the income and balances of such trust funds are not reduced as a result of the enactment of such Act.

SEC. 602. CUSTOMS USER FEES.

Section 13031(j)(3) of the Consolidated Omnibus Budget Reconciliation Act of 1985 (19 U.S.C. 58c(j)(3)) is amended by striking ''March 31, 2004'' and inserting ''December 31, 2014''.

SEC. 603. FISCAL YEAR 2005 MEDICARE PAYMENTS.

Notwithstanding any other provision of law, any letter of credit under part B of title XVIII of the Social Security Act (42 U.S.C. 1395j et seq.) that would otherwise be sent to the Treasury or the Federal Reserve Board on September 30, 2005, by a carrier with a contract under section 1842 of that Act (42 U.S.C. 1395u) shall be sent on October 1, 2005.

SEC. 604. SENSE OF SENATE WITH RESPECT TO PARTICIPATION IN CLINICAL TRIALS AND ACCESS TO SPECIALTY CARE.

(a) FINDINGS.—The Senate finds the following:

(1) Breast cancer is the most common form of cancer among women, excluding skin cancers.

(2) During 2004, 215,900 new cases of female invasive breast cancer will be diagnosed, and 40,110 women will die from the disease.

(3) In addition, 1,450 male breast cancer cases are projected to be diagnosed, and 470 men will die from the disease.

(4) Breast cancer is the second leading cause of cancer death among all women.

(5) This year 9,200 children are expected to be diagnosed with cancer.

(6) 1,510 children are expected to die from cancer this year.

(7) There are approximately 400,000 people diagnosed with multiple sclerosis in the United States and 200 more cases are diagnosed each week.

(8) Parkinson's disease is a progressive disorder of the central nervous system affecting 1,500,000 in the United States.

(9) An estimated 230,110 men will be diagnosed with prostate cancer this year.

(10) 29,500 men will die from prostate cancer this year. It is the leading cause of cancer in men and the second leading cause of death.

(11) While information obtained from clinical trials is essential to finding cures for diseases, it is still research which carries the risk of fatal results. Future efforts should be taken to protect the health and safety of adults and children who enroll in clinical trials.

(12) While employers and health plans should be responsible for covering the routine costs associated with federally approved or funded clinical trials, such employers and health plans should not be held legally responsible for the design, implementation, or outcome of such clinical trials, consistent with any applicable State or Federal liability statutes.

(b) SENSE OF THE SENATE.—It is the sense of the Senate that—

(1) men and women battling life-threatening, deadly diseases, including advanced breast or ovarian cancer, should have the opportunity to participate in a federally approved or funded clinical trial recommended by their physician;

(2) an individual should have the opportunity to participate in a federally approved or funded clinical trial recommended by their physician if—

(A) that individual—

(i) has a life-threatening or serious illness for which no standard treatment is effective;

(ii) is eligible to participate in a federally approved or funded clinical trial according to the trial protocol with respect to treatment of the illness;

(B) that individual's participation in the trial offers meaningful potential for significant clinical benefit for the individual; and

(C) either—

(i) the referring physician is a participating health care professional and has concluded that the individual's participation in the trial would be appropriate, based upon the individual meeting the conditions described in subparagraph (A); or

(ii) the participant, beneficiary, or enrollee provides medical and scientific information establishing that the individual's participation in the trial would be appropriate, based upon the individual meeting the conditions described in subparagraph (A);

(3) a child with a life-threatening illness, including cancer, should be allowed to participate in a federally approved or funded clinical trial if that participation meets the requirements of paragraph (2);

(4) a child with a rare cancer should be allowed to go to a cancer center capable of providing high quality care for that disease; and

(5) a health maintenance organization's decision that an in-network physician without the necessary expertise can provide care for a seriously ill patient, including a woman battling cancer, should be appealable to an independent, impartial body, and that this same right should be available to all Americans in need of access to high quality specialty care.

SEC. 605. SENSE OF THE SENATE REGARDING FAIR REVIEW PROCESS.

(a) FINDINGS.—The Senate finds the following:

(1) A fair, timely, impartial independent external appeals process is essential to any meaningful program of patient protection.

(2) The independence and objectivity of the review organization and review process must be ensured.

(3) It is incompatible with a fair and independent appeals process to allow a health maintenance organization to select the review organization that is entrusted with providing a neutral and unbiased medical review.

(4) The American Arbitration Association and arbitration standards adopted under chapter 44 of title 28, United States Code (28 U.S.C. 651 et seq.) both prohibit, as inherently unfair, the right of one party to a dispute to choose the judge in that dispute.

(b) SENSE OF THE SENATE.—It is the sense of the Senate that—

(1) every patient who is denied care by a health maintenance organization or other health insurance company should be entitled to a fair, speedy, impartial appeal to a review organization that has not been selected by the health plan;

(2) the States should be empowered to maintain and develop the appropriate process for selection of the independent external review entity;

(3) a child battling a rare cancer whose health maintenance organization has denied a covered treatment recommended by its physician should be entitled to a fair and impartial external appeal to a

review organization that has not been chosen by the organization or plan that has denied the care; and

(4) patient protection legislation should not preempt existing State laws in States where there already are strong laws in place regarding the selection of independent review organizations.

SEC. 606. ANNUAL REVIEW.

(a) IN GENERAL.—Not later than 24 months after the general effective date referred to in section 501(a)(1), and annually thereafter for each of the succeeding 4 calendar years (or until a repeal is effective under subsection (b)), the Secretary of Health and Human Services shall request that the Institute of Medicine of the National Academy of Sciences prepare and submit to the appropriate committees of Congress a report concerning the impact of this Act, and the amendments made by this Act, on the number of individuals in the United States with health insurance coverage.

(b) LIMITATION WITH RESPECT TO CERTAIN PLANS.—If the Secretary, in any report submitted under subsection (a), determines that more than 1,000,000 individuals in the United States have lost their health insurance coverage as a result of the enactment of this Act, as compared to the number of individuals with health insurance coverage in the 12-month period preceding the

date of enactment of this Act, section 402 of this Act shall be repealed effective on the date that is 12 month after the date on which the report is submitted, and the submission of any further reports under subsection (a) shall not be required.

(c) FUNDING.—From funds appropriated to the Department of Health and Human Services for fiscal years 2005 and 2006, the Secretary of Health and Human Services shall provide for such funding as the Secretary determines necessary for the conduct of the study of the National Academy of Sciences under this section.

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