Calendar No. 150

107TH CONGRESS
1ST SESSION

H. R. 2563

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 5, 2001
Received and read the first time

SEPTEMBER 6, 2001
Read the second time and placed on the calendar

AN ACT

To amend the Public Health Service Act, the Employee Retirement Income Security Act of 1974, and the Internal Revenue Code of 1986 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''.

(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 503A of the Employee Retirement Income Security Act of 1974.

(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.

Part 5 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 is amended by inserting after section 503 (29 U.S.C. 1133) the following:

"SEC. 503A. PROCEDURES FOR INITIAL CLAIMS FOR BENEFITS AND PRIOR AUTHORIZATION DETERMINATIONS.

''(a) PROCEDURES OF INITIAL CLAIMS FOR BENEFITS.—

''(1) IN GENERAL.—A group health plan, and a health insurance issuer offering health insurance coverage in connection with the group health plan, shall—

''(A) make a determination on an initial claim for benefits by a participant or beneficiary (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 or beneficiary is required to pay with respect to such claim for benefits; and

''(B) notify a participant or beneficiary (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 or beneficiary may be required to make with respect to such claim

for benefits, and of the right of the participant or beneficiary to an internal appeal under section 503B.

''(2) ACCESS TO INFORMATION.—

''(A) TIMELY PROVISION OF NECESSARY INFORMATION.—With respect to an initial claim for benefits, the participant or beneficiary (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 or beneficiary 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 or beneficiary (or authorized representative) may make an initial claim for benefits orally, but a group health plan, or health insurance issuer offering health insurance coverage in connection with the group health plan, may require that the participant or beneficiary (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 claim 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, and a health insurance issuer offering health insurance coverage in connection with the group health plan, 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, and a health insurance issuer offering health insurance coverage in connection with the group health plan, 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 or beneficiary (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 or beneficiary or the ability of the participant or beneficiary 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 503B(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, and a health insurance issuer offering health insurance coverage in connection with the group health plan, 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 or beneficiary (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 or beneficiary 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 503B.

''(e) DEFINITIONS.—For purposes of this section and sections 503B and 503C:

''(1) AUTHORIZED REPRESENTATIVE.—The term 'authorized representative' means, with respect to an individual who is a participant or beneficiary, 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 in connection with the group health plan.

''(3) DENIAL OF CLAIM FOR BENEFITS.—The term 'denial' means, with respect to a claim for ben-

efits, a denial (in whole or in part) of, or a failure to act in accordance with the applicable deadlines established under this section and section 503B upon, the claim for benefits and includes a failure to provide benefits (including items and services) required to be provided under title I of the Bipartisan Patient Protection Act.

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

''(5) OTHER DEFINITIONS.—Section 151 of the Bipartisan Patient Protection Act shall apply.''.

SEC. 103. INTERNAL APPEALS OF CLAIMS DENIALS.

Part 5 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 (as amended by section 503A) is amended further by inserting after section 503A (29 U.S.C. 1133A) the following:

''SEC. 503B. INTERNAL APPEALS OF CLAIMS DENIALS.

''(a) RIGHT TO INTERNAL APPEAL.—

''(1) IN GENERAL.—A participant or beneficiary (or authorized representative) may appeal any denial

of a claim for benefits under section 503A under the procedures described in this section.

''(2) TIME FOR APPEAL.—

''(A) IN GENERAL.—A group health plan, and a health insurance issuer offering health insurance coverage in connection with the group health plan, shall ensure that a participant or beneficiary (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 503A 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 participant or beneficiary 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 503A within the applicable timeline established for such a determination under such section is a denial of a claim for benefits for purposes this section and sections 503B and 503C 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 in connection with the group health plan, may waive the internal review process under this section. In such case the plan or issuer shall provide notice to the participant or beneficiary (or authorized representative) involved, the participant or beneficiary (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, or representative proceed directly to seek further appeal through external review under section 503C 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 determination, a participant or beneficiary (or authorized representative) may request such appeal orally. A group health plan, or health insurance issuer offering health insurance coverage in connection with the group health plan, may require that the participant or beneficiary (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 or beneficiary (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 or beneficiary 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.—Except as provided in this paragraph or paragraph (4), a group health plan, and a health insurance issuer offering health insurance coverage in connection with the group health plan, 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, and a health insurance issuer offering health insurance coverage in connection with the group health plan, 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 or beneficiary (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 or beneficiary or the ability of the participant or beneficiary 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 503A(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 503C 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, and a health insurance issuer offering health insurance coverage in connection with

the group health plan, shall make a retrospective determination on an appeal of a denial 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 a review panel including at least one prac-

ticing 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 or beneficiary (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 denial 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 503C.

"(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 or beneficiary 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 503C and instructions on how to initiate such a review.".

SEC. 104. INDEPENDENT EXTERNAL APPEALS PROCEDURES.

(a) IN GENERAL.—Part 5 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 (as

amended by sections 503A and 503B) is amended further by inserting after section 503B (29 U.S.C. 1133B) the following:

"SEC. 503C. INDEPENDENT EXTERNAL APPEALS PROCEDURES.

"(a) RIGHT TO EXTERNAL APPEAL.—A group health plan, and a health insurance issuer offering health insurance coverage in connection with the group health plan, shall provide in accordance with this section participants and beneficiaries (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 or beneficiary receives notice of the denial under section 503B(d) or notice of waiver of internal review under section 503B(a)(4) or the date on which the plan or issuer has failed to make a timely decision under section 503B(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, or health insurance issuer offering health insurance coverage in connection with the group health plan, 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 or beneficiary involved (or an authorized representative);

''(iii) except if waived by the plan or issuer under section 503B(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 503B;

''(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 or beneficiary (or authorized representative) for the release of necessary medical information or records of the participant or beneficiary 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 for such review may be made orally. A group health plan, or health insurance issuer offering health insurance coverage in connection with the group health plan, may require that the participant or beneficiary (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 a 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 or beneficiary 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 503B(a)(4).

''(III) REFUNDING OF FEE.—The filing fee paid under subparagraph (A)(iv) shall be refunded if the determination under the independent external review is to reverse 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 in connection with the group health plan, the plan or issuer shall immediately refer such request, and forward the plan or issuer's initial decision (including the information described in section 503B(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 or beneficiary (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 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

''(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 review panel, the entity shall provide notice to the plan or issuer,

the participant or beneficiary (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;

"(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 review panel, 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 review panel is not required, the entity shall provide notice of such determination to the participant or beneficiary (or authorized representative) 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 review panel composed of 3 independent medical reviewers 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 review panel 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 or reversed.

''(B) STANDARD FOR DETERMINATION.—The independent medical review panel's determination relating to the medical necessity and appropriateness, or the experimental or investigational nature, or the evaluation of the medical facts, of the item, service, or condition involved shall be based on the medical condition of the participant or beneficiary (including the medical records of the participant or beneficiary) 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 review panel to require that a group health plan, or health insurance issuer offering health insurance coverage in connection with the group health plan, 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) of the Bipartisan Patient Protection Act). 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 in connection with the group health plan and that is disclosed under section 121(b)(1) of the Bipartisan Patient Protection Act) 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 review panel 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 review panel or submitted by the plan, issuer, participant, or beneficiary (or an authorized representative), or treating health care professional.

''(iv) The plan or coverage document.

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

''(i) consider the claim under review without deference to the determinations made by the plan or issuer or the rec-

ommendation 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 experimental or investigational nature of the treatment.

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

"(i) the determination of the review panel;

"(ii) the specific reasons of the review panel 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 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 review panel may provide the plan or issuer and the treating health care professional with additional recommendations 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 review panel shall make a determination on a denial of a claim for benefits that is referred to the review panel 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 review panel 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 or beneficiary (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 or beneficiary or the ability of the participant or beneficiary 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 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 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 review panel 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 review panel 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, or beneficiary (or authorized representative) and the treating health care professional (if any) receives a copy of the written determination of the independent medical review panel prepared under subsection (d)(3)(F). Nothing in this paragraph shall be construed as preventing an entity or review panel from providing an initial oral notice of the review panel'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 review panel under this section shall be binding upon the plan or issuer involved.

''(B) COMPLIANCE WITH DETERMINATION.—If the determination of an independent medical review panel is to reverse the denial,

the plan or issuer, upon the receipt of such determination, shall authorize coverage to comply with the medical review panel's determination in accordance with the timeframe established by the medical review panel.

''(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 or beneficiary, where such failure to comply is caused by the plan or issuer, the participant, or beneficiary may obtain the items or services involved (in a manner consistent with the determination of the independent medical review panel) 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 or beneficiary 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 profes-

sional or to the participant or beneficiary (in the case of a participant or beneficiary who pays for the costs of such items or services).

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

"(C) FAILURE TO REIMBURSE.—Where a plan or issuer fails to provide reimbursement to a professional, participant, or beneficiary in accordance with this paragraph, the professional, participant, or beneficiary 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 in connection with the group health plan, any person who, acting in the capacity of authorizing the benefit, causes such refusal may, in the discretion of a court of competent jurisdiction, be liable to an aggrieved participant or beneficiary for a civil penalty in an amount of up to $1,000 a day from the date on which the determination was transmitted to the plan or issuer by the external 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 medical review panel, the Secretary shall assess a civil penalty of $10,000 against the plan and the plan shall pay such penalty to the participant or beneficiary involved.

"(B) CEASE AND DESIST ORDER AND ORDER OF ATTORNEY'S FEES.—In any action described in subparagraph (A) brought by a participant or beneficiary with respect to a group health plan, or a health insurance issuer offering health insurance coverage in connection with the group health plan, 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 review 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 in connection with the group health plan, for—

"(I) any pattern or practice of repeated refusal to authorize a benefit determined by an external review 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 appropriate 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 section or section 503A or 503B shall be construed as altering or eliminating any cause of action or legal rights or remedies of participants or beneficiaries, 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 an independent medical review panel 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, the review panel meets the requirements of paragraph (4) and at least 1 reviewer on the panel meets the requirements described in paragraph (5); and

''(C) compensation provided by the entity to each 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 or beneficiary (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 or beneficiary (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, each 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, the independent medical re-

view panel 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 individual 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 or beneficiary, 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 or beneficiary (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 or beneficiary.

''(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 connection with the group

health plan in a State, the State may provide for external review activities to be conducted by a qualified external review 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 or beneficiary (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 review panel.

"(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 identifiable health information obtained in the course of conducting external review activities; and

''(IV) in the case of 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 external 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 review panels it refers cases to).

''(III) Compliance with limitations on compensation (with respect to both the entity and independent medical review panels 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 review panels may not require coverage for specifically excluded benefits.

"(v) PERIOD OF CERTIFICATION OR RECERTIFICATION.—A certification or recertification 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 spe-

cifically 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 review panel 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 qualifiedprivate 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 review panel), 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 601 of the Bipartisan Patient Protection Act, 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 review panels and the number of denials that have been reversed by such panels; and

''(C) the extent to which independent medical review panels are requiring coverage for benefits that are specifically excluded under the plans 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 described 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 in connection with the group health plan 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 or beneficiaries.

(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 organi-

zation. 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 ad-

ministrative 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 in connection with the group health plan 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 consumer 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, 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 in connection with the group health plan or prospective coverage, including individuals covered under a group health plan or health insurance coverage in connection with the group health plan 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 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 (including physician pathology 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 cov-

erage 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 timely access to specialists).

SEC. 113. ACCESS TO EMERGENCY CARE.

(a) COVERAGE OF EMERGENCY SERVICES.—

(1) IN GENERAL.—If a group health plan, or health insurance coverage offered by a health insurance issuer, provides 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 given 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 and a 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 authorization 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 and a 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 pri-

mary 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, and a 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 and a health insurance issuer described in subsection (b) shall treat the provision 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 pri-

mary 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 in-

surance 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 pro-

vider 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 continuing 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 necessary 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 (and 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 (e) 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 and a 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, including 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 ad-

dress 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 503C(d)(3)(C) of the Bipartisan Patient Protection Act;

(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 information 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 Retire-

ment 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 authorization 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 provisions of this Act (excluding those described in paragraphs (1) through (17)) and of the amendments made thereby if such provisions 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.—The name and address of the designated decisionmaker (or decisionmakers) appointed under paragraph (2) of section 502(n) of the Employee Retirement Income Security Act of 1974 for purposes of such section and a description of the participants and beneficiaries with respect to whom each designated decisionmaker under the plan has assumed liability under section 502(n) of such Act.

(c) ADDITIONAL INFORMATION.—The informational materials to be provided upon the request of a participant, beneficiary, or enrollee shall include for each option available 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 section 101 and section 503A of the Employee Retirement Income Security Act of 1974, 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.

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 1852(j)(4) 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 1852(j)(4) of the Social Security Act to the Secretary, a Medicare+Choice 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 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 that is no less protective than 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 or under sections 503A, 503B, and 503C of the Employee Retirement Income Security Act of 1974.

(b) PROTECTION FOR QUALITY ADVOCACY BY HEALTH CARE PROFESSIONALS.—

(1) IN GENERAL.—A group health plan and a 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 li-

censure or certification and the same experience;

(B) the professional reasonably believes the information to be true;

(C) the information evidences either a violation of a law, rule, or regulation, of an applicable accreditation standard, or of a generally recognized professional or clinical standard or that a patient is in imminent hazard of loss of life or serious injury; and

(D) subject to subparagraphs (B) and (C) of paragraph (3), the professional has followed reasonable internal procedures of the plan, issuer, or institutional health care provider established for the purpose of addressing quality concerns before making the disclosure.

(3) EXCEPTION AND SPECIAL RULE.—

(A) GENERAL EXCEPTION.—Paragraph (1) does not protect disclosures that would violate Federal or State law or diminish or impair the rights of any person to the continued protection of confidentiality of communications provided by such law.

(B) NOTICE OF INTERNAL PROCEDURES.—Subparagraph (D) of paragraph (2) shall not

apply unless the internal procedures involved are reasonably expected to be known to the health care professional involved. For purposes of this subparagraph, a health care professional is reasonably expected to know of internal procedures if those procedures have been made available to the professional through distribution or posting.

(C) INTERNAL PROCEDURE EXCEPTION.—Subparagraph (D) of paragraph (2) also shall not apply if—

(i) the disclosure relates to an imminent hazard of loss of life or serious injury to a patient;

(ii) the disclosure is made to an appropriate private accreditation body pursuant to disclosure procedures established by the body; or

(iii) the disclosure is in response to an inquiry made in an investigation or proceeding of an appropriate public regulatory agency and the information disclosed is limited to the scope of the investigation or proceeding.

(4) ADDITIONAL CONSIDERATIONS.—It shall not be a violation of paragraph (1) to take an adverse action against a protected health care professional if the plan, issuer, or provider taking the adverse action involved demonstrates that it would have taken the same adverse action even in the absence of the activities protected under such paragraph.

(5) NOTICE.—A group health plan, health insurance issuer, and institutional health care provider shall post a notice, to be provided or approved by the Secretary of Labor, setting forth excerpts from, or summaries of, the pertinent provisions of this subsection and information pertaining to enforcement of such provisions.

(6) CONSTRUCTIONS.—

(A) DETERMINATIONS OF COVERAGE.—Nothing in this subsection shall be construed to prohibit a plan or issuer from making a determination not to pay for a particular medical treatment or service or the services of a type of health care professional.

(B) ENFORCEMENT OF PEER REVIEW PROTOCOLS AND INTERNAL PROCEDURES.—Nothing in this subsection shall be construed to pro-

hibit 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 714 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 ''nonparticipating'' means, with respect to a health care provider that provides health care items and services to a participant, beneficiary, or enrollee under group health plan or health insurance coverage, a health care provider that is not a participating health care provider with respect to such items and services.

(8) PARTICIPATING.—The term ''participating'' means, with respect to a health care provider that

provides health care items and services to a participant, beneficiary, or enrollee under group health plan or health insurance coverage offered by a health insurance issuer, a health care provider that furnishes such items and services under a contract or other arrangement with the plan or issuer.

(9) 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 and sections 503A, 503B, and 503C of the Employee Retirement Income Security Act of 1974 with respect to the plan or coverage.

(11) REFERENCES TO PROVISIONS GOVERNING CONSIDERATION OF CLAIMS AND APPEALS OF CLAIMS DECISIONS.—Any reference in this title to section 503A, 503B, or 503C of the Employee Retirement Income Security Act of 1974 shall be deemed, for purposes of the Public Health Service Act and the Internal Revenue Code of 1986, a ref-

erence to the provisions of such section as made applicable under section 2707 or 2753 of the Public Health Service Act or section 9813 of the Internal Revenue Code of 1986, as applicable.

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 (and the amendments made thereby) 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 (or such amendments).

(2) CONTINUED PREEMPTION WITH RESPECT TO GROUP HEALTH PLANS.—Nothing in this title (or the amendments made thereby) 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 (or the amendments made thereby).

(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 or the amendments made thereby (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 and only with respect to patient protection requirements under section 101 and subtitles B, C, and D and this subtitle.

(3) DEFINITIONS.—In this section:

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

(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 required 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 with respect to the patient protection involved.

(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 601, 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 (or the amendments made thereby).

(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 or the amendments made thereby 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. TREATMENT OF EXCEPTED BENEFITS.

(a) IN GENERAL.—The requirements of this title and the amendments made thereby shall not apply to excepted benefits (as defined in section 733(c) of the Employee Retirement Income Security Act of 1974), other than benefits described in section 733(c)(2)(A) of such Act, in the same manner as the provisions of part 7 of subtitle B of title I of such Act do not apply to such benefits under subsections (b) and (c) of section 732 of such Act.

(b) COVERAGE OF CERTAIN LIMITED SCOPE PLANS.—Only for purposes of applying the requirements of this title and sections 503A, 503B, and 503C of the Employee Retirement Income Security Act of 1974 under sections 2707 and 2753 of the Public Health Service Act, sections 503(b) and 714 of the Employee Retirement Income Security Act of 1974, and section 9813 of the Internal Revenue Code of 1986, the following sections shall be deemed not to apply:

(1) Section 2791(c)(2)(A) of the Public Health Service Act.

(2) Section 733(c)(2)(A) of the Employee Retirement Income Security Act of 1974.

(3) Section 9832(c)(2)(A) of the Internal Revenue Code of 1986.

SEC. 155. REGULATIONS.

The Secretaries of Health and Human Services, Labor, and the Treasury shall issue such regulations as may be necessary or appropriate to carry out this title and the amendments made thereby. 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 and the amendments made thereby.

SEC. 156. INCORPORATION INTO PLAN OR COVERAGE DOCUMENTS.

The requirements of this title and the amendments made thereby with respect to a group health plan or health insurance coverage are, subject to section 154, 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.

SEC. 157. PRESERVATION OF PROTECTIONS.

(a) IN GENERAL.—The rights under this Act (including the right to maintain a civil action and any other

rights under the amendments made by this Act) may not be waived, deferred, or lost pursuant to any agreement not authorized under this Act (or such amendments).

(b) EXCEPTION.—Subsection (a) shall not apply to an agreement providing for arbitration or participation in any other nonjudicial procedure to resolve a dispute if the agreement is entered into knowingly and voluntarily by the parties involved after the dispute has arisen or is pursuant to the terms of a collective bargaining agreement. Nothing in this subsection shall be construed to permit the waiver of the requirements of sections 503B and 503C of the Employee Retirement Income Security Act of 1974 (relating to internal and external review).

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 the patient protection requirements under title I of the Bipartisan Patient Protection Act and sections 503A through 503C of the Employee Retirement Income Security Act of 1974, and each health insurance issuer shall comply with such patient protection requirements 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 the patient protection requirements under title I of the Bipartisan Patient Protection Act and sections 503A through 503C of the Employee Retirement Income Security Act of 1974 (with respect to enrollees under individual health insurance coverage in the same manner as they apply to

participants and beneficiaries under group health insurance coverage) 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 sections 2707 and 2753 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.''.

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

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

(a) SENSE OF CONGRESS.—It is the sense of Congress that enrollees in Federal health insurance programs should have the same rights and privileges as those afforded under title I, under the amendments made by such title, and under the amendments made by subtitle A of title IV to participants and beneficiaries under group health plans.

(b) CONFORMING FEDERAL HEALTH INSURANCE PROGRAMS.—It is the sense of Congress that the President should require, by executive order, the Federal official with authority over each Federal health insurance program, to the extent feasible, to take such steps as are necessary to implement the rights and privileges described in subsection (a) with respect to such program.

(c) GAO REPORT ON ADDITIONAL STEPS REQUIRED.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General of the United States shall submit to Congress a report on statutory

changes that are required to implement such rights and privileges in a manner that is consistent with the missions of the Federal health insurance programs and that avoids unnecessary duplication or disruption of such programs.

(d) FEDERAL HEALTH INSURANCE PROGRAM.—In this section, the term ''Federal health insurance program'' means a Federal program that provides creditable coverage (as defined in section 2701(c)(1) of the Public Health Service Act) and includes a health program of the Department of Veterans Affairs.

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

Subtitle A—General Provisions

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 section 101 and subtitles B, C, D, and E 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 provides benefits in the form of health insurance coverage through a health insurance issuer, the plan shall be treated as meeting the following requirements of title I of the Bipartisan 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) 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).

''(4) 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.

''(5) TREATMENT OF SUBSTANTIALLY COMPLIANT STATE LAWS.—For purposes of applying this subsection in connection with health insurance coverage, 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.

''(6) 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 in-

clude 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)(1)(A) Subject to subparagraphs (B) and (C), 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 sections 503A, 503B, and 503C, and such requirements shall be deemed to be incorporated into this subsection.

''(B) With respect to the internal appeals process required to be established under section 503B, 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.

''(C) Pursuant to rules of the Secretary, insofar as a group health plan enters into a contract with a qualified external review entity for the conduct of external appeal activities in accordance with section 503C, 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.

''(2) In the case of a group health plan, compliance with the requirements of sections 503A, 503B, and 503C, and compliance with regulations promulgated by the Secretary, in connection with a denial of a claim under a group health plan shall be deemed compliance with subsection (a) with respect to such claim denial.

''(3) Terms used in this subsection which are defined in section 733 shall have the meanings provided such terms in such section.''.

(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) of the Bipartisan Patient Protection Act, as enforcible under section 714(c))'' after ''part 7''.

SEC. 402. AVAILABILITY OF CIVIL REMEDIES.

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

''(n) CAUSE OF ACTION RELATING TO CLAIMS FOR HEALTH BENEFITS.—

''(1) CAUSE OF ACTION.—

''(A) IN GENERAL.—With respect to an action commenced by a participant or beneficiary (or the estate of the participant or beneficiary) in connection with a claim for benefits under a group health plan, if—

''(i) a designated decisionmaker described in paragraph (2) fails to exercise ordinary care—

''(I) in making a determination denying the claim for benefits under section 503A (relating to an initial claim for benefits),

''(II) in making a determination denying the claim for benefits under

section 503B (relating to an internal appeal), or

''(III) in failing to authorize coverage in compliance with the written determination of an independent medical reviewer under section 503C(d)(3)(F) that reverses a determination denying the claim for benefits, and

''(ii) the delay in receiving, or failure to receive, benefits attributable to the failure described in clause (i) is the proximate cause of personal injury to, or death of, the participant or beneficiary,

such designated decisionmaker shall be liable to the participant or beneficiary (or the estate) for economic and noneconomic damages in connection with such failure and such injury or death (subject to paragraph (4)).

''(B) REBUTTABLE PRESUMPTION.—In the case of a cause of action under subparagraph (A)(i)(I) or (A)(i)(II), if an independent medical reviewer under section 503C(d) or 503C(e)(4)(B) upholds the determination denying the claim for benefits involved, there shall

be a presumption (rebuttable by clear and convincing evidence) that the designated decisionmaker exercised ordinary care in making such determination.

''(2) DESIGNATED DECISIONMAKER.—

''(A) APPOINTMENT.—

''(i) IN GENERAL.—The plan sponsor or named fiduciary of a group health plan shall, in accordance with this paragraph with respect to a participant or beneficiary, designate a person that meets the requirements of subparagraph (B) to serve as a designated decisionmaker with respect to the cause of action described in paragraph (1), except that—

''(I) with respect to health insurance coverage offered in connection with a group health plan, the health insurance issuer shall be the designated decisionmaker unless the plan sponsor and the issuer specifically agree in writing (on a form to be prescribed by the Secretary) to substitute another person as the designated decisionmaker; or

"(II) with respect to the designation of a person other than a plan sponsor or health insurance issuer, such person shall satisfy the requirements of subparagraph (D).

"(ii) PLAN DOCUMENTS.—The designated decisionmaker shall be specifically designated as such in the written instruments of the plan (under section 402(a)) and be identified as required under section 121(b)(20) of the Bipartisan Patient Protection Act.

"(B) REQUIREMENTS.—For purposes of this paragraph, a designated decisionmaker meets the requirements of this subparagraph with respect to any participant or beneficiary if—

"(i) such designation is in such form as may be specified in regulations prescribed by the Secretary,

"(ii) the designated decisionmaker—

"(I) meets the requirements of subparagraph (C),

"(II) assumes unconditionally all liability arising under this subsection

in connection with actions and failures to act described in subparagraph (A) (whether undertaken by the designated decisionmaker or the employer, plan, plan sponsor, or employee or agent thereof) during the period in which the designation under this paragraph is in effect relating to such participant or beneficiary, and

''(III) where subparagraph (C)(ii) applies, assumes unconditionally the exclusive authority under the group health plan to make determinations on claims for benefits (irrespective of whether they constitute medically reviewable determinations) under the plan with respect to such participant or beneficiary, and

''(iii) 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)(15) of the Bipartisan Patient Protection Act.

Any liability assumed by a designated decision-maker pursuant to this paragraph shall be in addition to any liability that it may otherwise have under applicable law.

"(C) QUALIFICATIONS FOR DESIGNATED DECISIONMAKERS.—

"(i) IN GENERAL.—Subject to clause (ii), an entity is qualified under this subparagraph 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 subparagraph (A) 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 certification of such ability. Such certification shall be provided to the plan sponsor or named fiduciary upon designation under this paragraph and not less frequently than annually thereafter, or if such designation constitutes a multiyear arrangement, in conjunction with the renewal of the arrangement.

''(ii) 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 insurance coverage offered by a health insurance issuer, such issuer is the only entity that may be qualified under this subparagraph 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.

''(D) REQUIREMENTS RELATING TO FINANCIAL OBLIGATIONS.—For purposes of subparagraphs (A)(i)(II) and (C)(i), the requirements relating to the financial obligation of an entity for liability shall include—

''(i) 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 subsection; or

''(ii) 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 subsection.

The appropriate amounts of liability insurance and minimum capital and surplus levels for purposes of clauses (i) and (ii) 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 subparagraph 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.

''(E) LIMITATION ON APPOINTMENT OF TREATING PHYSICIANS.—A treating physician

who directly delivered the care or treatment or provided services which is the subject of a cause of action by a participant or beneficiary under paragraph (1) may not be appointed (or deemed to be appointed) as a designated decisionmaker under this paragraph with respect to such participant or beneficiary.

''(F) FAILURE TO APPOINT.—With respect to any cause of action under paragraph (1) relating to a denial of a claim for benefits where a designated decisionmaker has not been appointed in accordance with this paragraph, the plan sponsor or named fiduciary responsible for determinations under section 503 shall be deemed to be the designated decisionmaker.

''(G) EFFECT OF APPOINTMENT.—The appointment of a designated decisionmaker in accordance with this paragraph shall not affect the liability of the appointing plan sponsor or named fiduciary for the failure of the plan sponsor or named fiduciary to comply with any other requirement of this title.

''(H) TREATMENT OF CERTAIN TRUST FUNDS.—For purposes of this subsection, the terms 'employer' and 'plan sponsor', in connec-

tion with the assumption by a designated decisionmaker of the liability of employer or other plan sponsor pursuant to this paragraph, shall be construed to include a trust fund maintained pursuant to section 302 of the Labor Management Relations Act, 1947 (29 U.S.C. 186) or the Railway Labor Act (45 U.S.C. 151 et seq.).

''(3) REQUIREMENT OF EXHAUSTION OF INDEPENDENT MEDICAL REVIEW.—

''(A) IN GENERAL.—Paragraph (1) shall apply only if—

''(i) a final determination denying a claim for benefits under section 503B has been referred for independent medical review under section 503C(d) and a written determination by an independent medical reviewer has been issued with respect to such review, or

''(ii) the qualified external review entity has determined under section 503C(c)(3) that a referral to an independent medical reviewer is not required.

''(B) INJUNCTIVE RELIEF FOR IRREPARABLE HARM.—A participant or beneficiary may seek relief under subsection (a)(1)(B) prior

to the exhaustion of administrative remedies under section 503B or 503C (as required under subparagraph (A)) if it is demonstrated to the court, by a preponderance of the evidence, that the exhaustion of such remedies would cause irreparable harm to the health of the participant or beneficiary. Any determinations that already have been made under section 503A, 503B, or 503C in such case, or that are made in such case while an action under this subparagraph is pending, shall be given due consideration by the court in any action under subsection (a)(1)(B) in such case. Notwithstanding the awarding of such relief under subsection (a)(1)(B) pursuant to this subparagraph, no relief shall be available under paragraph (1), 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.

"(4) LIMITATIONS ON RECOVERY OF DAMAGES.—

"(A) MAXIMUM AWARD OF NONECONOMIC DAMAGES.—The aggregate amount of liability for noneconomic loss in an action under paragraph (1) may not exceed $1,500,000.

"(B) LIMITATION ON AWARD OF PUNITIVE DAMAGES.—In the case of any action commenced pursuant to paragraph (1), the court may not award any punitive, exemplary, or similar damages against a defendant, except that the court may award punitive, exemplary, or similar damages (in addition to damages de-

scribed in subparagraph (A)), in an aggregate amount not to exceed $1,500,000, if—

''(i) the denial of a claim for benefits involved in the case was reversed by a written determination by an independent medical reviewer under section 503C(d)(3)(F); and

''(ii) there has been a failure to authorize coverage in compliance with such written determination.

''(C) PERMITTING APPLICATION OF LOWER STATE DAMAGE LIMITS.—A State may limit damages for noneconomic loss or punitive, exemplary, or similar damages in an action under paragraph (1) to amounts less than the amounts permitted under this paragraph.

''(5) ADMISSIBILITY.—In an action described in subclause (I) or (II) of paragraph (1)(A) relating to a denial of a claim for benefits, any determination by an independent medical reviewer under section 503C(d) or 503C(e)(4)(B) relating to such denial is admissible.

''(6) WAIVER OF INTERNAL REVIEW.—In the case of any cause of action under paragraph (1), the waiver or nonwaiver of internal review under section

503B(a)(4) by the group health plan, or health insurance issuer that offers health insurance coverage in connection with a group health plan, shall not be used in determining liability.

''(7) LIMITATIONS ON ACTIONS.—Paragraph (1) shall not apply in connection with any action that is commenced more than 5 years after the date on which the failure described in such paragraph occurred or, if earlier, not later than 2 years after the first date the participant or beneficiary became aware of the personal injury or death referred to in such paragraph.

''(8) EXCLUSION OF DIRECTED RECORDKEEPERS.—

''(A) IN GENERAL.—Paragraph (1) shall not apply with respect to a directed record keeper in connection with a group health plan.

''(B) DIRECTED RECORDKEEPER.—For purposes of this paragraph, the term 'directed record keeper' means, in connection with a group health plan, a person engaged in directed recordkeeping activities pursuant to the specific instructions of the plan, the employer, or another plan sponsor, including the distribution of enrollment information and distribution of dis-

closure materials under this Act or title I of the Bipartisan Patient Protection Act and whose duties do not include making determinations 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.

''(9) PROTECTION OF THE REGULATION OF QUALITY OF MEDICAL CARE UNDER STATE LAW.—Nothing in this subsection shall be construed to preclude any action under State law against a person or entity for liability or vicarious liability with respect to the delivery of medical care. A cause of action that is based on or otherwise relates to a group health plan's determination on a claim for benefits shall not be deemed to be the delivery of medical care under any State law for purposes of this paragraph. Any such cause of action shall be maintained exclusively under this section. Nothing in this paragraph shall be construed to alter, amend, modify, invalidate, impair, or supersede section 514.

''(10) COORDINATION WITH FIDUCIARY REQUIREMENTS.—A fiduciary shall not be treated as failing to meet any requirement of part 4 solely by reason of any action taken by a fiduciary which consists of full compliance with the reversal under section 503C (relating to independent external appeals procedures for group health plans) of a denial of claim for benefits (within the meaning of section 503C(i)(2)).

''(11) CONSTRUCTION.—Nothing in this subsection shall be construed as authorizing a cause of action under paragraph (1) for the failure of a group health plan or health insurance issuer to provide an item or service that is specifically excluded under the plan or coverage.

''(12) LIMITATION ON CLASS ACTION LITIGATION.—A claim or cause of action under this subsection may not be maintained as a class action, as a derivative action, or as an action on behalf of any group of 2 or more claimants.

''(13) 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.

''(14) RETROSPECTIVE CLAIMS FOR BENEFITS.—A cause of action shall not arise under paragraph (1) where the claim for benefits relates to an item or service that has already been 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.

''(15) 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 or of plan-related duties of the individuals unless the

individual acts in a fraudulent manner for personal enrichment.

''(16) DEFINITIONS AND RELATED RULES.—For purposes of this subsection:

''(A) CLAIM FOR BENEFITS.—The term 'claim for benefits' shall have the meaning given such term in section 503A(e).

''(B) GROUP HEALTH PLAN.—The term 'group health plan' shall have the meaning given such term in section 733(a).

''(C) HEALTH INSURANCE COVERAGE.—The term 'health insurance coverage' has the meaning given such term in section 733(b)(1).

''(D) HEALTH INSURANCE ISSUER.—The term 'health insurance issuer' has the meaning given such term in section 733(b)(2).

''(E) 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.

''(F) PERSONAL INJURY.—The term 'personal injury' means a physical injury and in-

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

''(G) TREATMENT OF EXCEPTED BENEFITS.—The provisions of this subsection (and subsection (a)(1)(C)) shall not apply to excepted benefits (as defined in section 733(c)), other than benefits described in section 733(c)(2)(A), in the same manner as the provisions of part 7 do not apply to such benefits under subsections (b) and (c) of section 732.

(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) AVAILABILITY OF ACTIONS IN STATE COURT.—

(1) JURISDICTION OF STATE COURTS.—Section 502(e)(1) of such Act (29 U.S.C. 1132(e)) is amended—

(A) in the first sentence, by striking ''subsection (a)(1)(B)'' and inserting ''paragraphs (1)(B), (1)(C), and (7) of subsection (a)'';

(B) in the second sentence, by striking ''paragraphs (1)(B) and (7)'' and inserting ''paragraphs (1)(B), (1)(C), and (7)''; and

(C) by adding at the end the following new sentence: ''State courts of competent jurisdiction in the State in which the plaintiff resides and district courts of the United States shall have concurrent jurisdiction over actions under subsections (a)(1)(C) and (n).''.

(2) LIMITATION ON REMOVABILITY OF CERTAIN ACTIONS IN STATE COURT.—Section 1445 of title 28, United States Code, is amended by adding at the end the following new subsection:

''(e)(1) A civil action brought in any State court under subsections (a)(1)(C) and (n) of section 502 of the Employee Retirement Income Security Act of 1974 against any party (other than the employer, plan, plan sponsor, or other entity treated under section 502(n) of such Act as such) arising from a medically reviewable determination may not be removed to any district court of the United States.

''(2) For purposes of paragraph (1), the term 'medically reviewable decision' means a denial of a claim for benefits under the plan which is described in section 503C(d)(2) of the Employee Retirement Income Security Act of 1974.''.

(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 applicable effective date under section 601.

SEC. 403. LIMITATION ON CERTAIN CLASS ACTION LITIGATION.

(a) IN GENERAL.—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:

''(o) LIMITATION ON CLASS ACTION LITIGATION.—Any claim or cause of action that is maintained under this section (other than under subsection (n)) or under section 1962 or 1964(c) of title 18, United States Code, 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.''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply with respect to actions commenced on or after August 2, 2001. Notwithstanding the preceding sentence, with respect to class actions, the amendment made by subsection (a) shall apply with respect to civil actions which are pending on such date in which a class action has not been certified as of such date.

SEC. 404. LIMITATIONS ON ACTIONS.

Section 502 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1132) (as amended by sections 402 and 403) is amended further by adding at the end the following new subsection:

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

''(1) IN GENERAL.—Except as provided in paragraph (2), no action may be brought under sub-

section (a)(1)(B), (a)(2), or (a)(3) by a participant or beneficiary seeking relief based on the application of any provision in section 101, subtitle B, or subtitle D of title I of the Bipartisan 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).

''(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.

(a) IN GENERAL.—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 sections 503A, 503B, 503C, and 714 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.''.

(b) CLERICAL AMENDMENTS.—The table of contents in section 1 of such Act is amended—

(1) by inserting after the item relating to section 503 the following new items:

''Sec. 503A. Procedures for initial claims for benefits and prior authorization determinations.
''Sec. 503B. Internal appeals of claims denials.
''Sec. 503C. Independent external appeals procedures.'';

(2) by inserting after the item relating to section 713 the following new item:

''Sec. 714. Patient protection standards.''; and

(3) by inserting after the item relating to section 734 the following new item:

''Sec. 735. Cooperation between Federal and State authorities.''.

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.

Subtitle B—Association Health Plans

SEC. 421. RULES GOVERNING ASSOCIATION HEALTH PLANS.

(a) IN GENERAL.—Subtitle B of title I of the Employee Retirement Income Security Act of 1974 is amended by adding after part 7 the following new part:

''PART 8—RULES GOVERNING ASSOCIATION HEALTH PLANS

''SEC. 801. ASSOCIATION HEALTH PLANS.

''(a) IN GENERAL.—For purposes of this part, the term 'association health plan' means a group health plan whose sponsor is (or is deemed under this part to be) described in subsection (b).

''(b) SPONSORSHIP.—The sponsor of a group health plan is described in this subsection if such sponsor—

''(1) is organized and maintained in good faith, with a constitution and bylaws specifically stating its purpose and providing for periodic meetings on at least an annual basis, as a bona fide trade association, a bona fide industry association (including a rural electric cooperative association or a rural telephone cooperative association), a bona fide professional association, or a bona fide chamber of commerce (or similar bona fide business association, in-

cluding a corporation or similar organization that operates on a cooperative basis (within the meaning of section 1381 of the Internal Revenue Code of 1986)), for substantial purposes other than that of obtaining or providing medical care;

''(2) is established as a permanent entity which receives the active support of its members and requires for membership payment on a periodic basis of dues or payments necessary to maintain eligibility for membership in the sponsor; and

''(3) does not condition membership, such dues or payments, or coverage under the plan on the basis of health status-related factors with respect to the employees of its members (or affiliated members), or the dependents of such employees, and does not condition such dues or payments on the basis of group health plan participation.

Any sponsor consisting of an association of entities which meet the requirements of paragraphs (1), (2), and (3) shall be deemed to be a sponsor described in this subsection.

''SEC. 802. CERTIFICATION OF ASSOCIATION HEALTH PLANS.

''(a) IN GENERAL.—The applicable authority shall prescribe by regulation, through negotiated rulemaking, a

procedure under which, subject to subsection (b), the applicable authority shall certify association health plans which apply for certification as meeting the requirements of this part.

''(b) STANDARDS.—Under the procedure prescribed pursuant to subsection (a), in the case of an association health plan that provides at least one benefit option which does not consist of health insurance coverage, the applicable authority shall certify such plan as meeting the requirements of this part only if the applicable authority is satisfied that the applicable requirements of this part are met (or, upon the date on which the plan is to commence operations, will be met) with respect to the plan.

''(c) REQUIREMENTS APPLICABLE TO CERTIFIED PLANS.—An association health plan with respect to which certification under this part is in effect shall meet the applicable requirements of this part, effective on the date of certification (or, if later, on the date on which the plan is to commence operations).

''(d) REQUIREMENTS FOR CONTINUED CERTIFICATION.—The applicable authority may provide by regulation, through negotiated rulemaking, for continued certification of association health plans under this part.

''(e) CLASS CERTIFICATION FOR FULLY INSURED PLANS.—The applicable authority shall establish a class

certification procedure for association health plans under which all benefits consist of health insurance coverage. Under such procedure, the applicable authority shall provide for the granting of certification under this part to the plans in each class of such association health plans upon appropriate filing under such procedure in connection with plans in such class and payment of the prescribed fee under section 807(a).

''(f) CERTIFICATION OF SELF-INSURED ASSOCIATION HEALTH PLANS.—An association health plan which offers one or more benefit options which do not consist of health insurance coverage may be certified under this part only if such plan consists of any of the following:

''(1) a plan which offered such coverage on the date of the enactment of the Bipartisan Patient Protection Act,

''(2) a plan under which the sponsor does not restrict membership to one or more trades and businesses or industries and whose eligible participating employers represent a broad cross-section of trades and businesses or industries, or

''(3) a plan whose eligible participating employers represent one or more trades or businesses, or one or more industries, consisting of any of the following: agriculture; equipment and automobile deal-

erships; barbering and cosmetology; certified public accounting practices; child care; construction; dance, theatrical and orchestra productions; disinfecting and pest control; financial services; fishing; foodservice establishments; hospitals; labor organizations; logging; manufacturing (metals); mining; medical and dental practices; medical laboratories; professional consulting services; sanitary services; transportation (local and freight); warehousing; wholesaling/distributing; or any other trade or business or industry which has been indicated as having average or above-average risk or health claims experience by reason of State rate filings, denials of coverage, proposed premium rate levels, or other means demonstrated by such plan in accordance with regulations which the Secretary shall prescribe through negotiated rulemaking.

"SEC. 803. REQUIREMENTS RELATING TO SPONSORS AND BOARDS OF TRUSTEES.

''(a) SPONSOR.—The requirements of this subsection are met with respect to an association health plan if the sponsor has met (or is deemed under this part to have met) the requirements of section 801(b) for a continuous period of not less than 3 years ending with the date of the application for certification under this part.

''(b) BOARD OF TRUSTEES.—The requirements of this subsection are met with respect to an association health plan if the following requirements are met:

''(1) FISCAL CONTROL.—The plan is operated, pursuant to a trust agreement, by a board of trustees which has complete fiscal control over the plan and which is responsible for all operations of the plan.

''(2) RULES OF OPERATION AND FINANCIAL CONTROLS.—The board of trustees has in effect rules of operation and financial controls, based on a 3-year plan of operation, adequate to carry out the terms of the plan and to meet all requirements of this title applicable to the plan.

''(3) RULES GOVERNING RELATIONSHIP TO PARTICIPATING EMPLOYERS AND TO CONTRACTORS.—

''(A) IN GENERAL.—Except as provided in subparagraphs (B) and (C), the members of the board of trustees are individuals selected from individuals who are the owners, officers, directors, or employees of the participating employers or who are partners in the participating employers and actively participate in the business.

''(B) LIMITATION.—

"(i) GENERAL RULE.—Except as provided in clauses (ii) and (iii), no such member is an owner, officer, director, or employee of, or partner in, a contract administrator or other service provider to the plan.

"(ii) LIMITED EXCEPTION FOR PROVIDERS OF SERVICES SOLELY ON BEHALF OF THE SPONSOR.—Officers or employees of a sponsor which is a service provider (other than a contract administrator) to the plan may be members of the board if they constitute not more than 25 percent of the membership of the board and they do not provide services to the plan other than on behalf of the sponsor.

"(iii) TREATMENT OF PROVIDERS OF MEDICAL CARE.—In the case of a sponsor which is an association whose membership consists primarily of providers of medical care, clause (i) shall not apply in the case of any service provider described in subparagraph (A) who is a provider of medical care under the plan.

''(C) CERTAIN PLANS EXCLUDED.—Subparagraph (A) shall not apply to an association health plan which is in existence on the date of the enactment of the Bipartisan Patient Protection Act.

''(D) SOLE AUTHORITY.—The board has sole authority under the plan to approve applications for participation in the plan and to contract with a service provider to administer the day-to-day affairs of the plan.

''(c) TREATMENT OF FRANCHISE NETWORKS.—In the case of a group health plan which is established and maintained by a franchiser for a franchise network consisting of its franchisees—

''(1) the requirements of subsection (a) and section 801(a)(1) shall be deemed met if such requirements would otherwise be met if the franchiser were deemed to be the sponsor referred to in section 801(b), such network were deemed to be an association described in section 801(b), and each franchisee were deemed to be a member (of the association and the sponsor) referred to in section 801(b); and

''(2) the requirements of section 804(a)(1) shall be deemed met.

The Secretary may by regulation, through negotiated rulemaking, define for purposes of this subsection the terms 'franchiser', 'franchise network', and 'franchisee'.

''(d) CERTAIN COLLECTIVELY BARGAINED PLANS.—

''(1) IN GENERAL.—In the case of a group health plan described in paragraph (2)—

''(A) the requirements of subsection (a) and section 801(a)(1) shall be deemed met;

''(B) the joint board of trustees shall be deemed a board of trustees with respect to which the requirements of subsection (b) are met; and

''(C) the requirements of section 804 shall be deemed met.

''(2) REQUIREMENTS.—A group health plan is described in this paragraph if—

''(A) the plan is a multiemployer plan; or

''(B) the plan is in existence on April 1, 2001, and would be described in section 3(40)(A)(i) but solely for the failure to meet the requirements of section 3(40)(C)(ii).

''(3) CONSTRUCTION.—A group health plan described in paragraph (2) shall only be treated as an association health plan under this part if the sponsor of the plan applies for, and obtains, certification

of the plan as an association health plan under this part.

"SEC. 804. PARTICIPATION AND COVERAGE REQUIREMENTS.

"(a) COVERED EMPLOYERS AND INDIVIDUALS.—The requirements of this subsection are met with respect to an association health plan if, under the terms of the plan—

"(1) each participating employer must be—

"(A) a member of the sponsor,

"(B) the sponsor, or

"(C) an affiliated member of the sponsor with respect to which the requirements of subsection (b) are met,

except that, in the case of a sponsor which is a professional association or other individual-based association, if at least one of the officers, directors, or employees of an employer, or at least one of the individuals who are partners in an employer and who actively participates in the business, is a member or such an affiliated member of the sponsor, participating employers may also include such employer; and

''(2) all individuals commencing coverage under the plan after certification under this part must be—

''(A) active or retired owners (including self-employed individuals), officers, directors, or employees of, or partners in, participating employers; or

''(B) the beneficiaries of individuals described in subparagraph (A).

''(b) COVERAGE OF PREVIOUSLY UNINSURED EMPLOYEES.—In the case of an association health plan in existence on the date of the enactment of the Bipartisan Patient Protection Act, an affiliated member of the sponsor of the plan may be offered coverage under the plan as a participating employer only if—

''(1) the affiliated member was an affiliated member on the date of certification under this part; or

''(2) during the 12-month period preceding the date of the offering of such coverage, the affiliated member has not maintained or contributed to a group health plan with respect to any of its employees who would otherwise be eligible to participate in such association health plan.

''(c) INDIVIDUAL MARKET UNAFFECTED.—The requirements of this subsection are met with respect to an association health plan if, under the terms of the plan, no participating employer may provide health insurance coverage in the individual market for any employee not covered under the plan which is similar to the coverage contemporaneously provided to employees of the employer under the plan, if such exclusion of the employee from coverage under the plan is based on a health status-related factor with respect to the employee and such employee would, but for such exclusion on such basis, be eligible for coverage under the plan.

''(d) PROHIBITION OF DISCRIMINATION AGAINST EMPLOYERS AND EMPLOYEES ELIGIBLE TO PARTICIPATE.—The requirements of this subsection are met with respect to an association health plan if—

''(1) under the terms of the plan, all employers meeting the preceding requirements of this section are eligible to qualify as participating employers for all geographically available coverage options, unless, in the case of any such employer, participation or contribution requirements of the type referred to in section 2711 of the Public Health Service Act are not met;

''(2) upon request, any employer eligible to participate is furnished information regarding all coverage options available under the plan; and

''(3) the applicable requirements of sections 701, 702, and 703 are met with respect to the plan.

''SEC. 805. OTHER REQUIREMENTS RELATING TO PLAN DOCUMENTS, CONTRIBUTION RATES, AND BENEFIT OPTIONS.

''(a) IN GENERAL.—The requirements of this section are met with respect to an association health plan if the following requirements are met:

''(1) CONTENTS OF GOVERNING INSTRUMENTS.—The instruments governing the plan include a written instrument, meeting the requirements of an instrument required under section 402(a)(1), which—

''(A) provides that the board of trustees serves as the named fiduciary required for plans under section 402(a)(1) and serves in the capacity of a plan administrator (referred to in section 3(16)(A));

''(B) provides that the sponsor of the plan is to serve as plan sponsor (referred to in section 3(16)(B)); and

''(C) incorporates the requirements of section 806.

''(2) CONTRIBUTION RATES MUST BE NONDISCRIMINATORY.—

''(A) The contribution rates for any participating small employer do not vary on the basis of the claims experience of such employer and do not vary on the basis of the type of business or industry in which such employer is engaged.

''(B) Nothing in this title or any other provision of law shall be construed to preclude an association health plan, or a health insurance issuer offering health insurance coverage in connection with an association health plan, from—

''(i) setting contribution rates based on the claims experience of the plan; or

''(ii) varying contribution rates for small employers in a State to the extent that such rates could vary using the same methodology employed in such State for regulating premium rates in the small group market with respect to health insurance coverage offered in connection with

bona fide associations (within the meaning of section 2791(d)(3) of the Public Health Service Act),

subject to the requirements of section 702(b) relating to contribution rates.

''(3) FLOOR FOR NUMBER OF COVERED INDIVIDUALS WITH RESPECT TO CERTAIN PLANS.—If any benefit option under the plan does not consist of health insurance coverage, the plan has as of the beginning of the plan year not fewer than 1,000 participants and beneficiaries.

''(4) MARKETING REQUIREMENTS.—

''(A) IN GENERAL.—If a benefit option which consists of health insurance coverage is offered under the plan, State-licensed insurance agents shall be used to distribute to small employers coverage which does not consist of health insurance coverage in a manner comparable to the manner in which such agents are used to distribute health insurance coverage.

''(B) STATE-LICENSED INSURANCE AGENTS.—For purposes of subparagraph (A), the term 'State-licensed insurance agents' means one or more agents who are licensed in a State and are subject to the laws of such

State relating to licensure, qualification, testing, examination, and continuing education of persons authorized to offer, sell, or solicit health insurance coverage in such State.

''(5) REGULATORY REQUIREMENTS.—Such other requirements as the applicable authority determines are necessary to carry out the purposes of this part, which shall be prescribed by the applicable authority by regulation through negotiated rulemaking.

''(b) ABILITY OF ASSOCIATION HEALTH PLANS TO DESIGN BENEFIT OPTIONS.—Subject to section 514(d), nothing in this part or any provision of State law (as defined in section 514(c)(1)) shall be construed to preclude an association health plan, or a health insurance issuer offering health insurance coverage in connection with an association health plan, from exercising its sole discretion in selecting the specific items and services consisting of medical care to be included as benefits under such plan or coverage, except (subject to section 514) in the case of any law to the extent that it (1) prohibits an exclusion of a specific disease from such coverage, or (2) is not preempted under section 731(a)(1) with respect to matters governed by section 711 or 712.

"SEC. 806. MAINTENANCE OF RESERVES AND PROVISIONS FOR SOLVENCY FOR PLANS PROVIDING HEALTH BENEFITS IN ADDITION TO HEALTH INSURANCE COVERAGE.

''(a) IN GENERAL.—The requirements of this section are met with respect to an association health plan if—

''(1) the benefits under the plan consist solely of health insurance coverage; or

''(2) if the plan provides any additional benefit options which do not consist of health insurance coverage, the plan—

''(A) establishes and maintains reserves with respect to such additional benefit options, in amounts recommended by the qualified actuary, consisting of—

''(i) a reserve sufficient for unearned contributions;

''(ii) a reserve sufficient for benefit liabilities which have been incurred, which have not been satisfied, and for which risk of loss has not yet been transferred, and for expected administrative costs with respect to such benefit liabilities;

''(iii) a reserve sufficient for any other obligations of the plan; and

''(iv) a reserve sufficient for a margin of error and other fluctuations, taking into account the specific circumstances of the plan; and

''(B) establishes and maintains aggregate and specific excess/stop loss insurance and solvency indemnification, with respect to such additional benefit options for which risk of loss has not yet been transferred, as follows:

''(i) The plan shall secure aggregate excess/stop loss insurance for the plan with an attachment point which is not greater than 125 percent of expected gross annual claims. The applicable authority may by regulation, through negotiated rulemaking, provide for upward adjustments in the amount of such percentage in specified circumstances in which the plan specifically provides for and maintains reserves in excess of the amounts required under subparagraph (A).

''(ii) The plan shall secure specific excess/stop loss insurance for the plan with an attachment point which is at least equal to an amount recommended by the plan's

qualified actuary. The applicable authority may by regulation, through negotiated rulemaking, provide for adjustments in the amount of such insurance in specified circumstances in which the plan specifically provides for and maintains reserves in excess of the amounts required under subparagraph (A).

''(iii) The plan shall secure indemnification insurance for any claims which the plan is unable to satisfy by reason of a plan termination.

Any regulations prescribed by the applicable authority pursuant to clause (i) or (ii) of subparagraph (B) may allow for such adjustments in the required levels of excess/stop loss insurance as the qualified actuary may recommend, taking into account the specific circumstances of the plan.

''(b) MINIMUM SURPLUS IN ADDITION TO CLAIMS RESERVES.—In the case of any association health plan described in subsection (a)(2), the requirements of this subsection are met if the plan establishes and maintains surplus in an amount at least equal to—

''(1) $500,000, or

''(2) such greater amount (but not greater than $2,000,000) as may be set forth in regulations prescribed by the applicable authority through negotiated rulemaking, based on the level of aggregate and specific excess/stop loss insurance provided with respect to such plan.

''(c) ADDITIONAL REQUIREMENTS.—In the case of any association health plan described in subsection (a)(2), the applicable authority may provide such additional requirements relating to reserves and excess/stop loss insurance as the applicable authority considers appropriate. Such requirements may be provided by regulation, through negotiated rulemaking, with respect to any such plan or any class of such plans.

''(d) ADJUSTMENTS FOR EXCESS/STOP LOSS INSURANCE.—The applicable authority may provide for adjustments to the levels of reserves otherwise required under subsections (a) and (b) with respect to any plan or class of plans to take into account excess/stop loss insurance provided with respect to such plan or plans.

''(e) ALTERNATIVE MEANS OF COMPLIANCE.—The applicable authority may permit an association health plan described in subsection (a)(2) to substitute, for all or part of the requirements of this section (except subsection (a)(2)(B)(iii)), such security, guarantee, hold-harmless ar-

rangement, or other financial arrangement as the applicable authority determines to be adequate to enable the plan to fully meet all its financial obligations on a timely basis and is otherwise no less protective of the interests of participants and beneficiaries than the requirements for which it is substituted. The applicable authority may take into account, for purposes of this subsection, evidence provided by the plan or sponsor which demonstrates an assumption of liability with respect to the plan. Such evidence may be in the form of a contract of indemnification, lien, bonding, insurance, letter of credit, recourse under applicable terms of the plan in the form of assessments of participating employers, security, or other financial arrangement.

''(f) MEASURES TO ENSURE CONTINUED PAYMENT OF BENEFITS BY CERTAIN PLANS IN DISTRESS.—

''(1) PAYMENTS BY CERTAIN PLANS TO ASSOCIATION HEALTH PLAN FUND.—

''(A) IN GENERAL.—In the case of an association health plan described in subsection (a)(2), the requirements of this subsection are met if the plan makes payments into the Association Health Plan Fund under this subparagraph when they are due. Such payments shall consist of annual payments in the amount of

$5,000, and, in addition to such annual payments, such supplemental payments as the Secretary may determine to be necessary under paragraph (2). Payments under this paragraph are payable to the Fund at the time determined by the Secretary. Initial payments are due in advance of certification under this part. Payments shall continue to accrue until a plan's assets are distributed pursuant to a termination procedure.

''(B) PENALTIES FOR FAILURE TO MAKE PAYMENTS.—If any payment is not made by a plan when it is due, a late payment charge of not more than 100 percent of the payment which was not timely paid shall be payable by the plan to the Fund.

''(C) CONTINUED DUTY OF THE SECRETARY.—The Secretary shall not cease to carry out the provisions of paragraph (2) on account of the failure of a plan to pay any payment when due.

''(2) PAYMENTS BY SECRETARY TO CONTINUE EXCESS/STOP LOSS INSURANCE COVERAGE AND INDEMNIFICATION INSURANCE COVERAGE FOR CERTAIN PLANS.—In any case in which the applicable

authority determines that there is, or that there is reason to believe that there will be: (A) a failure to take necessary corrective actions under section 809(a) with respect to an association health plan described in subsection (a)(2); or (B) a termination of such a plan under section 809(b) or 810(b)(8) (and, if the applicable authority is not the Secretary, certifies such determination to the Secretary), the Secretary shall determine the amounts necessary to make payments to an insurer (designated by the Secretary) to maintain in force excess/stop loss insurance coverage or indemnification insurance coverage for such plan, if the Secretary determines that there is a reasonable expectation that, without such payments, claims would not be satisfied by reason of termination of such coverage. The Secretary shall, to the extent provided in advance in appropriation Acts, pay such amounts so determined to the insurer designated by the Secretary.

''(3) ASSOCIATION HEALTH PLAN FUND.—

''(A) IN GENERAL.—There is established on the books of the Treasury a fund to be known as the 'Association Health Plan Fund'. The Fund shall be available for making payments pursuant to paragraph (2). The Fund

shall be credited with payments received pursuant to paragraph (1)(A), penalties received pursuant to paragraph (1)(B); and earnings on investments of amounts of the Fund under subparagraph (B).

''(B) INVESTMENT.—Whenever the Secretary determines that the moneys of the fund are in excess of current needs, the Secretary may request the investment of such amounts as the Secretary determines advisable by the Secretary of the Treasury in obligations issued or guaranteed by the United States.

''(g) EXCESS/STOP LOSS INSURANCE.—For purposes of this section—

''(1) AGGREGATE EXCESS/STOP LOSS INSURANCE.—The term 'aggregate excess/stop loss insurance' means, in connection with an association health plan, a contract—

''(A) under which an insurer (meeting such minimum standards as the applicable authority may prescribe by regulation through negotiated rulemaking) provides for payment to the plan with respect to aggregate claims under the plan in excess of an amount or amounts specified in such contract;

"(B) which is guaranteed renewable; and

"(C) which allows for payment of premiums by any third party on behalf of the insured plan.

"(2) SPECIFIC EXCESS/STOP LOSS INSURANCE.—The term 'specific excess/stop loss insurance' means, in connection with an association health plan, a contract—

"(A) under which an insurer (meeting such minimum standards as the applicable authority may prescribe by regulation through negotiated rulemaking) provides for payment to the plan with respect to claims under the plan in connection with a covered individual in excess of an amount or amounts specified in such contract in connection with such covered individual;

"(B) which is guaranteed renewable; and

"(C) which allows for payment of premiums by any third party on behalf of the insured plan.

"(h) INDEMNIFICATION INSURANCE.—For purposes of this section, the term 'indemnification insurance' means, in connection with an association health plan, a contract—

''(1) under which an insurer (meeting such minimum standards as the applicable authority may prescribe through negotiated rulemaking) provides for payment to the plan with respect to claims under the plan which the plan is unable to satisfy by reason of a termination pursuant to section 809(b) (relating to mandatory termination);

''(2) which is guaranteed renewable and noncancellable for any reason (except as the applicable authority may prescribe by regulation through negotiated rulemaking); and

''(3) which allows for payment of premiums by any third party on behalf of the insured plan.

''(i) RESERVES.—For purposes of this section, the term 'reserves' means, in connection with an association health plan, plan assets which meet the fiduciary standards under part 4 and such additional requirements regarding liquidity as the applicable authority may prescribe through negotiated rulemaking.

''(j) SOLVENCY STANDARDS WORKING GROUP.—

''(1) IN GENERAL.—Within 90 days after the date of the enactment of the Bipartisan Patient Protection Act, the applicable authority shall establish a Solvency Standards Working Group. In prescribing the initial regulations under this section, the applica-

ble authority shall take into account the recommendations of such Working Group.

''(2) MEMBERSHIP.—The Working Group shall consist of not more than 15 members appointed by the applicable authority. The applicable authority shall include among persons invited to membership on the Working Group at least one of each of the following:

''(A) a representative of the National Association of Insurance Commissioners;

''(B) a representative of the American Academy of Actuaries;

''(C) a representative of the State governments, or their interests;

''(D) a representative of existing self-insured arrangements, or their interests;

''(E) a representative of associations of the type referred to in section 801(b)(1), or their interests; and

''(F) a representative of multiemployer plans that are group health plans, or their interests.

"SEC. 807. REQUIREMENTS FOR APPLICATION AND RELATED REQUIREMENTS.

"(a) FILING FEE.—Under the procedure prescribed pursuant to section 802(a), an association health plan shall pay to the applicable authority at the time of filing an application for certification under this part a filing fee in the amount of $5,000, which shall be available in the case of the Secretary, to the extent provided in appropriation Acts, for the sole purpose of administering the certification procedures applicable with respect to association health plans.

"(b) INFORMATION TO BE INCLUDED IN APPLICATION FOR CERTIFICATION.—An application for certification under this part meets the requirements of this section only if it includes, in a manner and form which shall be prescribed by the applicable authority through negotiated rulemaking, at least the following information:

"(1) IDENTIFYING INFORMATION.—The names and addresses of—

"(A) the sponsor; and

"(B) the members of the board of trustees of the plan.

"(2) STATES IN WHICH PLAN INTENDS TO DO BUSINESS.—The States in which participants and beneficiaries under the plan are to be located and

the number of them expected to be located in each such State.

''(3) BONDING REQUIREMENTS.—Evidence provided by the board of trustees that the bonding requirements of section 412 will be met as of the date of the application or (if later) commencement of operations.

''(4) PLAN DOCUMENTS.—A copy of the documents governing the plan (including any bylaws and trust agreements), the summary plan description, and other material describing the benefits that will be provided to participants and beneficiaries under the plan.

''(5) AGREEMENTS WITH SERVICE PROVIDERS.—A copy of any agreements between the plan and contract administrators and other service providers.

''(6) FUNDING REPORT.—In the case of association health plans providing benefits options in addition to health insurance coverage, a report setting forth information with respect to such additional benefit options determined as of a date within the 120-day period ending with the date of the application, including the following:

"(A) RESERVES.—A statement, certified by the board of trustees of the plan, and a statement of actuarial opinion, signed by a qualified actuary, that all applicable requirements of section 806 are or will be met in accordance with regulations which the applicable authority shall prescribe through negotiated rulemaking.

"(B) ADEQUACY OF CONTRIBUTION RATES.—A statement of actuarial opinion, signed by a qualified actuary, which sets forth a description of the extent to which contribution rates are adequate to provide for the payment of all obligations and the maintenance of required reserves under the plan for the 12-month period beginning with such date within such 120-day period, taking into account the expected coverage and experience of the plan. If the contribution rates are not fully adequate, the statement of actuarial opinion shall indicate the extent to which the rates are inadequate and the changes needed to ensure adequacy.

"(C) CURRENT AND PROJECTED VALUE OF ASSETS AND LIABILITIES.—A statement of actuarial opinion signed by a qualified actuary,

which sets forth the current value of the assets and liabilities accumulated under the plan and a projection of the assets, liabilities, income, and expenses of the plan for the 12-month period referred to in subparagraph (B). The income statement shall identify separately the plan's administrative expenses and claims.

''(D) COSTS OF COVERAGE TO BE CHARGED AND OTHER EXPENSES.—A statement of the costs of coverage to be charged, including an itemization of amounts for administration, reserves, and other expenses associated with the operation of the plan.

''(E) OTHER INFORMATION.—Any other information as may be determined by the applicable authority, by regulation through negotiated rulemaking, as necessary to carry out the purposes of this part.

''(c) FILING NOTICE OF CERTIFICATION WITH STATES.—A certification granted under this part to an association health plan shall not be effective unless written notice of such certification is filed with the applicable State authority of each State in which at least 25 percent of the participants and beneficiaries under the plan are located. For purposes of this subsection, an individual

shall be considered to be located in the State in which a known address of such individual is located or in which such individual is employed.

''(d) NOTICE OF MATERIAL CHANGES.—In the case of any association health plan certified under this part, descriptions of material changes in any information which was required to be submitted with the application for the certification under this part shall be filed in such form and manner as shall be prescribed by the applicable authority by regulation through negotiated rulemaking. The applicable authority may require by regulation, through negotiated rulemaking, prior notice of material changes with respect to specified matters which might serve as the basis for suspension or revocation of the certification.

''(e) REPORTING REQUIREMENTS FOR CERTAIN ASSOCIATION HEALTH PLANS.—An association health plan certified under this part which provides benefit options in addition to health insurance coverage for such plan year shall meet the requirements of section 503B by filing an annual report under such section which shall include information described in subsection (b)(6) with respect to the plan year and, notwithstanding section 503C(a)(1)(A), shall be filed with the applicable authority not later than 90 days after the close of the plan year (or on such later date as may be prescribed by the applicable authority).

The applicable authority may require by regulation through negotiated rulemaking such interim reports as it considers appropriate.

''(f) ENGAGEMENT OF QUALIFIED ACTUARY.—The board of trustees of each association health plan which provides benefits options in addition to health insurance coverage and which is applying for certification under this part or is certified under this part shall engage, on behalf of all participants and beneficiaries, a qualified actuary who shall be responsible for the preparation of the materials comprising information necessary to be submitted by a qualified actuary under this part. The qualified actuary shall utilize such assumptions and techniques as are necessary to enable such actuary to form an opinion as to whether the contents of the matters reported under this part—

''(1) are in the aggregate reasonably related to the experience of the plan and to reasonable expectations; and

''(2) represent such actuary's best estimate of anticipated experience under the plan.

The opinion by the qualified actuary shall be made with respect to, and shall be made a part of, the annual report.

"SEC. 808. NOTICE REQUIREMENTS FOR VOLUNTARY TERMINATION.

"Except as provided in section 809(b), an association health plan which is or has been certified under this part may terminate (upon or at any time after cessation of accruals in benefit liabilities) only if the board of trustees—

"(1) not less than 60 days before the proposed termination date, provides to the participants and beneficiaries a written notice of intent to terminate stating that such termination is intended and the proposed termination date;

"(2) develops a plan for winding up the affairs of the plan in connection with such termination in a manner which will result in timely payment of all benefits for which the plan is obligated; and

"(3) submits such plan in writing to the applicable authority.

Actions required under this section shall be taken in such form and manner as may be prescribed by the applicable authority by regulation through negotiated rulemaking.

"SEC. 809. CORRECTIVE ACTIONS AND MANDATORY TERMINATION.

"(a) ACTIONS TO AVOID DEPLETION OF RESERVES.—An association health plan which is certified under this part and which provides benefits other than health insurance coverage shall continue to meet the re-

quirements of section 806, irrespective of whether such certification continues in effect. The board of trustees of such plan shall determine quarterly whether the requirements of section 806 are met. In any case in which the board determines that there is reason to believe that there is or will be a failure to meet such requirements, or the applicable authority makes such a determination and so notifies the board, the board shall immediately notify the qualified actuary engaged by the plan, and such actuary shall, not later than the end of the next following month, make such recommendations to the board for corrective action as the actuary determines necessary to ensure compliance with section 806. Not later than 30 days after receiving from the actuary recommendations for corrective actions, the board shall notify the applicable authority (in such form and manner as the applicable authority may prescribe by regulation through negotiated rulemaking) of such recommendations of the actuary for corrective action, together with a description of the actions (if any) that the board has taken or plans to take in response to such recommendations. The board shall thereafter report to the applicable authority, in such form and frequency as the applicable authority may specify to the board, regarding corrective action taken by the board until the requirements of section 806 are met.

''(b) MANDATORY TERMINATION.—In any case in which—

''(1) the applicable authority has been notified under subsection (a) of a failure of an association health plan which is or has been certified under this part and is described in section 806(a)(2) to meet the requirements of section 806 and has not been notified by the board of trustees of the plan that corrective action has restored compliance with such requirements; and

''(2) the applicable authority determines that there is a reasonable expectation that the plan will continue to fail to meet the requirements of section 806,

the board of trustees of the plan shall, at the direction of the applicable authority, terminate the plan and, in the course of the termination, take such actions as the applicable authority may require, including satisfying any claims referred to in section 806(a)(2)(B)(iii) and recovering for the plan any liability under subsection (a)(2)(B)(iii) or (e) of section 806, as necessary to ensure that the affairs of the plan will be, to the maximum extent possible, wound up in a manner which will result in timely provision of all benefits for which the plan is obligated.

"SEC. 810. TRUSTEESHIP BY THE SECRETARY OF INSOLVENT ASSOCIATION HEALTH PLANS PROVIDING HEALTH BENEFITS IN ADDITION TO HEALTH INSURANCE COVERAGE.

''(a) APPOINTMENT OF SECRETARY AS TRUSTEE FOR INSOLVENT PLANS.—Whenever the Secretary determines that an association health plan which is or has been certified under this part and which is described in section 806(a)(2) will be unable to provide benefits when due or is otherwise in a financially hazardous condition, as shall be defined by the Secretary by regulation through negotiated rulemaking, the Secretary shall, upon notice to the plan, apply to the appropriate United States district court for appointment of the Secretary as trustee to administer the plan for the duration of the insolvency. The plan may appear as a party and other interested persons may intervene in the proceedings at the discretion of the court. The court shall appoint such Secretary trustee if the court determines that the trusteeship is necessary to protect the interests of the participants and beneficiaries or providers of medical care or to avoid any unreasonable deterioration of the financial condition of the plan. The trusteeship of such Secretary shall continue until the conditions described in the first sentence of this subsection are remedied or the plan is terminated.

''(b) POWERS AS TRUSTEE.—The Secretary, upon appointment as trustee under subsection (a), shall have the power—

''(1) to do any act authorized by the plan, this title, or other applicable provisions of law to be done by the plan administrator or any trustee of the plan;

''(2) to require the transfer of all (or any part) of the assets and records of the plan to the Secretary as trustee;

''(3) to invest any assets of the plan which the Secretary holds in accordance with the provisions of the plan, regulations prescribed by the Secretary through negotiated rulemaking, and applicable provisions of law;

''(4) to require the sponsor, the plan administrator, any participating employer, and any employee organization representing plan participants to furnish any information with respect to the plan which the Secretary as trustee may reasonably need in order to administer the plan;

''(5) to collect for the plan any amounts due the plan and to recover reasonable expenses of the trusteeship;

''(6) to commence, prosecute, or defend on behalf of the plan any suit or proceeding involving the plan;

''(7) to issue, publish, or file such notices, statements, and reports as may be required by the Secretary by regulation through negotiated rulemaking or required by any order of the court;

''(8) to terminate the plan (or provide for its termination in accordance with section 809(b)) and liquidate the plan assets, to restore the plan to the responsibility of the sponsor, or to continue the trusteeship;

''(9) to provide for the enrollment of plan participants and beneficiaries under appropriate coverage options; and

''(10) to do such other acts as may be necessary to comply with this title or any order of the court and to protect the interests of plan participants and beneficiaries and providers of medical care.

''(c) NOTICE OF APPOINTMENT.—As soon as practicable after the Secretary's appointment as trustee, the Secretary shall give notice of such appointment to—

''(1) the sponsor and plan administrator;

''(2) each participant;

''(3) each participating employer; and

''(4) if applicable, each employee organization which, for purposes of collective bargaining, represents plan participants.

''(d) ADDITIONAL DUTIES.—Except to the extent inconsistent with the provisions of this title, or as may be otherwise ordered by the court, the Secretary, upon appointment as trustee under this section, shall be subject to the same duties as those of a trustee under section 704 of title 11, United States Code, and shall have the duties of a fiduciary for purposes of this title.

''(e) OTHER PROCEEDINGS.—An application by the Secretary under this subsection may be filed notwithstanding the pendency in the same or any other court of any bankruptcy, mortgage foreclosure, or equity receivership proceeding, or any proceeding to reorganize, conserve, or liquidate such plan or its property, or any proceeding to enforce a lien against property of the plan.

''(f) JURISDICTION OF COURT.—

''(1) IN GENERAL.—Upon the filing of an application for the appointment as trustee or the issuance of a decree under this section, the court to which the application is made shall have exclusive jurisdiction of the plan involved and its property wherever located with the powers, to the extent consistent with

the purposes of this section, of a court of the United States having jurisdiction over cases under chapter 11 of title 11, United States Code. Pending an adjudication under this section such court shall stay, and upon appointment by it of the Secretary as trustee, such court shall continue the stay of, any pending mortgage foreclosure, equity receivership, or other proceeding to reorganize, conserve, or liquidate the plan, the sponsor, or property of such plan or sponsor, and any other suit against any receiver, conservator, or trustee of the plan, the sponsor, or property of the plan or sponsor. Pending such adjudication and upon the appointment by it of the Secretary as trustee, the court may stay any proceeding to enforce a lien against property of the plan or the sponsor or any other suit against the plan or the sponsor.

''(2) VENUE.—An action under this section may be brought in the judicial district where the sponsor or the plan administrator resides or does business or where any asset of the plan is situated. A district court in which such action is brought may issue process with respect to such action in any other judicial district.

''(g) PERSONNEL.—In accordance with regulations which shall be prescribed by the Secretary through negotiated rulemaking, the Secretary shall appoint, retain, and compensate accountants, actuaries, and other professional service personnel as may be necessary in connection with the Secretary's service as trustee under this section.

''SEC. 811. STATE ASSESSMENT AUTHORITY.

''(a) IN GENERAL.—Notwithstanding section 514, a State may impose by law a contribution tax on an association health plan described in section 806(a)(2), if the plan commenced operations in such State after the date of the enactment of the Bipartisan Patient Protection Act.

''(b) CONTRIBUTION TAX.—For purposes of this section, the term 'contribution tax' imposed by a State on an association health plan means any tax imposed by such State if—

''(1) such tax is computed by applying a rate to the amount of premiums or contributions, with respect to individuals covered under the plan who are residents of such State, which are received by the plan from participating employers located in such State or from such individuals;

''(2) the rate of such tax does not exceed the rate of any tax imposed by such State on premiums or contributions received by insurers or health main-

tenance organizations for health insurance coverage offered in such State in connection with a group health plan;

''(3) such tax is otherwise nondiscriminatory; and

''(4) the amount of any such tax assessed on the plan is reduced by the amount of any tax or assessment otherwise imposed by the State on premiums, contributions, or both received by insurers or health maintenance organizations for health insurance coverage, aggregate excess/stop loss insurance (as defined in section 806(g)(1)), specific excess/stop loss insurance (as defined in section 806(g)(2)), other insurance related to the provision of medical care under the plan, or any combination thereof provided by such insurers or health maintenance organizations in such State in connection with such plan.

''SEC. 812. DEFINITIONS AND RULES OF CONSTRUCTION.

''(a) DEFINITIONS.—For purposes of this part—

''(1) GROUP HEALTH PLAN.—The term 'group health plan' has the meaning provided in section 733(a)(1) (after applying subsection (b) of this section).

''(2) MEDICAL CARE.—The term 'medical care' has the meaning provided in section 733(a)(2).

''(3) HEALTH INSURANCE COVERAGE.—The term 'health insurance coverage' has the meaning provided in section 733(b)(1).

''(4) HEALTH INSURANCE ISSUER.—The term 'health insurance issuer' has the meaning provided in section 733(b)(2).

''(5) APPLICABLE AUTHORITY.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), the term 'applicable authority' means, in connection with an association health plan—

''(i) the State recognized pursuant to subsection (c) of section 506 as the State to which authority has been delegated in connection with such plan; or

''(ii) if there if no State referred to in clause (i), the Secretary.

''(B) EXCEPTIONS.—

''(i) JOINT AUTHORITIES.—Where such term appears in section 808(3), section 807(e) (in the first instance), section 809(a) (in the second instance), section 809(a) (in the fourth instance), and section 809(b)(1), such term means, in connection with an association health plan, the

Secretary and the State referred to in subparagraph (A)(i) (if any) in connection with such plan.

''(ii) REGULATORY AUTHORITIES.—Where such term appears in section 802(a) (in the first instance), section 802(d), section 802(e), section 803(d), section 805(a)(5), section 806(a)(2), section 806(b), section 806(c), section 806(d), paragraphs (1)(A) and (2)(A) of section 806(g), section 806(h), section 806(i), section 806(j), section 807(a) (in the second instance), section 807(b), section 807(d), section 807(e) (in the second instance), section 808 (in the matter after paragraph (3)), and section 809(a) (in the third instance), such term means, in connection with an association health plan, the Secretary.

''(6) HEALTH STATUS-RELATED FACTOR.—The term 'health status-related factor' has the meaning provided in section 733(d)(2).

''(7) INDIVIDUAL MARKET.—

''(A) IN GENERAL.—The term 'individual market' means the market for health insurance

coverage offered to individuals other than in connection with a group health plan.

''(B) TREATMENT OF VERY SMALL GROUPS.—

''(i) IN GENERAL.—Subject to clause (ii), such term includes coverage offered in connection with a group health plan that has fewer than 2 participants as current employees or participants described in section 732(d)(3) on the first day of the plan year.

''(ii) STATE EXCEPTION.—Clause (i) shall not apply in the case of health insurance coverage offered in a State if such State regulates the coverage described in such clause in the same manner and to the same extent as coverage in the small group market (as defined in section 2791(e)(5) of the Public Health Service Act) is regulated by such State.

''(8) PARTICIPATING EMPLOYER.—The term 'participating employer' means, in connection with an association health plan, any employer, if any individual who is an employee of such employer, a partner in such employer, or a self-employed individual

who is such employer (or any dependent, as defined under the terms of the plan, of such individual) is or was covered under such plan in connection with the status of such individual as such an employee, partner, or self-employed individual in relation to the plan.

''(9) APPLICABLE STATE AUTHORITY.—The term 'applicable State authority' means, with respect to a health insurance issuer in a State, the State insurance commissioner or official or officials designated by the State to enforce the requirements of title XXVII of the Public Health Service Act for the State involved with respect to such issuer.

''(10) QUALIFIED ACTUARY.—The term 'qualified actuary' means an individual who is a member of the American Academy of Actuaries or meets such reasonable standards and qualifications as the Secretary may provide by regulation through negotiated rulemaking.

''(11) AFFILIATED MEMBER.—The term 'affiliated member' means, in connection with a sponsor—

''(A) a person who is otherwise eligible to be a member of the sponsor but who elects an affiliated status with the sponsor,

''(B) in the case of a sponsor with members which consist of associations, a person who is a member of any such association and elects an affiliated status with the sponsor, or

''(C) in the case of an association health plan in existence on the date of the enactment of the Bipartisan Patient Protection Act, a person eligible to be a member of the sponsor or one of its member associations.

''(12) LARGE EMPLOYER.—The term 'large employer' means, in connection with a group health plan with respect to a plan year, an employer who employed an average of at least 51 employees on business days during the preceding calendar year and who employs at least 2 employees on the first day of the plan year.

''(13) SMALL EMPLOYER.—The term 'small employer' means, in connection with a group health plan with respect to a plan year, an employer who is not a large employer.

''(b) RULES OF CONSTRUCTION.—

''(1) EMPLOYERS AND EMPLOYEES.—For purposes of determining whether a plan, fund, or program is an employee welfare benefit plan which is an association health plan, and for purposes of applying

this title in connection with such plan, fund, or program so determined to be such an employee welfare benefit plan—

"(A) in the case of a partnership, the term 'employer' (as defined in section 3(5)) includes the partnership in relation to the partners, and the term 'employee' (as defined in section 3(6)) includes any partner in relation to the partnership; and

"(B) in the case of a self-employed individual, the term 'employer' (as defined in section 3(5)) and the term 'employee' (as defined in section 3(6)) shall include such individual.

"(2) PLANS, FUNDS, AND PROGRAMS TREATED AS EMPLOYEE WELFARE BENEFIT PLANS.—In the case of any plan, fund, or program which was established or is maintained for the purpose of providing medical care (through the purchase of insurance or otherwise) for employees (or their dependents) covered thereunder and which demonstrates to the Secretary that all requirements for certification under this part would be met with respect to such plan, fund, or program if such plan, fund, or program were a group health plan, such plan, fund, or program shall be treated for purposes of this title as an

employee welfare benefit plan on and after the date of such demonstration.''.

(b) CONFORMING AMENDMENTS TO PREEMPTION RULES.—

(1) Section 514(b)(6) of such Act (29 U.S.C. 1144(b)(6)) is amended by adding at the end the following new subparagraph:

''(E) The preceding subparagraphs of this paragraph do not apply with respect to any State law in the case of an association health plan which is certified under part 8.''.

(2) Section 514 of such Act (29 U.S.C. 1144) is amended—

(A) in subsection (b)(4), by striking ''Subsection (a)'' and inserting ''Subsections (a) and (e)'';

(B) in subsection (b)(5), by striking ''subsection (a)'' in subparagraph (A) and inserting ''subsection (a) of this section and subsections (a)(2)(B) and (b) of section 805'', and by striking ''subsection (a)'' in subparagraph (B) and inserting ''subsection (a) of this section or subsection (a)(2)(B) or (b) of section 805'';

(C) by redesignating subsection (d) as subsection (e); and

(D) by inserting after subsection (c) the following new subsection:

''(d)(1) Except as provided in subsection (b)(4), the provisions of this title shall supersede any and all State laws insofar as they may now or hereafter preclude, or have the effect of precluding, a health insurance issuer from offering health insurance coverage in connection with an association health plan which is certified under part 8.

''(2) Except as provided in paragraphs (4) and (5) of subsection (b) of this section—

''(A) In any case in which health insurance coverage of any policy type is offered under an association health plan certified under part 8 to a participating employer operating in such State, the provisions of this title shall supersede any and all laws of such State insofar as they may preclude a health insurance issuer from offering health insurance coverage of the same policy type to other employers operating in the State which are eligible for coverage under such association health plan, whether or not such other employers are participating employers in such plan.

''(B) In any case in which health insurance coverage of any policy type is offered under an associa-

tion health plan in a State and the filing, with the applicable State authority, of the policy form in connection with such policy type is approved by such State authority, the provisions of this title shall supersede any and all laws of any other State in which health insurance coverage of such type is offered, insofar as they may preclude, upon the filing in the same form and manner of such policy form with the applicable State authority in such other State, the approval of the filing in such other State.

''(3) For additional provisions relating to association health plans, see subsections (a)(2)(B) and (b) of section 805.

''(4) For purposes of this subsection, the term 'association health plan' has the meaning provided in section 801(a), and the terms 'health insurance coverage', 'participating employer', and 'health insurance issuer' have the meanings provided such terms in section 811, respectively.''.

(3) Section 514(b)(6)(A) of such Act (29 U.S.C. 1144(b)(6)(A)) is amended—

(A) in clause (i)(II), by striking ''and'' at the end;

(B) in clause (ii), by inserting ''and which does not provide medical care (within the mean-

ing of section 733(a)(2)),'' after ''arrangement,'', and by striking ''title.'' and inserting ''title, and''; and

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

''(iii) subject to subparagraph (E), in the case of any other employee welfare benefit plan which is a multiple employer welfare arrangement and which provides medical care (within the meaning of section 733(a)(2)), any law of any State which regulates insurance may apply.''.

(4) Section 514(e) of such Act (as redesignated by paragraph (2)(C)) is amended—

(A) by striking ''Nothing'' and inserting ''(1) Except as provided in paragraph (2), nothing''; and

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

''(2) Nothing in any other provision of law enacted on or after the date of the enactment of the Bipartisan Patient Protection Act shall be construed to alter, amend, modify, invalidate, impair, or supersede any provision of this title, except by specific cross-reference to the affected section.''.

(c) PLAN SPONSOR.—Section 3(16)(B) of such Act (29 U.S.C. 102(16)(B)) is amended by adding at the end the following new sentence: ''Such term also includes a person serving as the sponsor of an association health plan under part 8.''.

(d) DISCLOSURE OF SOLVENCY PROTECTIONS RELATED TO SELF-INSURED AND FULLY INSURED OPTIONS UNDER ASSOCIATION HEALTH PLANS.—Section 102(b) of such Act (29 U.S.C. 102(b)) is amended by adding at the end the following: ''An association health plan shall include in its summary plan description, in connection with each benefit option, a description of the form of solvency or guarantee fund protection secured pursuant to this Act or applicable State law, if any.''.

(e) SAVINGS CLAUSE.—Section 731(c) of such Act is amended by inserting ''or part 8'' after ''this part''.

(f) REPORT TO THE CONGRESS REGARDING CERTIFICATION OF SELF-INSURED ASSOCIATION HEALTH PLANS.—Not later than January 1, 2006, the Secretary of Labor shall report to the Committee on Education and the Workforce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate the effect association health plans have had, if any, on reducing the number of uninsured individuals.

(g) CLERICAL AMENDMENT.—The table of contents in section 1 of the Employee Retirement Income Security Act of 1974 is amended by inserting after the item relating to section 734 the following new items:

SEC. 422. CLARIFICATION OF TREATMENT OF SINGLE EMPLOYER ARRANGEMENTS.

Section 3(40)(B) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1002(40)(B)) is amended—

(1) in clause (i), by inserting ''for any plan year of any such plan, or any fiscal year of any such other arrangement;'' after ''single employer'', and by inserting ''during such year or at any time during the preceding 1-year period'' after ''control group'';

(2) in clause (iii)—

(A) by striking ''common control shall not be based on an interest of less than 25 percent''

and inserting ''an interest of greater than 25 percent may not be required as the minimum interest necessary for common control''; and

(B) by striking ''similar to'' and inserting ''consistent and coextensive with'';

(3) by redesignating clauses (iv) and (v) as clauses (v) and (vi), respectively; and

(4) by inserting after clause (iii) the following new clause:

''(iv) in determining, after the application of clause (i), whether benefits are provided to employees of two or more employers, the arrangement shall be treated as having only one participating employer if, after the application of clause (i), the number of individuals who are employees and former employees of any one participating employer and who are covered under the arrangement is greater than 75 percent of the aggregate number of all individuals who are employees or former employees of participating employers and who are covered under the arrangement;''.

SEC. 423. CLARIFICATION OF TREATMENT OF CERTAIN COLLECTIVELY BARGAINED ARRANGEMENTS.

(a) IN GENERAL.—Section 3(40)(A)(i) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1002(40)(A)(i)) is amended to read as follows:

''(i)(I) under or pursuant to one or more collective bargaining agreements which are reached pursuant to collective bargaining described in section 8(d) of the National Labor Relations Act (29 U.S.C. 158(d)) or paragraph Fourth of section 2 of the Railway Labor Act (45 U.S.C. 152, paragraph Fourth) or which are reached pursuant to labor-management negotiations under similar provisions of State public employee relations laws, and (II) in accordance with subparagraphs (C), (D), and (E);''.

(b) LIMITATIONS.—Section 3(40) of such Act (29 U.S.C. 1002(40)) is amended by adding at the end the following new subparagraphs:

''(C) For purposes of subparagraph (A)(i)(II), a plan or other arrangement shall be treated as established or maintained in accordance with this subparagraph only if the following requirements are met:

''(i) The plan or other arrangement, and the employee organization or any other entity sponsoring the plan or other arrangement, do not—

"(I) utilize the services of any licensed insurance agent or broker for soliciting or enrolling employers or individuals as participating employers or covered individuals under the plan or other arrangement; or

"(II) pay any type of compensation to a person, other than a full time employee of the employee organization (or a member of the organization to the extent provided in regulations prescribed by the Secretary through negotiated rulemaking), that is related either to the volume or number of employers or individuals solicited or enrolled as participating employers or covered individuals under the plan or other arrangement, or to the dollar amount or size of the contributions made by participating employers or covered individuals to the plan or other arrangement;

except to the extent that the services used by the plan, arrangement, organization, or other entity consist solely of preparation of documents necessary for compliance with the reporting and disclosure requirements of part 1 or administrative, investment, or consulting services unrelated to solicitation or enrollment of covered individuals.

''(ii) As of the end of the preceding plan year, the number of covered individuals under the plan or other arrangement who are neither—

''(I) employed within a bargaining unit covered by any of the collective bargaining agreements with a participating employer (nor covered on the basis of an individual's employment in such a bargaining unit); nor

''(II) present employees (or former employees who were covered while employed) of the sponsoring employee organization, of an employer who is or was a party to any of the collective bargaining agreements, or of the plan or other arrangement or a related plan or arrangement (nor covered on the basis of such present or former employment),

does not exceed 15 percent of the total number of individuals who are covered under the plan or arrangement and who are present or former employees who are or were covered under the plan or arrangement pursuant to a collective bargaining agreement with a participating employer. The requirements of the preceding provisions of this clause shall be treated as satisfied if, as of the end of the preceding plan year, such covered individuals are comprised solely

of individuals who were covered individuals under the plan or other arrangement as of the date of the enactment of the Bipartisan Patient Protection Act and, as of the end of the preceding plan year, the number of such covered individuals does not exceed 25 percent of the total number of present and former employees enrolled under the plan or other arrangement.

''(iii) The employee organization or other entity sponsoring the plan or other arrangement certifies to the Secretary each year, in a form and manner which shall be prescribed by the Secretary through negotiated rulemaking that the plan or other arrangement meets the requirements of clauses (i) and (ii).

''(D) For purposes of subparagraph (A)(i)(II), a plan or arrangement shall be treated as established or maintained in accordance with this subparagraph only if—

''(i) all of the benefits provided under the plan or arrangement consist of health insurance coverage; or

''(ii)(I) the plan or arrangement is a multiemployer plan; and

''(II) the requirements of clause (B) of the proviso to clause (5) of section 302(c) of the Labor

Management Relations Act, 1947 (29 U.S.C. 186(c)) are met with respect to such plan or other arrangement.

''(E) For purposes of subparagraph (A)(i)(II), a plan or arrangement shall be treated as established or maintained in accordance with this subparagraph only if—

''(i) the plan or arrangement is in effect as of the date of the enactment of the Bipartisan Patient Protection Act; or

''(ii) the employee organization or other entity sponsoring the plan or arrangement—

''(I) has been in existence for at least 3 years; or

''(II) demonstrates to the satisfaction of the Secretary that the requirements of subparagraphs (C) and (D) are met with respect to the plan or other arrangement.''.

(c) CONFORMING AMENDMENTS TO DEFINITIONS OF PARTICIPANT AND BENEFICIARY.—Section 3(7) of such Act (29 U.S.C. 1002(7)) is amended by adding at the end the following new sentence: ''Such term includes an individual who is a covered individual described in paragraph (40)(C)(ii).''.

SEC. 424. ENFORCEMENT PROVISIONS RELATING TO ASSOCIATION HEALTH PLANS.

(a) CRIMINAL PENALTIES FOR CERTAIN WILLFUL MISREPRESENTATIONS.—Section 501 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1131) is amended—

(1) by inserting ''(a)'' after ''SEC. 501.''; and

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

''(b) Any person who willfully falsely represents, to any employee, any employee's beneficiary, any employer, the Secretary, or any State, a plan or other arrangement established or maintained for the purpose of offering or providing any benefit described in section 3(1) to employees or their beneficiaries as—

''(1) being an association health plan which has been certified under part 8;

''(2) having been established or maintained under or pursuant to one or more collective bargaining agreements which are reached pursuant to collective bargaining described in section 8(d) of the National Labor Relations Act (29 U.S.C. 158(d)) or paragraph Fourth of section 2 of the Railway Labor Act (45 U.S.C. 152, paragraph Fourth) or which are reached pursuant to labor-management negotiations

under similar provisions of State public employee relations laws; or

''(3) being a plan or arrangement with respect to which the requirements of subparagraph (C), (D), or (E) of section 3(40) are met,

shall, upon conviction, be imprisoned not more than 5 years, be fined under title 18, United States Code, or both.''.

(b) CEASE ACTIVITIES ORDERS.—Section 502 of such Act (29 U.S.C. 1132), as amended by sections 141 and 143, is further amended by adding at the end the following new subsection:

''(p) ASSOCIATION HEALTH PLAN CEASE AND DESIST ORDERS.—

''(1) IN GENERAL.—Subject to paragraph (2), upon application by the Secretary showing the operation, promotion, or marketing of an association health plan (or similar arrangement providing benefits consisting of medical care (as defined in section 733(a)(2))) that—

''(A) is not certified under part 8, is subject under section 514(b)(6) to the insurance laws of any State in which the plan or arrangement offers or provides benefits, and is not li-

censed, registered, or otherwise approved under the insurance laws of such State; or

''(B) is an association health plan certified under part 8 and is not operating in accordance with the requirements under part 8 for such certification,

a district court of the United States shall enter an order requiring that the plan or arrangement cease activities.

''(2) EXCEPTION.—Paragraph (1) shall not apply in the case of an association health plan or other arrangement if the plan or arrangement shows that—

''(A) all benefits under it referred to in paragraph (1) consist of health insurance coverage; and

''(B) with respect to each State in which the plan or arrangement offers or provides benefits, the plan or arrangement is operating in accordance with applicable State laws that are not superseded under section 514.

''(3) ADDITIONAL EQUITABLE RELIEF.—The court may grant such additional equitable relief, including any relief available under this title, as it deems necessary to protect the interests of the pub-

lic and of persons having claims for benefits against the plan.''.

(c) RESPONSIBILITY FOR CLAIMS PROCEDURE.—Section 503 of such Act (29 U.S.C. 1133), as amended by section 301(b), is amended by adding at the end the following new subsection:

''(c) ASSOCIATION HEALTH PLANS.—The terms of each association health plan which is or has been certified under part 8 shall require the board of trustees or the named fiduciary (as applicable) to ensure that the requirements of this section are met in connection with claims filed under the plan.''.

SEC. 425. COOPERATION BETWEEN FEDERAL AND STATE AUTHORITIES.

Section 506 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1136) is amended by adding at the end the following new subsection:

''(c) CONSULTATION WITH STATES WITH RESPECT TO ASSOCIATION HEALTH PLANS.—

''(1) AGREEMENTS WITH STATES.—The Secretary shall consult with the State recognized under paragraph (2) with respect to an association health plan regarding the exercise of—

''(A) the Secretary's authority under sections 502 and 504 to enforce the requirements for certification under part 8; and

''(B) the Secretary's authority to certify association health plans under part 8 in accordance with regulations of the Secretary applicable to certification under part 8.

''(2) RECOGNITION OF PRIMARY DOMICILE STATE.—In carrying out paragraph (1), the Secretary shall ensure that only one State will be recognized, with respect to any particular association health plan, as the State to with which consultation is required. In carrying out this paragraph, the Secretary shall take into account the places of residence of the participants and beneficiaries under the plan and the State in which the trust is maintained.''.

SEC. 426. EFFECTIVE DATE AND TRANSITIONAL AND OTHER RULES.

(a) EFFECTIVE DATE.—The amendments made by sections 421, 424, and 425 shall take effect one year from the date of the enactment. The amendments made by sections 422 and 423 shall take effect on the date of the enactment of this Act. The Secretary of Labor shall first issue all regulations necessary to carry out the amendments made by this subtitle within one year from the date

of the enactment. Such regulations shall be issued through negotiated rulemaking.

(b) EXCEPTION.—Section 801(a)(2) of the Employee Retirement Income Security Act of 1974 (added by section 421) does not apply in connection with an association health plan (certified under part 8 of subtitle B of title I of such Act) existing on the date of the enactment of this Act, if no benefits provided thereunder as of the date of the enactment of this Act consist of health insurance coverage (as defined in section 733(b)(1) of such Act).

(c) TREATMENT OF CERTAIN EXISTING HEALTH BENEFITS PROGRAMS.—

(1) IN GENERAL.—In any case in which, as of the date of the enactment of this Act, an arrangement is maintained in a State for the purpose of providing benefits consisting of medical care for the employees and beneficiaries of its participating employers, at least 200 participating employers make contributions to such arrangement, such arrangement has been in existence for at least 10 years, and such arrangement is licensed under the laws of one or more States to provide such benefits to its participating employers, upon the filing with the applicable authority (as defined in section 812(a)(5) of the Employee Retirement Income Security Act of

1974 (as amended by this subtitle)) by the arrangement of an application for certification of the arrangement under part 8 of subtitle B of title I of such Act—

(A) such arrangement shall be deemed to be a group health plan for purposes of title I of such Act;

(B) the requirements of sections 801(a)(1) and 803(a)(1) of the Employee Retirement Income Security Act of 1974 shall be deemed met with respect to such arrangement;

(C) the requirements of section 803(b) of such Act shall be deemed met, if the arrangement is operated by a board of directors which—

(i) is elected by the participating employers, with each employer having one vote; and

(ii) has complete fiscal control over the arrangement and which is responsible for all operations of the arrangement;

(D) the requirements of section 804(a) of such Act shall be deemed met with respect to such arrangement; and

(E) the arrangement may be certified by any applicable authority with respect to its operations in any State only if it operates in such State on the date of certification.

The provisions of this subsection shall cease to apply with respect to any such arrangement at such time after the date of the enactment of this Act as the applicable requirements of this subsection are not met with respect to such arrangement.

(2) DEFINITIONS.—For purposes of this subsection, the terms ''group health plan'', ''medical care'', and ''participating employer'' shall have the meanings provided in section 812 of the Employee Retirement Income Security Act of 1974, except that the reference in paragraph (7) of such section to an ''association health plan'' shall be deemed a reference to an arrangement referred to in this subsection.

TITLE V—AMENDMENTS TO THE INTERNAL REVENUE CODE OF 1986

Subtitle A—Application of Patient Protection Provisions

SEC. 501. APPLICATION TO GROUP HEALTH PLANS UNDER THE INTERNAL REVENUE CODE OF 1986.

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

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

"Sec. 9813. Standard relating to patients' bill of rights.";

and

(2) by inserting after section 9812 the following:

"SEC. 9813. STANDARD RELATING TO PATIENTS' BILL OF RIGHTS.

"A group health plan shall comply with the requirements of title I of the Bipartisan Patient Protection Act and sections 503A through 503C of the Employee Retirement Income Security Act of 1974 (as in effect as of the date of the enactment of such Act), and such requirements shall be deemed to be incorporated into this section.".

SEC. 502. CONFORMING ENFORCEMENT FOR WOMEN'S HEALTH AND CANCER RIGHTS.

Subchapter B of chapter 100 of the Internal Revenue Code of 1986, as amended by section 501, is further amended—

(1) in the table of sections, by inserting after the item relating to section 9813 the following new item:

"Sec. 9814. Standard relating to women's health and cancer rights.";

and

(2) by inserting after section 9813 the following:

"SEC. 9814. STANDARD RELATING TO WOMEN'S HEALTH AND CANCER RIGHTS.

''The provisions of section 713 of the Employee Retirement Income Security Act of 1974 (as in effect as of the date of the enactment of this section) shall apply to group health plans as if included in this subchapter.''.

Subtitle B—Health Care Coverage Access Tax Incentives

SEC. 511. EXPANSION OF AVAILABILITY OF ARCHER MEDICAL SAVINGS ACCOUNTS.

(a) REPEAL OF LIMITATIONS ON NUMBER OF MEDICAL SAVINGS ACCOUNTS.—

(1) IN GENERAL.—Subsections (i) and (j) of section 220 of the Internal Revenue Code of 1986 are hereby repealed.

(2) CONFORMING AMENDMENTS.—

(A) Paragraph (1) of section 220(c) of such Code is amended by striking subparagraph (D).

(B) Section 138 of such Code is amended by striking subsection (f).

(b) AVAILABILITY NOT LIMITED TO ACCOUNTS FOR EMPLOYEES OF SMALL EMPLOYERS AND SELF-EMPLOYED INDIVIDUALS.—

(1) IN GENERAL.—Subparagraph (A) of section 220(c)(1) of such Code (relating to eligible individual) is amended to read as follows:

''(A) IN GENERAL.—The term 'eligible individual' means, with respect to any month, any individual if—

''(i) such individual is covered under a high deductible health plan as of the 1st day of such month, and

''(ii) such individual is not, while covered under a high deductible health plan, covered under any health plan—

"(I) which is not a high deductible health plan, and

"(II) which provides coverage for any benefit which is covered under the high deductible health plan.".

(2) CONFORMING AMENDMENTS.—

(A) Section 220(c)(1) of such Code is amended by striking subparagraph (C).

(B) Section 220(c) of such Code is amended by striking paragraph (4) (defining small employer) and by redesignating paragraph (5) as paragraph (4).

(C) Section 220(b) of such Code is amended by striking paragraph (4) (relating to deduction limited by compensation) and by redesignating paragraphs (5), (6), and (7) as paragraphs (4), (5), and (6), respectively.

(c) INCREASE IN AMOUNT OF DEDUCTION ALLOWED FOR CONTRIBUTIONS TO MEDICAL SAVINGS ACCOUNTS.—

(1) IN GENERAL.—Paragraph (2) of section 220(b) of such Code is amended to read as follows:

"(2) MONTHLY LIMITATION.—The monthly limitation for any month is the amount equal to 1/12 of the annual deductible (as of the first day of such

month) of the individual's coverage under the high deductible health plan.''.

(2) CONFORMING AMENDMENT.—Clause (ii) of section 220(d)(1)(A) of such Code is amended by striking ''75 percent of''.

(d) BOTH EMPLOYERS AND EMPLOYEES MAY CONTRIBUTE TO MEDICAL SAVINGS ACCOUNTS.—Paragraph (4) of section 220(b) of such Code (as redesignated by subsection (b)(2)(C)) is amended to read as follows:

''(4) COORDINATION WITH EXCLUSION FOR EMPLOYER CONTRIBUTIONS.—The limitation which would (but for this paragraph) apply under this subsection to the taxpayer for any taxable year shall be reduced (but not below zero) by the amount which would (but for section 106(b)) be includible in the taxpayer's gross income for such taxable year.''.

(e) REDUCTION OF PERMITTED DEDUCTIBLES UNDER HIGH DEDUCTIBLE HEALTH PLANS.—

(1) IN GENERAL.—Subparagraph (A) of section 220(c)(2) of such Code (defining high deductible health plan) is amended—

(A) by striking ''$1,500'' in clause (i) and inserting ''$1,000''; and

(B) by striking ''$3,000'' in clause (ii) and inserting ''$2,000''.

(2) CONFORMING AMENDMENT.—Subsection (g) of section 220 of such Code is amended to read as follows:

''(g) COST-OF-LIVING ADJUSTMENT.—

''(1) IN GENERAL.—In the case of any taxable year beginning in a calendar year after 1998, each dollar amount in subsection (c)(2) shall be increased by an amount equal to—

''(A) such dollar amount, multiplied by

''(B) the cost-of-living adjustment determined under section 1(f)(3) for the calendar year in which such taxable year begins by substituting 'calendar year 1997' for 'calendar year 1992' in subparagraph (B) thereof.

''(2) SPECIAL RULES.—In the case of the $1,000 amount in subsection (c)(2)(A)(i) and the $2,000 amount in subsection (c)(2)(A)(ii), paragraph (1)(B) shall be applied by substituting 'calendar year 2000' for 'calendar year 1997'.

''(3) ROUNDING.—If any increase under paragraph (1) or (2) is not a multiple of $50, such increase shall be rounded to the nearest multiple of $50.''.

(f) PROVIDING INCENTIVES FOR PREFERRED PROVIDER ORGANIZATIONS TO OFFER MEDICAL SAVINGS ACCOUNTS.—

(1) PREVENTIVE CARE COVERAGE PERMITTED.—Clause (ii) of section 220(c)(2)(B) of such Code is amended by striking ''preventive care if'' and all that follows and inserting ''preventive care''.

(2) TREATMENT OF NETWORK SERVICES.—Subparagraph (B) of section 220(c)(2) of such Code is amended by adding at the end the following new clause:

''(iii) TREATMENT OF NETWORK SERVICES.—In the case of a health plan which provides benefits for services provided by providers in a network (as defined in section 161 of the Patient's Bill of Rights Act of 2001) and which would (without regard to services provided by providers outside the network) be a high deductible health plan, such plan shall not fail to be a high deductible health plan because—

''(I) the annual deductible for services provided by providers outside the network exceeds the applicable

maximum dollar amount in clause (i) or (ii), or

''(II) the annual out-of-pocket expenses required to be paid for services provided by providers outside the network exceeds the applicable dollar amount in clause (iii).

The annual deductible taken into account under subsection (b)(2) with respect to a plan to which the preceding sentence applies shall be the annual deductible for services provided by providers within the network.''.

(g) MEDICAL SAVINGS ACCOUNTS MAY BE OFFERED UNDER CAFETERIA PLANS.—Subsection (f) of section 125 of such Code is amended by striking ''106(b),''.

(h) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 2001.

SEC. 512. DEDUCTION FOR 100 PERCENT OF HEALTH INSURANCE COSTS OF SELF-EMPLOYED INDIVIDUALS.

(a) IN GENERAL.—Paragraph (1) of section 162(l) of the Internal Revenue Code of 1986 is amended to read as follows:

''(1) ALLOWANCE OF DEDUCTION.—In the case of an individual who is an employee within the meaning of section 401(c)(1), there shall be allowed as a deduction under this section an amount equal to 100 percent of the amount paid during the taxable year for insurance which constitutes medical care for the taxpayer and the taxpayer's spouse and dependents.''.

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to taxable years beginning after December 31, 2001.

SEC. 513. CREDIT FOR HEALTH INSURANCE EXPENSES OF SMALL BUSINESSES.

(a) IN GENERAL.—Subpart D of part IV of subchapter A of chapter 1 of the Internal Revenue Code of 1986 (relating to business-related credits) is amended by adding at the end the following:

''SEC. 45E. SMALL BUSINESS HEALTH INSURANCE EXPENSES.

''(a) GENERAL RULE.—For purposes of section 38, in the case of a small employer, the health insurance credit determined under this section for the taxable year is an amount equal to the applicable percentage of the expenses paid by the taxpayer during the taxable year for health

insurance coverage for such year provided under a new health plan for employees of such employer.

''(b) APPLICABLE PERCENTAGE.—For purposes of subsection (a), the applicable percentage is—

''(1) in the case of insurance purchased as a member of a qualified health benefit purchasing coalition (as defined in section 9841), 30 percent, and

''(2) in the case of insurance not described in paragraph (1), 20 percent.

''(c) LIMITATIONS.—

''(1) PER EMPLOYEE DOLLAR LIMITATION.—The amount of expenses taken into account under subsection (a) with respect to any employee for any taxable year shall not exceed—

''(A) $2,000 in the case of self-only coverage, and

''(B) $5,000 in the case of family coverage.

In the case of an employee who is covered by a new health plan of the employer for only a portion of such taxable year, the limitation under the preceding sentence shall be an amount which bears the same ratio to such limitation (determined without regard to this sentence) as such portion bears to the entire taxable year.

''(2) PERIOD OF COVERAGE.—Expenses may be taken into account under subsection (a) only with respect to coverage for the 4-year period beginning on the date the employer establishes a new health plan.

''(d) DEFINITIONS.—For purposes of this section—

''(1) HEALTH INSURANCE COVERAGE.—The term 'health insurance coverage' has the meaning given such term by section 9832(b)(1).

''(2) NEW HEALTH PLAN.—

''(A) IN GENERAL.—The term 'new health plan' means any arrangement of the employer which provides health insurance coverage to employees if—

''(i) such employer (and any predecessor employer) did not establish or maintain such arrangement (or any similar arrangement) at any time during the 2 taxable years ending prior to the taxable year in which the credit under this section is first allowed, and

''(ii) such arrangement provides health insurance coverage to at least 70 percent of the qualified employees of such employer.

''(B) QUALIFIED EMPLOYEE.—

''(i) IN GENERAL.—The term 'qualified employee' means any employee of an employer if the annual rate of such employee's compensation (as defined in section 414(s)) exceeds $10,000.

''(ii) TREATMENT OF CERTAIN EMPLOYEES.—The term 'employee' shall include a leased employee within the meaning of section 414(n).

''(3) SMALL EMPLOYER.—The term 'small employer' has the meaning given to such term by section 4980D(d)(2); except that only qualified employees shall be taken into account.

''(e) SPECIAL RULES.—

''(1) CERTAIN RULES MADE APPLICABLE.—For purposes of this section, rules similar to the rules of section 52 shall apply.

''(2) AMOUNTS PAID UNDER SALARY REDUCTION ARRANGEMENTS.—No amount paid or incurred pursuant to a salary reduction arrangement shall be taken into account under subsection (a).

''(f) TERMINATION.—This section shall not apply to expenses paid or incurred by an employer with respect to

any arrangement established on or after January 1, 2010.''.

(b) CREDIT TO BE PART OF GENERAL BUSINESS CREDIT.—Section 38(b) of such Code (relating to current year business credit) is amended by striking ''plus'' at the end of paragraph (12), by striking the period at the end of paragraph (13) and inserting '', plus'', and by adding at the end the following:

''(14) in the case of a small employer (as defined in section 45E(d)(3)), the health insurance credit determined under section 45E(a).''.

(c) NO CARRYBACKS.—Subsection (d) of section 39 of such Code (relating to carryback and carryforward of unused credits) is amended by adding at the end the following:

''(10) NO CARRYBACK OF SECTION 45E CREDIT BEFORE EFFECTIVE DATE.—No portion of the unused business credit for any taxable year which is attributable to the employee health insurance expenses credit determined under section 45E may be carried back to a taxable year ending before the date of the enactment of section 45E.''.

(d) DENIAL OF DOUBLE BENEFIT.—Section 280C of such Code is amended by adding at the end the following new subsection:

''(d) CREDIT FOR SMALL BUSINESS HEALTH INSURANCE EXPENSES.—

''(1) IN GENERAL.—No deduction shall be allowed for that portion of the expenses (otherwise allowable as a deduction) taken into account in determining the credit under section 45E for the taxable year which is equal to the amount of the credit determined for such taxable year under section 45E(a).

''(2) CONTROLLED GROUPS.—Persons treated as a single employer under subsection (a) or (b) of section 52 shall be treated as 1 person for purposes of this section.''.

(e) CLERICAL AMENDMENT.—The table of sections for subpart D of part IV of subchapter A of chapter 1 of such Code is amended by adding at the end the following:

''Sec. 45E. Small business health insurance expenses.''.

(f) EFFECTIVE DATE.—The amendments made by this section shall apply to amounts paid or incurred in taxable years beginning after December 31, 2001, for arrangements established after the date of the enactment of this Act.

SEC. 514. CERTAIN GRANTS BY PRIVATE FOUNDATIONS TO QUALIFIED HEALTH BENEFIT PURCHASING COALITIONS.

(a) IN GENERAL.—Section 4942 of the Internal Revenue Code of 1986 (relating to taxes on failure to distribute income) is amended by adding at the end the following:

''(k) CERTAIN QUALIFIED HEALTH BENEFIT PURCHASING COALITION DISTRIBUTIONS.—

''(1) IN GENERAL.—For purposes of subsection (g), sections 170, 501, 507, 509, and 2522, and this chapter, a qualified health benefit purchasing coalition distribution by a private foundation shall be considered to be a distribution for a charitable purpose.

''(2) QUALIFIED HEALTH BENEFIT PURCHASING COALITION DISTRIBUTION.—For purposes of paragraph (1)—

''(A) IN GENERAL.—The term 'qualified health benefit purchasing coalition distribution' means any amount paid or incurred by a private foundation to or on behalf of a qualified health benefit purchasing coalition (as defined in section 9841) for purposes of payment or reimbursement of amounts paid or incurred in

connection with the establishment and maintenance of such coalition.

''(B) EXCLUSIONS.—Such term shall not include any amount used by a qualified health benefit purchasing coalition (as so defined)—

''(i) for the purchase of real property,

''(ii) as payment to, or for the benefit of, members (or employees or affiliates of such members) of such coalition, or

''(iii) for any expense paid or incurred more than 48 months after the date of establishment of such coalition.

''(3) TERMINATION.—This subsection shall not apply—

''(A) to qualified health benefit purchasing coalition distributions paid or incurred after December 31, 2009, and

''(B) with respect to start-up costs of a coalition which are paid or incurred after December 31, 2010.''.

(b) QUALIFIED HEALTH BENEFIT PURCHASING COALITION.—

(1) IN GENERAL.—Chapter 100 of such Code (relating to group health plan requirements) is

amended by adding at the end the following new subchapter:

"Subchapter D—Qualified Health Benefit Purchasing Coalition

"SEC. 9841. QUALIFIED HEALTH BENEFIT PURCHASING COALITION.

"(a) IN GENERAL.—A qualified health benefit purchasing coalition is a private not-for-profit corporation which—

"(1) sells health insurance through State licensed health insurance issuers in the State in which the employers to which such coalition is providing insurance are located, and

"(2) establishes to the Secretary, under State certification procedures or other procedures as the Secretary may provide by regulation, that such coalition meets the requirements of this section.

"(b) BOARD OF DIRECTORS.—

"(1) IN GENERAL.—Each purchasing coalition under this section shall be governed by a Board of Directors.

"(2) ELECTION.—The Secretary shall establish procedures governing election of such Board.

''(3) MEMBERSHIP.—The Board of Directors shall—

''(A) be composed of representatives of the members of the coalition, in equal number, including small employers and employee representatives of such employers, but

''(B) not include other interested parties, such as service providers, health insurers, or insurance agents or brokers which may have a conflict of interest with the purposes of the coalition.

''(c) MEMBERSHIP OF COALITION.—

''(1) IN GENERAL.—A purchasing coalition shall accept all small employers residing within the area served by the coalition as members if such employers request such membership.

''(2) OTHER MEMBERS.—The coalition, at the discretion of its Board of Directors, may be open to individuals and large employers.

''(3) VOTING.—Members of a purchasing coalition shall have voting rights consistent with the rules established by the State.

''(d) DUTIES OF PURCHASING COALITIONS.—Each purchasing coalition shall—

''(1) enter into agreements with small employers (and, at the discretion of its Board, with individuals and other employers) to provide health insurance benefits to employees and retirees of such employers,

''(2) where feasible, enter into agreements with 3 or more unaffiliated, qualified licensed health plans, to offer benefits to members,

''(3) offer to members at least 1 open enrollment period of at least 30 days per calendar year,

''(4) serve a significant geographical area and market to all eligible members in that area, and

''(5) carry out other functions provided for under this section.

''(e) LIMITATION ON ACTIVITIES.—A purchasing coalition shall not—

''(1) perform any activity (including certification or enforcement) relating to compliance or licensing of health plans,

''(2) assume insurance or financial risk in relation to any health plan, or

''(3) perform other activities identified by the State as being inconsistent with the performance of its duties under this section.

''(f) ADDITIONAL REQUIREMENTS FOR PURCHASING COALITIONS.—As provided by the Secretary in regulations, a purchasing coalition shall be subject to requirements similar to the requirements of a group health plan under this chapter.

''(g) RELATION TO OTHER LAWS.—

''(1) PREEMPTION OF STATE FICTITIOUS GROUP LAWS.—Requirements (commonly referred to as fictitious group laws) relating to grouping and similar requirements for health insurance coverage are preempted to the extent such requirements impede the establishment and operation of qualified health benefit purchasing coalitions.

''(2) ALLOWING SAVINGS TO BE PASSED THROUGH.—Any State law that prohibits health insurance issuers from reducing premiums on health insurance coverage sold through a qualified health benefit purchasing coalition to reflect administrative savings is preempted. This paragraph shall not be construed to preempt State laws that impose restrictions on premiums based on health status, claims history, industry, age, gender, or other underwriting factors.

''(3) NO WAIVER OF HIPAA REQUIREMENTS.—Nothing in this section shall be construed to change

the obligation of health insurance issuers to comply with the requirements of title XXVII of the Public Health Service Act with respect to health insurance coverage offered to small employers in the small group market through a qualified health benefit purchasing coalition.

''(h) DEFINITION OF SMALL EMPLOYER.—For purposes of this section—

''(1) IN GENERAL.—The term 'small employer' means, with respect to any calendar year, any employer if such employer employed an average of at least 2 and not more than 50 qualified employees on business days during either of the 2 preceding calendar years. For purposes of the preceding sentence, a preceding calendar year may be taken into account only if the employer was in existence throughout such year.

''(2) EMPLOYERS NOT IN EXISTENCE IN PRECEDING YEAR.—In the case of an employer which was not in existence throughout the 1st preceding calendar year, the determination under paragraph (1) shall be based on the average number of qualified employees that it is reasonably expected such employer will employ on business days in the current calendar year.''.

(2) CONFORMING AMENDMENT.—The table of subchapters for chapter 100 of such Code is amended by adding at the end the following item:

''Subchapter D. Qualified health benefit purchasing coalition.''.

(c) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to taxable years beginning after December 31, 2001.

SEC. 515. STATE GRANT PROGRAM FOR MARKET INNOVATION.

(a) IN GENERAL.—The Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall establish a program (in this section referred to as the ''program'') to award demonstration grants under this section to States to allow States to demonstrate the effectiveness of innovative ways to increase access to health insurance through market reforms and other innovative means. Such innovative means may include (and are not limited to) any of the following:

(1) Alternative group purchasing or pooling arrangements, such as purchasing cooperatives for small businesses, reinsurance pools, or high risk pools.

(2) Individual or small group market reforms.

(3) Consumer education and outreach.

(4) Subsidies to individuals, employers, or both, in obtaining health insurance.

(b) SCOPE; DURATION.—The program shall be limited to not more than 10 States and to a total period of 5 years, beginning on the date the first demonstration grant is made.

(c) CONDITIONS FOR DEMONSTRATION GRANTS.—

(1) IN GENERAL.—The Secretary may not provide for a demonstration grant to a State under the program unless the Secretary finds that under the proposed demonstration grant—

(A) the State will provide for demonstrated increase of access for some portion of the existing uninsured population through a market innovation (other than merely through a financial expansion of a program initiated before the date of the enactment of this Act);

(B) the State will comply with applicable Federal laws;

(C) the State will not discriminate among participants on the basis of any health status-related factor (as defined in section 2791(d)(9) of the Public Health Service Act), except to the extent a State wishes to focus on populations that otherwise would not obtain health insurance because of such factors; and

(D) the State will provide for such evaluation, in coordination with the evaluation required under subsection (d), as the Secretary may specify.

(2) APPLICATION.—The Secretary shall not provide a demonstration grant under the program to a State unless—

(A) the State submits to the Secretary such an application, in such a form and manner, as the Secretary specifies;

(B) the application includes information regarding how the demonstration grant will address issues such as governance, targeted population, expected cost, and the continuation after the completion of the demonstration grant period; and

(C) the Secretary determines that the demonstration grant will be used consistent with this section.

(3) FOCUS.—A demonstration grant proposal under section need not cover all uninsured individuals in a State or all health care benefits with respect to such individuals.

(d) EVALUATION.—The Secretary shall enter into a contract with an appropriate entity outside the Depart-

ment of Health and Human Services to conduct an overall evaluation of the program at the end of the program period. Such evaluation shall include an analysis of improvements in access, costs, quality of care, or choice of coverage, under different demonstration grants.

(e) OPTION TO PROVIDE FOR INITIAL PLANNING GRANTS.—Notwithstanding the previous provisions of this section, under the program the Secretary may provide for a portion of the amounts appropriated under subsection (f) (not to exceed $5,000,000) to be made available to any State for initial planning grants to permit States to develop demonstration grant proposals under the previous provisions of this section.

(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated $100,000,000 for each fiscal year to carry out this section. Amounts appropriated under this subsection shall remain available until expended.

(g) STATE DEFINED.—For purposes of this section, the term ''State'' has the meaning given such term for purposes of title XIX of the Social Security Act.

TITLE VI—EFFECTIVE DATES; COORDINATION IN IMPLEMENTATION

SEC. 601. EFFECTIVE DATES.

(a) GROUP HEALTH COVERAGE.—

(1) IN GENERAL.—Subject to paragraph (2) and subsection (d), the amendments made by sections 201(a), 401, 403, 501, and 502 (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 October 1, 2002 (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, 403, 501, and 502 (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 of-

fering 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. 602. 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. 603. SEVERABILITY.

(a) IN GENERAL.—Except as provided in subsections (b) and (c), 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.

(b) DEPENDENCE OF REMEDIES ON APPEALS.—If any provision of section 503A, 503B, or 503C of the Employee Retirement Income Security Act of 1974 (as inserted by section 131) or the application of either such section to any person or circumstance is held to be uncon-

stitutional, section 502(n) of such Act (as inserted by section 402) shall be deemed to be null and void and shall be given no force or effect.

(c) REMEDIES.—If any provision of section 502(n) of the Employee Retirement Income Security Act of 1974 (as inserted by section 402), or the application of such section to any person or circumstance, is held to be unconstitutional, the remainder of such section shall be deemed to be null and void and shall be given no force or effect.

TITLE VII—MISCELLANEOUS PROVISIONS

SEC. 701. NO IMPACT ON SOCIAL SECURITY TRUST FUNDS.

(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 established 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. 702. 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 ''2003'' and inserting ''2011, except that fees may not be charged under paragraphs (9) and (10) of such subsection after March 31, 2006''.

SEC. 703. FISCAL YEAR 2002 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, 2002, by a carrier with a contract under section 1842 of that Act (42 U.S.C. 1395u) shall be sent on October 1, 2002.

SEC. 704. SENSE OF THE 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 2001, 182,800 new cases of female invasive breast cancer will be diagnosed, and 40,800 women will die from the disease.

(3) In addition, 1,400 male breast cancer cases are projected to be diagnosed, and 400 men will die from the disease.

(4) Breast cancer is the second leading cause of cancer death among all women and the leading cause of cancer death among women between ages 40 and 55.

(5) This year 8,600 children are expected to be diagnosed with cancer.

(6) 1,500 children are expected to die from cancer this year.

(7) There are approximately 333,000 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 1,000,000 in the United States.

(9) An estimated 198,100 men will be diagnosed with prostate cancer this year.

(10) 31,500 men will die from prostate cancer this year. It is the second leading cause of cancer in men.

(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 appro-

priate, 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. 705. 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. 706. ANNUAL REVIEW.

(a) IN GENERAL.—Not later than 24 months after the general effective date referred to in section 601(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 indi-

viduals 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 the 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 2003 and 2004, 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.

SEC. 707. DEFINITION OF BORN-ALIVE INFANT.

(a) IN GENERAL.—Chapter 1 of title 1, United States Code, is amended by adding at the end the following:

"§ 8. 'Person', 'human being', 'child', and 'individual' as including born-alive infant

''(a) In determining the meaning of any Act of Congress, or of any ruling, regulation, or interpretation of the various administrative bureaus and agencies of the United States, the words 'person', 'human being', 'child', and 'in-

dividual', shall include every infant member of the species homo sapiens who is born alive at any stage of development.

''(b) As used in this section, the term 'born alive', with respect to a member of the species homo sapiens, means the complete expulsion or extraction from his or her mother of that member, at any stage of development, who after such expulsion or extraction breathes or has a beating heart, pulsation of the umbilical cord, or definite movement of voluntary muscles, regardless of whether the umbilical cord has been cut, and regardless of whether the expulsion or extraction occurs as a result of natural or induced labor, caesarean section, or induced abortion.

''(c) Nothing in this section shall be construed to affirm, deny, expand, or contract any legal status or legal right applicable to any member of the species homo sapiens at any point prior to being born alive as defined in this section.''.

(b) CLERICAL AMENDMENT.—The table of sections at the beginning of chapter 1 of title 1, United States Code, is amended by adding at the end the following new item:

"8. 'Person', 'human being', 'child', and 'individual' as including born-alive infant.".

Passed the House of Representatives August 2, 2001.

Attest: JEFF TRANDAHL,

Clerk.

Calendar No. 150

107TH CONGRESS
1ST SESSION

H. R. 2563

AN ACT

To amend the Public Health Service Act, the Employee Retirement Income Security Act of 1974, and the Internal Revenue Code of 1986 to protect consumers in managed care plans and other health coverage.

SEPTEMBER 5, 2001

Received and read the first time

SEPTEMBER 6, 2001

Read the second time and placed on the calendar