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107TH CONGRESS
1ST SESSION

H. R. 2367

To amend the Employee Retirement Income Security Act of 1974, the Public Health Service Act, and the Internal Revenue Code of 1986 to provide for accountability of health plans.

IN THE HOUSE OF REPRESENTATIVES

JUNE 28, 2001

Mr. SESSIONS (for himself and Mr. WELDON of Florida) introduced the following bill; which was referred to the Committee on Education and the Workforce, and in addition to the Committees on Energy and Commerce, and Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To amend the Employee Retirement Income Security Act of 1974, the Public Health Service Act, and the Internal Revenue Code of 1986 to provide for accountability of health plans.

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

SECTION 1. SHORT TITLE AND TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Patient Care Dispute Resolution Act of 2001''.

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

Sec. 1. Short title and table of contents.
Sec. 2. Consideration by plans of claims for benefits and reviews by plans of denials of such claims.
"Sec. 503A. Utilization review activities.
"Sec. 503B. Procedures for initial claims for benefits and prior authorization determinations.
"Sec. 503C. Internal appeals of claims denials.
"Sec. 503D. Independent external appeals procedures.
"Sec. 503E. Effect of Federal review standards for group health plans on availability of legal remedies under State law.
"Sec. 503F. Definitions relating to group health plans.
Sec. 3. State flexibility in applying accountability rules to health insurance issuers.
Sec. 4. Effective dates and related rules.
Sec. 5. Regulations; coordination.
Sec. 6. No benefit requirements.
Sec. 7. Severability.

SEC. 2. CONSIDERATION BY PLANS OF CLAIMS FOR BENEFITS AND REVIEWS BY PLANS OF DENIALS OF SUCH CLAIMS.

(a) AMENDMENTS TO THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974.—

(1) IN GENERAL.—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 new sections:

"SEC. 503A. 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 503B.

''(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 physicians or dentists, as determined by the plan, pursuant to the program. Such criteria shall include written clinical review criteria that are based on valid clinical evidence where available and that are directed specifically at meeting the needs of at-risk populations and covered individuals with chronic conditions or severe illnesses, including gender-specific criteria and pediatric-specific criteria where available and appropriate.

''(B) CONTINUING USE OF STANDARDS IN RETROSPECTIVE REVIEW.—If a health care service has been specifically pre-authorized or approved for a participant or beneficiary under such a program, the program shall not, pursuant to retrospective review, revise or modify the specific standards, criteria, or procedures used for the utilization review for procedures, treatment, and services delivered to the participant or beneficiary during the same course of treatment.

"(C) REVIEW OF SAMPLE OF CLAIMS DENIALS.—Such a program shall provide for an evaluation of the clinical appropriateness of at least a sample of denials of claims for benefits.

"(c) CONDUCT OF PROGRAM ACTIVITIES.—

"(1) ADMINISTRATION BY PHYSICIANS OR DENTISTS.—A utilization review program shall be administered by qualified physicians or dentists who shall oversee review decisions.

"(2) USE OF QUALIFIED, INDEPENDENT PERSONNEL.—

"(A) IN GENERAL.—A utilization review program shall provide for the conduct of utilization review activities only through personnel who are qualified and have received appropriate training in the conduct of such activities under the program.

"(B) PROHIBITION OF CONTINGENT COMPENSATION ARRANGEMENTS.—Such a program shall not, with respect to utilization review activities, permit or provide compensation or anything of value to its employees, agents, or contractors in a manner that encourages denials of claims for benefits.

''(C) PROHIBITION OF CONFLICTS.—Such a program shall not permit a health care professional who is providing health care services to an individual to perform utilization review activities in connection with the health care services being provided to the individual.

''(3) ACCESSIBILITY OF REVIEW.—Such a program shall provide that appropriate personnel performing utilization review activities under the program, including the utilization review administrator, are reasonably accessible by toll-free telephone during normal business hours to discuss patient care and allow response to telephone requests, and that appropriate provision is made to receive and respond promptly to calls received during other hours.

''(4) LIMITS ON FREQUENCY.—Such a program shall not provide for the performance of utilization review activities with respect to a class of services furnished to an individual more frequently than is reasonably required to assess whether the services under review are medically necessary or appropriate.

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

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

"(1) IN GENERAL.—A group health plan, or health insurance issuer offering health insurance coverage in connection with a 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 503C.

''(2) ACCESS TO 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.

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

''(B) EXPEDITED DETERMINATION.—Notwithstanding subparagraph (A), a group health

plan, or health insurance issuer offering health insurance coverage in connection with a 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 as soon as possible based on the medical exigencies of the case involved and 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 hos-

pitalization), 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 as soon as possible in accordance with the medical exigencies of the case, with sufficient time prior to the termination or reduction to allow for an appeal under section 503C(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 requir-

ing plans or issuers to provide coverage of care that would exceed the coverage limitations for such care.

"(2) RETROSPECTIVE DETERMINATION.—A group health plan, or health insurance issuer offering health insurance coverage in connection with a group health plan, shall make a retrospective determination on a claim for benefits as soon as possible in accordance with the medical exigencies of the case 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 as soon as possible in accordance with the medical exigencies of the case and 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 average 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 503C.

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

''(a) RIGHT TO INTERNAL APPEAL.—

''(1) IN GENERAL.—A participant or beneficiary of a group health plan (or authorized representative) may appeal any denial of a claim for benefits under section 503B under the procedures described in this section.

''(2) TIME FOR APPEAL.—

''(A) IN GENERAL.—A group health plan, or health insurance issuer offering health insurance coverage in connection with a 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 503B 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 503B 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 section 503D 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 a 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 503D 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 a 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.—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.

''(3) PRIOR AUTHORIZATION DETERMINATIONS.—

''(A) IN GENERAL.—A group health plan, or health insurance issuer offering health insurance coverage in connection with a group health plan, shall make a determination on an appeal of a denial of a claim for benefits under this subsection as soon as possible in accordance with the medical exigencies of the case but in no case later than 14 days from the date on which the plan or issuer receives information that is reasonably necessary to enable the plan

or issuer to make a determination on the appeal and in no case later than 28 days after the date the request for the appeal is received.

"(B) EXPEDITED DETERMINATION.—Notwithstanding subparagraph (A), a group health plan, or health insurance issuer offering health insurance coverage in connection with a 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 as soon as possible based on the medical exigencies of the case involved and 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 503B(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 as soon as possible in accordance with the medical exigencies of the case, with sufficient time prior to the termination or reduction to allow for an external appeal under section 503D to be completed before the termination or reduction takes effect.

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

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

''(c) CONDUCT OF REVIEW.—

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

''(2) APPROPRIATE REVIEW OF MEDICAL DECISIONS.—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, shall be made by a physician (allopathic or osteopathic) or dentist with appropriate expertise (including, in the case of a child,

appropriate pediatric expertise) 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 as soon as possible in accordance with the medical exigencies of the case and 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 503D.

''(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 average 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 503D and instructions on how to initiate such a review.

"SEC. 503D. 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 a 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 in any case in which the amount involved exceeds $100.

''(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 503C(d) or notice of waiver of internal review under section 503C(a)(4) or the date on which the plan or issuer has failed to make a timely decision under section 503C(d)(2).

''(2) FILING OF REQUEST.—

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

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

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

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

''(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 medical information or records of the participant or beneficiary to the qualified external review entity for the sole purpose 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 sub-

section (e), the request may be made orally. A group health plan, or health insurance issuer offering health insurance coverage, 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 an external review without regard to whether and when a written confirmation of such request is made.

''(ii) EXCEPTION TO FILING FEE REQUIREMENT.—

''(I) INDIGENCY.—Payment of a filing fee shall not be required under subparagraph (A)(iv) where there is a certification (in a form and manner specified in guidelines established by the 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 503C(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, the plan or issuer shall immediately refer such request, and forward the plan or issuer's initial decision (including the information described in section 503C(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 en-

tity 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 cov-

erage 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 for the conduct of an independent medical review, 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 an average participant or beneficiary;

''(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 conducting independent medical review under subsection (d), 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 comprised of 3 members meeting the requirements

of subsection (g) 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, reversed, or modified.

''(B) STANDARD FOR DETERMINATION.—The independent medical review panel's determination relating to the medical necessity and appropriateness, or the experimental or investigation nature, or the evaluation of the medical facts of the item, service, or condition shall be based on the medical condition of the participant 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, 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 or coverage document, except to the extent that the application or interpretation of the exclusion or limitation involves a determination described in paragraph (2).

"(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 independent medical 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 subtitle, 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 recommendation of the treating health care professional (if any); and

''(ii) consider, but not be bound by the definition used by the plan or issuer of 'medically necessary and appropriate', or 'experimental or investigational', or other

substantially equivalent terms that are used by the plan or issuer to describe medical necessity and appropriateness or 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 panel;

''(ii) the specific reasons of the 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.

''(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 under subsection (d) on a denial of a claim for benefits in accordance with the medical exigencies of the case but not 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 under subsection (d) 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 de-

termination 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 as soon as possible based on the medical exigencies of the case involved and 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 subclause 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 under subsection (d) in the

case of a retrospective determination concerting a denial of a claim for benefits not 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 panel from providing an initial oral notice of the determination.

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

''(f) COMPLIANCE.—

''(1) FAILURE TO COMPLY WITH TIMELINES FOR REVIEW.—In any case in which a decision by a medical review panel is not made within the applica-

ble timeline under subsection (e)(1), the Secretary may assess a civil penalty against the plan or issuer of up to $1,000 a day from the date on which such action is required under such timeline and ending on the date on which such action is taken, except that, in any case in which such action is not taken within 7 business days following the date on which such action is required, the Secretary may assess, in lieu of such civil penalty, a civil penalty not to exceed $500,000.

''(2) 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 panel's determination in accordance with the timeframe established by the panel.

''(C) FAILURE TO COMPLY.—If a plan or issuer fails to comply with the timeframe estab-

lished under subparagraph (B) with respect to a participant or beneficiary, the Secretary may assess a civil penalty against the plan or issuer of up to $3,000,000.

''(3) PROTECTION OF LEGAL RIGHTS.—Nothing in this subsection or subtitle shall be construed as altering or eliminating any cause of action or legal rights or remedies of participants, beneficiaries, and others under State or Federal law (including sections 502 and 503), including the right to file judicial actions to enforce rights.

''(4) TREATMENT OF AMOUNTS COLLECTED AS ASSESSMENTS.—Amounts collected pursuant to any assessment under this subsection shall be credited to a special fund established in the Treasury of the United States for assessments under this subsection. The amounts so credited, to the extent and in the amounts provided in advance in appropriations Acts, shall be available to defray expenses incurred in carrying out this section. The amounts so credited shall not be scored as receipts under section 252 of the Balanced Budget and Emergency Deficit Control Act of 1985, and the amounts so credited shall be credited as a discretionary offset to discretionary spending to the extent that the amounts so credited

are made available for expenditure in appropriations Acts.

''(5) EXEMPTION FROM LIABILITY FOR COMPLIANCE WITH DECISIONS OF INDEPENDENT MEDICAL REVIEW PANEL.—A health care provider shall not be liable under any provision of law for any act or failure to act by such provider which is in compliance with any requirement imposed by the decision of an independent medical review panel under this section.

''(g) QUALIFICATIONS OF MEMBERS OF INDEPENDENT MEDICAL REVIEW PANELS.—

''(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 member of the panel meets the qualifications described in paragraphs (2) and (3);

''(B) with respect to each review the requirements described in paragraphs (4) and (5) for the panel are met; and

''(C) compensation provided by the entity to each member of the panel is consistent with paragraph (6).

''(2) LICENSURE AND EXPERTISE.—Each member of the independent medical review panel 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 member of the independent medical review panel 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 a member of an independent medical review panel 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 a member of an independent medical review panel 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 a member of an independent medical review panel 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, the members of an independent medical review panel shall be practicing physicians (allopathic or osteopathic) of the same or similar specialty as a physician who typically treats the condition, makes the diagnosis, or provides the type of treatment under review; or

''(ii) by a health care professional (other than a physician), at least two of the members of an independent medical review panel shall be practicing physicians (allopathic or osteopathic) of the same or

similar specialty as the health care professional who typically treats the condition, makes the diagnosis, or provides the type of treatment under review, and, if determined appropriate by the qualified external review entity, the third member of such panel shall be a practicing health care professional (other than such a physician) of such a same or similar specialty.

''(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 member of an independent medical review panel shall have expertise under paragraph (2) in pediatrics.

''(6) LIMITATIONS ON REVIEWER COMPENSATION.—Compensation provided by a qualified external review entity to a member of an independent medical review panel 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 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.

''(B) STATE AUTHORITY WITH RESPECT TO QUALIFIED EXTERNAL REVIEW ENTITIES FOR HEALTH INSURANCE ISSUERS.—With respect to health insurance issuers offering health insurance coverage in a State, the State may provide for external review activities to be conducted by a qualified external appeal entity that is designated by the State or that is selected by the State in a manner determined by the State to assure an unbiased determination.

''(2) CONTRACT WITH QUALIFIED EXTERNAL REVIEW ENTITY.—Except as provided in paragraph (1)(B), the external review process of a plan or issuer under this section shall be conducted under a contract between the plan or issuer and 1 or more qualified external review entities (as defined in paragraph (4)(A)).

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

''(A) be consistent with the standards the 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 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 Secretary; or

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

In taking action under subclause (I), the 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 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 recertification, shall review the matters described in clause (iv).

''(iii) APPROVAL OF QUALIFIED PRIVATE STANDARD-SETTING ORGANIZATIONS.—For purposes of clause (i)(II), the 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 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) 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 Secretary or by the organization providing such certification upon a showing of cause.

''(D) PROVISION OF INFORMATION.—

''(i) IN GENERAL.—A qualified external review entity shall provide to the Secretary (or the State in the case of external review activities provided for by a State pursuant to paragraph (1)(B)), in such manner and at such times as such Secretary (or State) 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 (or State) 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 de-

scribed 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 an 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 qualified private standard-setting organization, at the request of the organization, the entity shall provide the organization with the information provided to the 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 Secretary and qualified private standard-setting organizations to conduct oversight of qualified external re-

view 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 a member of 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.

"SEC. 503E. EFFECT OF FEDERAL REVIEW STANDARDS FOR GROUP HEALTH PLANS ON AVAILABILITY OF LEGAL REMEDIES UNDER STATE LAW.

"(a) IN GENERAL.—Subject to subsection (b), in the case of any denial of a claim for benefits under a group health plan with respect to which external review has been completed under section 503D, nothing in section 503A, 503B, 503C, or 503D shall be construed to alter, amend,

modify, invalidate, impair, or supersede any provision of State law (as defined in section 514(c)(1)) to the extent that such provision provides a legal remedy for injury or wrongful death resulting from such denial.

''(b) TREATMENT OF DELAYS BY EXTERNAL REVIEW ENTITIES AND INDEPENDENT MEDICAL REVIEWERS.—Notwithstanding subsection (a), this title supersedes any provision of State law to the extent it provides for liability for any violation of a timeline under section 503D applicable to external review entities or independent medical review panels (except with respect to any liability of any such entity or any member of any such panel permitted under section 503D(h)(4)(E)).

''SEC. 503F. DEFINITIONS RELATING TO GROUP HEALTH PLANS.

''For purposes of this part—

''(1) GROUP HEALTH PLAN.—The term 'group health plan' has the meaning given such term in section 733(a), except that such term includes a employee welfare benefit plan treated as a group health plan under section 732(d) or defined as such a plan under section 607(1).

''(2) HEALTH CARE PROFESSIONAL.—The term 'health care professional' means an individual who is licensed, accredited, or certified under State law to

provide specified health care services and who is operating within the scope of such licensure, accreditation, or certification.

''(3) HEALTH CARE PROVIDER.—The term 'health care provider' includes an allopathic or osteopathic physician or other health care professional, as well as an institutional or other facility or agency that provides health care services and that is licensed, accredited, or certified to provide health care items and services under applicable State law.

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

''(5) 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.

''(6) 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.

''(7) 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.

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

''(9) 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.''.

(2) CONFORMING AMENDMENTS.—

(A) CAUSE OF ACTION TO COLLECT ASSESSMENTS.—Section 502(a)(6) of such Act (29 U.S.C. 1132(a)(6)) is amended—

(i) by striking ''or under'' and inserting '', under''; and

(ii) by striking the period and inserting the following: '', or under section 503D(f).''.

(B) SATISFACTION OF ERISA CLAIMS PROCEDURE REQUIREMENT.—Section 503 of such Act (29 U.S.C. 1133) is amended by inserting ''(a)'' after ''SEC. 503.'' and by adding at the end the following new subsection:

''(b) In the case of a group health plan (as defined in section 733) compliance with the requirements of sections 503A through 503D in the case of a claims denial shall be deemed compliance with subsection (a) with respect to such claims denial.''.

(3) 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 503 the following:

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

''Sec. 503E. Effect of Federal review standards for group health plans on availability of legal remedies under State law.
''Sec. 503F. Definitions relating to group health plans.''.

(b) CONFORMING AMENDMENTS TO PUBLIC HEALTH SERVICE ACT.—

(1) GROUP HEALTH PLANS.—Title XXVII of the Public Health Service Act is amended by inserting after section 2706 the following new section:

''SEC. 2707. STANDARD RELATING TO ACCOUNTABILITY.

''Subject to section 2724(c), a group health plan, and health insurance coverage offered in connection with a group health plan, shall comply with the requirements of sections 503A through 503D of the Employee Retirement Income Security Act of 1974 (as in effect as of the day after the date of the enactment of such Act) and such requirements shall be deemed to be incorporated into this section. For purposes of this section, references in such sections 503A through 503D to the Secretary shall be deemed references to the Secretary of Health and Human Services.''.

(2) INDIVIDUAL HEALTH PLANS.—Title XXVII of the Public Health Service Act is amended by inserting after section 2752 the following new section:

''SEC. 2753. STANDARD RELATING TO ACCOUNTABILITY.

''Subject to section 2762A(c), the provisions of sections 503A through 503D of the Employee Retirement Income Security Act of 1974 (as in effect as of the day after

the date of the enactment of such Act) shall apply to health insurance coverage offered by a health insurance issuer in the individual market for an enrollee in the same manner as they apply to health insurance coverage offered by a health insurance issuer for a participant or beneficiary in connection with a group health plan in the small or large group market and the requirements referred to in such section shall be deemed to be incorporated into this section. For purposes of this section, references in such sections 503A through 503D to the Secretary shall be deemed references to the Secretary of Health and Human Services.''.

(c) CONFORMING AMENDMENTS TO THE INTERNAL REVENUE CODE OF 1986.—Subchapter B of chapter 100 of the Internal Revenue Code of 1986 is amended—

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

''Sec. 9813. Standard relating to plan accountability.'';

and

(2) by inserting after section 9814 the following:

''SEC. 9813. STANDARD RELATING TO PLAN ACCOUNTABILITY.

''A group health plan shall comply with the requirements of sections 503A through 503D of the Employee

Retirement Income Security Act of 1974 (as in effect as of the day after the date of the enactment of such Act) and such requirements shall be deemed to be incorporated into this section. For purposes of this section, references in such sections 503A through 503D to the Secretary shall be deemed references to the Secretary of the Treasury.''.

SEC. 3. STATE FLEXIBILITY IN APPLYING ACCOUNTABILITY RULES TO HEALTH INSURANCE ISSUERS.

(a) AMENDMENTS TO THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974.—Part 5 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 (as amended by section 2) is amended further—

(1) by redesignating section 503F as section 503G; and

(2) by inserting after section 503E the following new section:

''SEC. 503F. STATE FLEXIBILITY IN APPLYING ACCOUNTABILITY RULES TO HEALTH INSURANCE ISSUERS.

''(a) STATE FLEXIBILITY.—The requirements of section 503A, 503B, 503C, or 503D shall not apply with respect to health insurance coverage (and to a group health plan insofar as it provides benefits in the form of health insurance coverage) in a State—

''(1) before January 1, 2004; and

"(2) on or after such date, during any period for which the State certifies to the Patients' Protection Certification Board (established under subsection (b)) that the State has in effect a State law (as defined in section 2723(d)(1) of the Public Health Service Act)—

"(A) that provides rules relating to consideration of claims for benefits or review of denials of such claims under such section 503A, 503B, 503C, or 503D; and

"(B) that—

"(i) adopts the Federal rules under such section with respect to the consideration or review; or

"(ii) is consistent with the purposes of such section,

and the Board has not found such certification invalid under subsection (b)(2)(A).

"(b) PATIENTS' PROTECTION CERTIFICATION BOARD; CERTIFICATION REVIEW PROCESS.—

"(1) ESTABLISHMENT OF BOARD.—

"(A) IN GENERAL.—There is hereby established in the Health Resources and Services Administration of the Department of Health and Human Services a Patients' Protection Certifi-

cation Board (in this section referred to as the 'Board').

''(B) COMPOSITION.—The Board shall be composed of 13 members appointed by the President, by and with the advice and consent of the Senate, from among individuals who represent consumers and employers or have expertise in law, medicine, insurance, employee benefits, and related fields. Members shall first be appointed to the Board not earlier than February 1, 2002, and no later than May 1, 2002.

''(C) TERMS.—The terms of members of the Board shall be for 3 years except that for the members first appointed the President shall designate staggered terms of 3 years for 2 members, 2 years for 2 members, and 1 year for one member. A vacancy in the Board shall be filled in the same manner in which the original appointment was made and a member appointed to fill a vacancy occurring before the expiration of the term for which the member's predecessor was appointed shall be appointed only for the remainder of that term.

''(D) COMPENSATION.—To the extent provided in advance in appropriations Acts, while

serving on the business of the Board (including travel time), each member of the Board—

"(i) shall be entitled to receive compensation at the daily equivalent of the annual rate of basic pay provided for level IV of the Executive Schedule under section 5315 of title 5, United States Code for each day (including travel time) during which the member is engaged in the actual performance of duties as such a member; and

"(ii) while so serving away from home and the member's regular place of business, may be allowed travel expenses, as authorized by the Board.

"(2) DUTIES.—

"(A) REVIEW OF CERTIFICATIONS SUBMITTED.—

"(i) IN GENERAL.—The Board shall review certifications submitted under subsection (a)(2).

"(ii) DEFERENCE TO STATES.—Such a certification submitted for a State law with respect to the requirements of a section is deemed valid unless, within 90 days

after the date of its submittal to the Board, the Board finds that there is clear and convincing evidence of substantial noncompliance of the State law with the requirements of subsection (a)(2)(B).

''(B) ANNUAL CONGRESSIONAL REPORTS.—The Board shall submit to Congress an annual report on its activities. The first annual report shall focus specifically on the development by the Board of criteria for the evaluation of State laws and any other activities of the Board during its first year of operation.

''(3) ORGANIZATION.—

''(A) CHAIR.—The Board shall elect a member of the Board to serve as chair.

''(B) MEETINGS.—The Board shall meet at least quarterly and otherwise at the call of the chair or upon the written request of a majority of its members.

''(C) QUORUM.—Seven members of the Board shall constitute a quorum thereof, but a lesser number may hold hearings and take testimony.

''(4) DIRECTOR AND STAFF; EXPERTS AND CONSULTANTS.—To the extent provided in advance in appropriations Acts, the Board may—

''(A) employ and fix the compensation of an Executive Director and such other personnel as may be necessary to carry out the Board's duties, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service;

''(B) procure temporary and intermittent services under section 3109(b) of title 5, United States Code; and

''(C) provide transportation and subsistence for persons serving the Board without compensation.

''(5) POWERS.—

''(A) OBTAINING OFFICIAL DATA.—

''(i) IN GENERAL.—The Board may secure directly from any department or agency of the United States information necessary to enable it to carry out its duties.

''(ii) REQUEST OF CHAIR.—Upon request of the chair, the head of that department or agency shall furnish that informa-

tion to the Board on an agreed upon schedule.

''(B) AGENCY ASSISTANCE.—The Board may seek such assistance and support as may be required in the performance of its duties from the Secretary of Health and Human Services, acting through the Health Resources and Services Administration. Any employee of such Administration may be detailed to the Board to assist the Board in carrying out its duties.

''(C) CONTRACT AUTHORITY.—To the extent provided in advance in appropriations Acts, the Board may enter into contracts or make other arrangements for facilities and services as may be necessary for the conduct of the work of the Board (without regard to section 3709 of the Revised Statutes (41 U.S.C. 5)).

''(D) HEARINGS.—The Board may, for the purpose of carrying out its duties, hold hearings, sit and act at times and places, take testimony, and receive evidence as the Board considers appropriate. The Board may administer oaths or affirmations to witnesses appearing before it. To the extent provided in advance in appropriation Acts, the Board may pay reasonable

travel expenses to witnesses for travel incident to hearings held by the Board. Nothing in this subsection shall be construed as authorizing the issuance of subpoenas in support of its duties.

''(E) RULES.—The Board may prescribe such rules and regulations as it deems necessary to carry out this subsection.

''(6) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this subsection—

''(A) for fiscal year 2002, $500,000,

''(B) for fiscal year 2003, $1,000,000, and

''(C) for subsequent fiscal years, such sums as may be necessary.

''(c) RELATIONSHIP TO GROUP HEALTH PLAN REQUIREMENTS.—Nothing in this section shall be construed to affect or modify the provisions of section 514 with respect to group health plans (insofar as they provide benefits other than in the form of health insurance coverage).

''(d) CONFORMING REGULATIONS.—The Secretary may issue regulations to coordinate the requirements on group health plans under sections 503A through 503D with the requirements imposed under the other provisions of this title.''.

(2) CLERICAL AMENDMENT.—The table of contents in section 1 of such Act (as amended by section 2) is amended further—

(A) in the item relating to section 503F, by striking ''Sec. 503F.'' and inserting ''Sec. 503G.''; and

(B) by inserting after the item relating to section 503E, the following:

''Sec. 503F. State flexibility in applying accountability rules to health insurance issuers.''.

(b) STATE FLEXIBILITY IN APPLYING ACCOUNTABILITY RULES UNDER THE PUBLIC HEALTH SERVICE ACT.—

(1) GROUP HEALTH PLANS AND GROUP HEALTH INSURANCE COVERAGE.—Title XXVII of the Public Health Service Act is amended—

(A) in section 2723(a)(1) (42 U.S.C. 300gg–23(a)(1)), by inserting ''and section 2724'' after ''Subject to paragraph (2)''; and

(B) by inserting after section 2723 the following new section:

''SEC. 2724. STATE FLEXIBILITY IN APPLYING ACCOUNTABILITY RULES.

''(a) IN GENERAL.—The provisions of section 503F of the Employee Retirement Income Security Act of 1974 apply with respect to the rules under section 2707 (only

as applied with respect to group health plans under section 2721(b)) in the same manner as such provisions apply to comparable rules with respect to health insurance coverage provided in connection with a group health plan.

''(b) RELATIONSHIP TO GROUP HEALTH PLAN REQUIREMENTS.—Nothing in this section 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 (insofar as it provides benefits other than in the form of health insurance coverage).''.

(2) INDIVIDUAL HEALTH INSURANCE COVERAGE.—Title XXVII of the Public Health Service Act is amended—

(A) in section 2762(a) (42 U.S.C. 300gg–62(a)(1)), by inserting ''and section 2762A'' after ''Subject to subsection (b)''; and

(B) by inserting after section 2762 the following new section:

''SEC. 2762A. STATE FLEXIBILITY IN APPLYING ACCOUNTABILITY RULES.

''The provisions of section 2724 apply in relation to the rules under section 2755 (relating to accountability) with respect to individual health insurance coverage in the same manner as those provisions apply in relation to the

rules under section 2709, as applied to group health plans under section 2721(b).''.

SEC. 4. EFFECTIVE DATES AND RELATED RULES.

(a) IN GENERAL.—The provisions of this Act, including the amendments made by this Act, shall apply—

(1) to group health plans, and health insurance coverage offered in connection with such plans, on the later of—

(A) plan years beginning on or after January 1 of the first calendar year that begins more than 1 year after the date of the enactment of this Act; or

(B) plan years beginning on or after 18 months after the date on which the Secretary of Health and Human Services and the Secretary of Labor issue final regulations, subject to the notice and comment period required under subchapter 2 of chapter 5 of title 5, United States Code, necessary to carry out such provisions and the amendments made by this Act; and

(2) to individual health insurance coverage beginning on or after the effective date described in paragraph (1)(A).

(b) COVERAGE OF LIMITED SCOPE PLANS.—Section 2791(c)(2)(A) of the Public Health Service Act (42 U.S.C.

300gg–91(c)(2)(A)) and section 733(c)(2)(A) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1186(c)(2)(A)) shall be deemed not to apply for purposes of applying the provisions of the amendments made by this Act.

SEC. 5. REGULATIONS; COORDINATION.

(a) AUTHORITY.—The Secretaries of Health and Human Services, Labor, and the Treasury shall issue such regulations as may be necessary or appropriate to carry out the amendments made by this Act before the effective date thereof.

(b) COORDINATION IN IMPLEMENTATION.—The Secretary of Labor, the Secretary of Health and Human Services, and the Secretary of the Treasury shall ensure, through the execution of an interagency memorandum of understanding among such Secretaries, that—

(1) regulations, rulings, and interpretations issued by such Secretaries relating to the same matter over which such Secretaries have responsibility under the amendments made by this Act 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.

(c) USE OF INTERIM FINAL RULES.—Such Secretaries may promulgate any interim final rules as the Secretaries determine are appropriate to carry out this Act.

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

SEC. 6. NO BENEFIT REQUIREMENTS.

Nothing in the amendments made by this Act 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.

SEC. 7. SEVERABILITY.

If any provision of this Act, an amendment made by this Act, or the application of such provision or amendment to any person or circumstance is held to be unconstitutional, the remainder of this Act, the amendments made

by this Act, and the application of the provisions of such to any person or circumstance shall not be affected thereby.

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