AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

107TH CONGRESS
1ST SESSION

S. 6

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.

IN THE SENATE OF THE UNITED STATES

JANUARY 22, 2001

Mr. DASCHLE (for himself, Mr. KENNEDY, Mr. AKAKA, Mr. BIDEN, Mr. BINGAMAN, Mrs. BOXER, Mr. BYRD, Mrs. CARNAHAN, Mr. CARPER, Mr. CLELAND, Mrs. CLINTON, Mr. CONRAD, Mr. CORZINE, Mr. DAYTON, Mr. DODD, Mr. DORGAN, Mr. DURBIN, Mr. EDWARDS, Mr. GRAHAM, Mr. HARKIN, Mr. HOLLINGS, Mr. INOUYE, Mr. JOHNSON, Mr. KERRY, Ms. LANDRIEU, Mr. LEAHY, Mr. LEVIN, Ms. MIKULSKI, Mrs. MURRAY, Mr. NELSON of Florida, Mr. REED, Mr. REID, Mr. ROCKEFELLER, Mr. SARBANES, Mr. SCHUMER, Ms. STABENOW, Mr. TORRICELLI, Mr. WELLSTONE, and Mr. WYDEN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

---

A BILL

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 ''Patients' Bill of Rights Act''.

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

TITLE I—IMPROVING MANAGED CARE

Subtitle A—Grievance and Appeals

SEC. 101. UTILIZATION REVIEW ACTIVITIES.

(a) COMPLIANCE WITH REQUIREMENTS.—

(1) IN GENERAL.—A group health plan, and a health insurance issuer that provides health insurance coverage, shall conduct utilization review activities in connection with the provision of benefits under such plan or coverage only in accordance with a utilization review program that meets the requirements of this section.

(2) USE OF OUTSIDE AGENTS.—Nothing in this section shall be construed as preventing a group health plan or health insurance issuer from arranging through a contract or otherwise for persons or entities to conduct utilization review activities on behalf of the plan or issuer, so long as such activities are conducted in accordance with a utilization review program that meets the requirements of this section.

(3) UTILIZATION REVIEW DEFINED.—For purposes of this section, the terms ''utilization review'' and ''utilization review activities'' mean procedures used to monitor or evaluate the use or coverage, clinical necessity, appropriateness, efficacy, or efficiency of health care services, procedures or settings, and includes prospective review, concurrent review, second opinions, case management, discharge planning, or retrospective review.

(b) WRITTEN POLICIES AND CRITERIA.—

(1) WRITTEN POLICIES.—A utilization review program shall be conducted consistent with written policies and procedures that govern all aspects of the program.

(2) USE OF WRITTEN CRITERIA.—

(A) IN GENERAL.—Such a program shall utilize written clinical review criteria developed

with input from a range of appropriate actively practicing health care professionals, as determined by the plan, pursuant to the program. Such criteria shall include written clinical review criteria that are based on valid clinical evidence where available and that are directed specifically at meeting the needs of at-risk populations and covered individuals with chronic conditions or severe illnesses, including gender-specific criteria and pediatric-specific criteria where available and appropriate.

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

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

(c) CONDUCT OF PROGRAM ACTIVITIES.—

(1) ADMINISTRATION BY HEALTH CARE PROFESSIONALS.—A utilization review program shall be administered by qualified health care professionals who shall oversee review decisions.

(2) USE OF QUALIFIED, INDEPENDENT PERSONNEL.—

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

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

(C) PROHIBITION OF CONFLICTS.—Such a program shall not permit a health care professional who is providing health care services to an individual to perform utilization review ac-

tivities in connection with the health care services being provided to the individual.

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

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

(d) DEADLINE FOR DETERMINATIONS.—

(1) PRIOR AUTHORIZATION SERVICES.—

(A) IN GENERAL.—Except as provided in paragraph (2), in the case of a utilization review activity involving the prior authorization of health care items and services for an individual, the utilization review program shall make a determination concerning such authorization, and

provide notice of the determination to the individual or the individual's designee and the individual's health care provider by telephone and in printed form, as soon as possible in accordance with the medical exigencies of the case, and in no event later than the deadline specified in subparagraph (B).

(B) DEADLINE.—

(i) IN GENERAL.—Subject to clauses (ii) and (iii), the deadline specified in this subparagraph is 14 days after the date of receipt of the request for prior authorization.

(ii) EXTENSION PERMITTED WHERE NOTICE OF ADDITIONAL INFORMATION REQUIRED.—If a utilization review program—

(I) receives a request for a prior authorization;

(II) determines that additional information is necessary to complete the review and make the determination on the request; and

(III) notifies the requester, not later than five business days after the

date of receiving the request, of the need for such specified additional information,

the deadline specified in this subparagraph is 14 days after the date the program receives the specified additional information, but in no case later than 28 days after the date of receipt of the request for the prior authorization. This clause shall not apply if the deadline is specified in clause (iii).

(iii) EXPEDITED CASES.—In the case of a situation described in section 102(c)(1)(A), the deadline specified in this subparagraph is 72 hours after the time of the request for prior authorization.

(2) ONGOING CARE.—

(A) CONCURRENT REVIEW.—

(i) IN GENERAL.—Subject to subparagraph (B), in the case of a concurrent review of ongoing care (including hospitalization), which results in a termination or reduction of such care, the plan must provide by telephone and in printed form notice of the concurrent review determination to the individual or the individual's designee and

the individual's health care provider as soon as possible in accordance with the medical exigencies of the case, with sufficient time prior to the termination or reduction to allow for an appeal under section 102(c)(1)(A) to be completed before the termination or reduction takes effect.

(ii) CONTENTS OF NOTICE.—Such notice shall include, with respect to ongoing health care items and services, the number of ongoing services approved, the new total of approved services, the date of onset of services, and the next review date, if any, as well as a statement of the individual's rights to further appeal.

(B) EXCEPTION.—Subparagraph (A) shall not be interpreted as requiring plans or issuers to provide coverage of care that would exceed the coverage limitations for such care.

(3) PREVIOUSLY PROVIDED SERVICES.—In the case of a utilization review activity involving retrospective review of health care services previously provided for an individual, the utilization review program shall make a determination concerning such services, and provide notice of the determination to

the individual or the individual's designee and the individual's health care provider by telephone and in printed form, within 30 days of the date of receipt of information that is reasonably necessary to make such determination, but in no case later than 60 days after the date of receipt of the claim for benefits.

(4) FAILURE TO MEET DEADLINE.—In a case in which a group health plan or health insurance issuer fails to make a determination on a claim for benefit under paragraph (1), (2)(A), or (3) by the applicable deadline established under the respective paragraph, the failure shall be treated under this subtitle as a denial of the claim as of the date of the deadline.

(5) REFERENCE TO SPECIAL RULES FOR EMERGENCY SERVICES, MAINTENANCE CARE, AND POST-STABILIZATION CARE.—For waiver of prior authorization requirements in certain cases involving emergency services and maintenance care and post-stabilization care, see subsections (a)(1) and (b) of section 113, respectively.

(e) NOTICE OF DENIALS OF CLAIMS FOR BENEFITS.—

(1) IN GENERAL.—Notice of a denial of claims for benefits under a utilization review program shall be provided in printed form and written in a manner calculated to be understood by the participant, beneficiary, or enrollee and shall include—

(A) the reasons for the denial (including the clinical rationale);

(B) instructions on how to initiate an appeal under section 102; and

(C) notice of the availability, upon request of the individual (or the individual's designee) of the clinical review criteria relied upon to make such denial.

(2) SPECIFICATION OF ANY ADDITIONAL INFORMATION.—Such a notice shall also specify what (if any) additional necessary information must be provided to, or obtained by, the person making the denial in order to make a decision on such an appeal.

(f) CLAIM FOR BENEFITS AND DENIAL OF CLAIM FOR BENEFITS DEFINED.—For purposes of this subtitle:

(1) CLAIM FOR BENEFITS.—The term ''claim for benefits'' means any request for coverage (including authorization of coverage), for eligibility, or for payment in whole or in part, for an item or serv-

ice under a group health plan or health insurance coverage.

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

SEC. 102. INTERNAL APPEALS PROCEDURES.

(a) RIGHT OF REVIEW.—

(1) IN GENERAL.—Each group health plan, and each health insurance issuer offering health insurance coverage—

(A) shall provide adequate notice in writing to any participant or beneficiary under such plan, or enrollee under such coverage, whose claim for benefits under the plan or coverage has been denied (within the meaning of section 101(f)(2)), setting forth the specific reasons for such denial of claim for benefits and rights to any further review or appeal, written in a manner calculated to be understood by the participant, beneficiary, or enrollee; and

(B) shall afford such a participant, beneficiary, or enrollee (and any provider or other person acting on behalf of such an individual with the individual's consent or without such consent if the individual is medically unable to provide such consent) who is dissatisfied with such a denial of claim for benefits a reasonable opportunity (of not less than 180 days) to request and obtain a full and fair review by a named fiduciary (with respect to such plan) or named appropriate individual (with respect to such coverage) of the decision denying the claim.

(2) TREATMENT OF ORAL REQUESTS.—The request for review under paragraph (1)(B) may be made orally, but, in the case of an oral request, shall be followed by a request in writing.

(b) INTERNAL REVIEW PROCESS.—

(1) CONDUCT OF REVIEW.—

(A) IN GENERAL.—A review of a denial of claim under this section shall be made by an individual who—

(i) in a case involving medical judgment, shall be a physician or, in the case of limited scope coverage (as defined in

subparagraph (B)), shall be an appropriate specialist;

(ii) has been selected by the plan or issuer; and

(iii) did not make the initial denial in the internally appealable decision.

(B) LIMITED SCOPE COVERAGE DEFINED.—For purposes of subparagraph (A), the term ''limited scope coverage'' means a group health plan or health insurance coverage the only benefits under which are for benefits described in section 2791(c)(2)(A) of the Public Health Service Act (42 U.S.C. 300gg–91(c)(2)).

(2) TIME LIMITS FOR INTERNAL REVIEWS.—

(A) IN GENERAL.—Having received such a request for review of a denial of claim, the plan or issuer shall, in accordance with the medical exigencies of the case but not later than the deadline specified in subparagraph (B), complete the review on the denial and transmit to the participant, beneficiary, enrollee, or other person involved a decision that affirms, reverses, or modifies the denial. If the decision does not reverse the denial, the plan or issuer shall transmit, in printed form, a notice that

sets forth the grounds for such decision and that includes a description of rights to any further appeal. Such decision shall be treated as the final decision of the plan. Failure to issue such a decision by such deadline shall be treated as a final decision affirming the denial of claim.

(B) DEADLINE.—

(i) IN GENERAL.—Subject to clauses (ii) and (iii), the deadline specified in this subparagraph is 14 days after the date of receipt of the request for internal review.

(ii) EXTENSION PERMITTED WHERE NOTICE OF ADDITIONAL INFORMATION REQUIRED.—If a group health plan or health insurance issuer—

(I) receives a request for internal review;

(II) determines that additional information is necessary to complete the review and make the determination on the request; and

(III) notifies the requester, not later than five business days after the date of receiving the request, of the

need for such specified additional information,

the deadline specified in this subparagraph is 14 days after the date the plan or issuer receives the specified additional information, but in no case later than 28 days after the date of receipt of the request for the internal review. This clause shall not apply if the deadline is specified in clause (iii).

(iii) EXPEDITED CASES.—In the case of a situation described in subsection (c)(1)(A), the deadline specified in this subparagraph is 72 hours after the time of the request for review.

(c) EXPEDITED REVIEW PROCESS.—

(1) IN GENERAL.—A group health plan, and a health insurance issuer, shall establish procedures in writing for the expedited consideration of requests for review under subsection (b) in situations—

(A) in which the application of the normal timeframe for making a determination could seriously jeopardize the life or health of the participant, beneficiary, or enrollee or such an individual's ability to regain maximum function; or

(B) described in section 101(d)(2) (relating to requests for continuation of ongoing care which would otherwise be reduced or terminated).

(2) PROCESS.—Under such procedures—

(A) the request for expedited review may be submitted orally or in writing by an individual or provider who is otherwise entitled to request the review;

(B) all necessary information, including the plan's or issuer's decision, shall be transmitted between the plan or issuer and the requester by telephone, facsimile, or other similarly expeditious available method; and

(C) the plan or issuer shall expedite the review in the case of any of the situations described in subparagraph (A) or (B) of paragraph (1).

(3) DEADLINE FOR DECISION.—The decision on the expedited review must be made and communicated to the parties as soon as possible in accordance with the medical exigencies of the case, and in no event later than 72 hours after the time of receipt of the request for expedited review, except that in a case described in paragraph (1)(B), the decision

must be made before the end of the approved period of care.

(d) WAIVER OF PROCESS.—A plan or issuer may waive its rights for an internal review under subsection (b). In such case the participant, beneficiary, or enrollee involved (and any designee or provider involved) shall be relieved of any obligation to complete the review involved and may, at the option of such participant, beneficiary, enrollee, designee, or provider, proceed directly to seek further appeal through any applicable external appeals process.

SEC. 103. EXTERNAL APPEALS PROCEDURES.

(a) RIGHT TO EXTERNAL APPEAL.—

(1) IN GENERAL.—A group health plan, and a health insurance issuer offering health insurance coverage, shall provide for an external appeals process that meets the requirements of this section in the case of an externally appealable decision described in paragraph (2), for which a timely appeal is made either by the plan or issuer or by the participant, beneficiary, or enrollee (and any provider or other person acting on behalf of such an individual with the individual's consent or without such consent if such an individual is medically unable to provide

such consent). The appropriate Secretary shall establish standards to carry out such requirements.

(2) EXTERNALLY APPEALABLE DECISION DEFINED.—

(A) IN GENERAL.—For purposes of this section, the term ''externally appealable decision'' means a denial of claim for benefits (as defined in section 101(f)(2))—

(i) that is based in whole or in part on a decision that the item or service is not medically necessary or appropriate or is investigational or experimental; or

(ii) in which the decision as to whether a benefit is covered involves a medical judgment.

(B) INCLUSION.—Such term also includes a failure to meet an applicable deadline for internal review under section 102.

(C) EXCLUSIONS.—Such term does not include—

(i) specific exclusions or express limitations on the amount, duration, or scope of coverage that do not involve medical judgment; or

(ii) a decision regarding whether an individual is a participant, beneficiary, or enrollee under the plan or coverage.

(3) EXHAUSTION OF INTERNAL REVIEW PROCESS.—Except as provided under section 102(d), a plan or issuer may condition the use of an external appeal process in the case of an externally appealable decision upon a final decision in an internal review under section 102, but only if the decision is made in a timely basis consistent with the deadlines provided under this subtitle.

(4) FILING FEE REQUIREMENT.—

(A) IN GENERAL.—Subject to subparagraph (B), a plan or issuer may condition the use of an external appeal process upon payment to the plan or issuer of a filing fee that does not exceed $25.

(B) EXCEPTION FOR INDIGENCY.—The plan or issuer may not require payment of the filing fee in the case of an individual participant, beneficiary, or enrollee who certifies (in a form and manner specified in guidelines established by the Secretary of Health and Human Services) that the individual is indigent (as defined in such guidelines).

(C) REFUNDING FEE IN CASE OF SUCCESSFUL APPEALS.—The plan or issuer shall refund payment of the filing fee under this paragraph if the recommendation of the external appeal entity is to reverse or modify the denial of a claim for benefits which is the subject of the appeal.

(b) GENERAL ELEMENTS OF EXTERNAL APPEALS PROCESS.—

(1) CONTRACT WITH QUALIFIED EXTERNAL APPEAL ENTITY.—

(A) CONTRACT REQUIREMENT.—Except as provided in subparagraph (D), the external appeal process under this section of a plan or issuer shall be conducted under a contract between the plan or issuer and one or more qualified external appeal entities (as defined in subsection (c)).

(B) LIMITATION ON PLAN OR ISSUER SELECTION.—

(i) IN GENERAL.—The applicable authority shall implement procedures—

(I) to assure that the selection process among qualified external appeal entities will not create any incen-

tives for external appeal entities to make a decision in a biased manner; and

(II) for auditing a sample of decisions by such entities to assure that no such decisions are made in a biased manner.

(ii) LIMITATION ON ABILITY TO INFLUENCE SELECTION.—No selection process established by the applicable authority under this subsection shall provide the participant, beneficiary, or enrollee or the plan or issuer with the ability to determine or influence the selection of a qualified external appeal entity to review the appeal of the participant, beneficiary, or enrollee.

(C) OTHER TERMS AND CONDITIONS.—The terms and conditions of a contract under this paragraph shall be consistent with the standards the appropriate Secretary shall establish to assure there is no real or apparent conflict of interest in the conduct of external appeal activities. Such contract shall provide that all costs of the process (except those incurred by the participant, beneficiary, enrollee, or

treating professional in support of the appeal) shall be paid by the plan or issuer, and not by the participant, beneficiary, or enrollee. The previous sentence shall not be construed as applying to the imposition of a filing fee under subsection (a)(4).

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

(2) ELEMENTS OF PROCESS.—An external appeal process shall be conducted consistent with standards established by the appropriate Secretary that include at least the following:

(A) FAIR AND DE NOVO DETERMINATION.—The process shall provide for a fair, de novo determination. However, nothing in this paragraph shall be construed as providing for coverage of items and services for which bene-

fits are specifically excluded under the plan or coverage.

(B) STANDARD OF REVIEW.—An external appeal entity shall determine whether the plan's or issuer's decision is in accordance with the medical needs of the patient involved (as determined by the entity) taking into account, as of the time of the entity's determination, the patient's medical condition and any relevant and reliable evidence the entity obtains under subparagraph (D). If the entity determines the decision is in accordance with such needs, the entity shall affirm the decision and to the extent that the entity determines the decision is not in accordance with such needs, the entity shall reverse or modify the decision.

(C) CONSIDERATION OF PLAN OR COVERAGE DEFINITIONS.—In making such determination, the external appeal entity shall consider (but not be bound by) any language in the plan or coverage document relating to the definitions of the terms medical necessity, medically necessary or appropriate, or experimental, investigational, or related terms.

(D) EVIDENCE.—

(i) IN GENERAL.—An external appeal entity shall include, among the evidence taken into consideration—

(I) the decision made by the plan or issuer upon internal review under section 102 and any guidelines or standards used by the plan or issuer in reaching such decision;

(II) any personal health and medical information supplied with respect to the individual whose denial of claim for benefits has been appealed; and

(III) the opinion of the individual's treating physician or health care professional.

(ii) ADDITIONAL EVIDENCE.—Such entity may also take into consideration but not be limited to the following evidence (to the extent available):

(I) The results of studies that meet professionally recognized standards of validity and replicability or that have been published in peer-reviewed journals.

(II) The results of professional consensus conferences conducted or financed in whole or in part by one or more Government agencies.

(III) Practice and treatment guidelines prepared or financed in whole or in part by Government agencies.

(IV) Government-issued coverage and treatment policies.

(V) Community standard of care and generally accepted principles of professional medical practice.

(VI) To the extent that the entity determines it to be free of any conflict of interest, the opinions of individuals who are qualified as experts in one or more fields of health care which are directly related to the matters under appeal.

(VII) To the extent that the entity determines it to be free of any conflict of interest, the results of peer reviews conducted by the plan or issuer involved.

(E) DETERMINATION CONCERNING EXTERNALLY APPEALABLE DECISIONS.—A qualified external appeal entity shall determine—

(i) whether a denial of claim for benefits is an externally appealable decision (within the meaning of subsection (a)(2));

(ii) whether an externally appealable decision involves an expedited appeal; and

(iii) for purposes of initiating an external review, whether the internal review process has been completed.

(F) OPPORTUNITY TO SUBMIT EVIDENCE.—Each party to an externally appealable decision may submit evidence related to the issues in dispute.

(G) PROVISION OF INFORMATION.—The plan or issuer involved shall provide timely access to the external appeal entity to information and to provisions of the plan or health insurance coverage relating to the matter of the externally appealable decision, as determined by the entity.

(H) TIMELY DECISIONS.—A determination by the external appeal entity on the decision shall—

(i) be made orally or in writing and, if it is made orally, shall be supplied to the parties in writing as soon as possible;

(ii) be made in accordance with the medical exigencies of the case involved, but in no event later than 21 days after the date (or, in the case of an expedited appeal, 72 hours after the time) of requesting an external appeal of the decision;

(iii) state, in layperson's language, the basis for the determination, including, if relevant, any basis in the terms or conditions of the plan or coverage; and

(iv) inform the participant, beneficiary, or enrollee of the individual's rights (including any limitation on such rights) to seek further review by the courts (or other process) of the external appeal determination.

(I) COMPLIANCE WITH DETERMINATION.—If the external appeal entity reverses or modifies the denial of a claim for benefits, the plan or issuer shall—

(i) upon the receipt of the determination, authorize benefits in accordance with such determination;

(ii) take such actions as may be necessary to provide benefits (including items or services) in a timely manner consistent with such determination; and

(iii) submit information to the entity documenting compliance with the entity's determination and this subparagraph.

(c) QUALIFICATIONS OF EXTERNAL APPEAL ENTITIES.—

(1) IN GENERAL.—For purposes of this section, the term ''qualified external appeal entity'' means, in relation to a plan or issuer, an entity that is certified under paragraph (2) as meeting the following requirements:

(A) The entity meets the independence requirements of paragraph (3).

(B) The entity conducts external appeal activities through a panel of not fewer than three clinical peers.

(C) The entity has sufficient medical, legal, and other expertise and sufficient staffing to conduct external appeal activities for the plan

or issuer on a timely basis consistent with subsection (b)(2)(G).

(D) The entity meets such other requirements as the appropriate Secretary may impose.

(2) INITIAL CERTIFICATION OF EXTERNAL APPEAL ENTITIES.—

(A) IN GENERAL.—In order to be treated as a qualified external appeal entity with respect to—

(i) a group health plan, the entity must be certified (and, in accordance with subparagraph (B), periodically recertified) as meeting the requirements of paragraph (1)—

(I) by the Secretary of Labor;

(II) under a process recognized or approved by the Secretary of Labor; or

(III) to the extent provided in subparagraph (C)(i), by a qualified private standard-setting organization (certified under such subparagraph); or

(ii) a health insurance issuer operating in a State, the entity must be certified (and, in accordance with subparagraph (B), periodically recertified) as meeting such requirements—

(I) by the applicable State authority (or under a process recognized or approved by such authority); or

(II) if the State has not established a certification and recertification process for such entities, by the Secretary of Health and Human Services, under a process recognized or approved by such Secretary, or to the extent provided in subparagraph (C)(ii), by a qualified private standard-setting organization (certified under such subparagraph).

(B) RECERTIFICATION PROCESS.—The appropriate Secretary shall develop standards for the recertification of external appeal entities. Such standards shall include a review of—

(i) the number of cases reviewed;

(ii) a summary of the disposition of those cases;

(iii) the length of time in making determinations on those cases;

(iv) updated information of what was required to be submitted as a condition of certification for the entity's performance of external appeal activities; and

(v) such information as may be necessary to assure the independence of the entity from the plans or issuers for which external appeal activities are being conducted.

(C) CERTIFICATION OF QUALIFIED PRIVATE STANDARD-SETTING ORGANIZATIONS.—

(i) FOR EXTERNAL REVIEWS UNDER GROUP HEALTH PLANS.—For purposes of subparagraph (A)(i)(III), the Secretary of Labor may provide for a process for certification (and periodic recertification) of qualified private standard-setting organizations which provide for certification of external review entities. Such an organization shall only be certified if the organization does not certify an external review entity unless it meets standards required for cer-

tification of such an entity by such Secretary under subparagraph (A)(i)(I).

(ii) FOR EXTERNAL REVIEWS OF HEALTH INSURANCE ISSUERS.—For purposes of subparagraph (A)(ii)(II), the Secretary of Health and Human Services may provide for a process for certification (and periodic recertification) of qualified private standard-setting organizations which provide for certification of external review entities. Such an organization shall only be certified if the organization does not certify an external review entity unless it meets standards required for certification of such an entity by such Secretary under subparagraph (A)(ii)(II).

(D) REQUIREMENT OF SUFFICIENT NUMBER OF CERTIFIED ENTITIES.—The appropriate Secretary shall certify and recertify a sufficient number of external appeal entities under this paragraph to ensure the timely and efficient provision of external review services.

(3) INDEPENDENCE REQUIREMENTS.—

(A) IN GENERAL.—A clinical peer or other entity meets the independence requirements of this paragraph if—

(i) the peer or entity does not have a familial, financial, or professional relationship with any related party;

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

(iii) except as provided in paragraph (4), the plan and the issuer have no recourse against the peer or entity in connection with the external review; and

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

(B) RELATED PARTY.—For purposes of this paragraph, the term ''related party'' means—

(i) with respect to—

(I) a group health plan or health insurance coverage offered in connec-

tion with such a plan, the plan or the health insurance issuer offering such coverage; or

(II) individual health insurance coverage, the health insurance issuer offering such coverage,

or any plan sponsor, fiduciary, officer, director, or management employee of such plan or issuer;

(ii) the health care professional that provided the health care involved in the coverage decision;

(iii) the institution at which the health care involved in the coverage decision is provided;

(iv) the manufacturer of any drug or other item that was included in the health care involved in the coverage decision; or

(v) any other party determined under any regulations which the Secretary may prescribe to have a substantial interest in the coverage decision.

(4) LIMITATION ON LIABILITY OF REVIEWERS.—No qualified external appeal entity having a contract with a plan or issuer under this part and

no person who is employed by any such entity or who furnishes professional services to such entity, shall be held by reason of the performance of any duty, function, or activity required or authorized pursuant to this section, to have violated any criminal law, or to be civilly liable under any law of the United States or of any State (or political subdivision thereof) if due care was exercised in the performance of such duty, function, or activity and there was no actual malice or gross misconduct in the performance of such duty, function, or activity.

(d) EXTERNAL APPEAL DETERMINATION BINDING ON PLAN.—The determination by an external appeal entity under this section is binding on the plan and issuer involved in the determination.

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

(1) MONETARY PENALTIES.—In any case in which the determination of an external review entity is not followed by a group health plan, or by a health insurance issuer offering health insurance coverage, any person who, acting in the capacity of authorizing the benefit, causes such refusal may, in the discretion in a court of competent jurisdiction,

be liable to an aggrieved participant, beneficiary, or enrollee for a civil penalty in an amount of up to $1,000 a day from the date on which the determination was transmitted to the plan or issuer by the external review entity until the date the refusal to provide the benefit is corrected.

(2) CEASE AND DESIST ORDER AND ORDER OF ATTORNEY'S FEES.—In any action described in paragraph (1) brought by a participant, beneficiary, or enrollee with respect to a group health plan, or a health insurance issuer offering health insurance coverage, in which a plaintiff alleges that a person referred to in such paragraph has taken an action resulting in a refusal of a benefit determined by an external appeal entity in violation of such terms of the plan, coverage, or this subtitle, or has failed to take an action for which such person is responsible under the plan, coverage, or this title and which is necessary under the plan or coverage for authorizing a benefit, the court shall cause to be served on the defendant an order requiring the defendant—

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

(B) to pay to the plaintiff a reasonable attorney's fee and other reasonable costs relating

to the prosecution of the action on the charges on which the plaintiff prevails.

(3) ADDITIONAL CIVIL PENALTIES.—

(A) IN GENERAL.—In addition to any penalty imposed under paragraph (1) or (2), the appropriate Secretary may assess a civil penalty against a person acting in the capacity of authorizing a benefit determined by an external review entity for one or more group health plans, or health insurance issuers offering health insurance coverage, for—

(i) any pattern or practice of repeated refusal to authorize a benefit determined by an external appeal entity in violation of the terms of such a plan, coverage, or this title; or

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

(B) STANDARD OF PROOF AND AMOUNT OF PENALTY.—Such penalty shall be payable only upon proof by clear and convincing evidence of such pattern or practice and shall be in an amount not to exceed the lesser of—

(i) 25 percent of the aggregate value of benefits shown by the appropriate Secretary to have not been provided, or unlawfully delayed, in violation of this section under such pattern or practice; or

(ii) $500,000.

(4) REMOVAL AND DISQUALIFICATION.—Any person acting in the capacity of authorizing benefits who has engaged in any such pattern or practice described in paragraph (3)(A) with respect to a plan or coverage, upon the petition of the appropriate Secretary, may be removed by the court from such position, and from any other involvement, with respect to such a plan or coverage, and may be precluded from returning to any such position or involvement for a period determined by the court.

(f) PROTECTION OF LEGAL RIGHTS.—Nothing in this subtitle shall be construed as altering or eliminating any cause of action or legal rights or remedies of participants, beneficiaries, enrollees, and others under State or Federal law (including sections 502 and 503 of the Employee Retirement Income Security Act of 1974), including the right to file judicial actions to enforce rights.

SEC. 104. ESTABLISHMENT OF A GRIEVANCE PROCESS.

(a) ESTABLISHMENT OF GRIEVANCE SYSTEM.—

(1) IN GENERAL.—A group health plan, and a health insurance issuer in connection with the provision of health insurance coverage, shall establish and maintain a system to provide for the presentation and resolution of oral and written grievances brought by individuals who are participants, beneficiaries, or enrollees, or health care providers or other individuals acting on behalf of an individual and with the individual's consent or without such consent if the individual is medically unable to provide such consent, regarding any aspect of the plan's or issuer's services.

(2) GRIEVANCE DEFINED.—In this section, the term ''grievance'' means any question, complaint, or concern brought by a participant, beneficiary or enrollee that is not a claim for benefits (as defined in section 101(f)(1)).

(b) GRIEVANCE SYSTEM.—Such system shall include the following components with respect to individuals who are participants, beneficiaries, or enrollees:

(1) Written notification to all such individuals and providers of the telephone numbers and business addresses of the plan or issuer personnel responsible for resolution of grievances and appeals.

(2) A system to record and document, over a period of at least three previous years, all grievances and appeals made and their status.

(3) A process providing for timely processing and resolution of grievances.

(4) Procedures for follow-up action, including the methods to inform the person making the grievance of the resolution of the grievance.

Grievances are not subject to appeal under the previous provisions of this subtitle.

Subtitle B—Access to Care

SEC. 111. CONSUMER CHOICE OPTION.

(a) IN GENERAL.—If—

(1) a health insurance issuer providing health insurance coverage in connection with a group health plan offers to enrollees health insurance coverage which provides for coverage of services only if such services are furnished through health care professionals and providers who are members of a network of health care professionals and providers who have entered into a contract with the issuer to provide such services, or

(2) a group health plan offers to participants or beneficiaries health benefits which provide for coverage of services only if such services are furnished

through health care professionals and providers who are members of a network of health care professionals and providers who have entered into a contract with the plan to provide such services,

then the issuer or plan shall also offer or arrange to be offered to such enrollees, participants, or beneficiaries (at the time of enrollment and during an annual open season as provided under subsection (c)) the option of health insurance coverage or health benefits which provide for coverage of such services which are not furnished through health care professionals and providers who are members of such a network unless such enrollees, participants, or beneficiaries are offered such non-network coverage through another group health plan or through another health insurance issuer in the group market.

(b) ADDITIONAL COSTS.—The amount of any additional premium charged by the health insurance issuer or group health plan for the additional cost of the creation and maintenance of the option described in subsection (a) and the amount of any additional cost sharing imposed under such option shall be borne by the enrollee, participant, or beneficiary unless it is paid by the health plan sponsor or group health plan through agreement with the health insurance issuer.

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

SEC. 112. CHOICE OF HEALTH CARE PROFESSIONAL.

(a) PRIMARY CARE.—If a group health plan, or a health insurance issuer that offers health insurance coverage, requires or provides for designation by a participant, beneficiary, or enrollee of a participating primary care provider, then the plan or issuer shall permit each participant, beneficiary, and enrollee to designate any participating primary care provider who is available to accept such individual.

(b) SPECIALISTS.—

(1) IN GENERAL.—Subject to paragraph (2), a group health plan and a health insurance issuer that offers health insurance coverage shall permit each participant, beneficiary, or enrollee to receive medically necessary or appropriate specialty care, pursuant to appropriate referral procedures, from any qualified participating health care professional who is available to accept such individual for such care.

(2) LIMITATION.—Paragraph (1) shall not apply to specialty care if the plan or issuer clearly

informs participants, beneficiaries, and enrollees of the limitations on choice of participating health care professionals with respect to such care.

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

SEC. 113. ACCESS TO EMERGENCY CARE.

(a) COVERAGE OF EMERGENCY SERVICES.—

(1) IN GENERAL.—If a group health plan, or health insurance coverage offered by a health insurance issuer, provides any benefits with respect to services in an emergency department of a hospital, the plan or issuer shall cover emergency services (as defined in paragraph (2)(B))—

(A) without the need for any prior authorization determination;

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

(C) in a manner so that, if such services are provided to a participant, beneficiary, or enrollee—

(i) by a nonparticipating health care provider with or without prior authorization; or

(ii) by a participating health care provider without prior authorization,

the participant, beneficiary, or enrollee is not liable for amounts that exceed the amounts of liability that would be incurred if the services were provided by a participating health care provider with prior authorization; and

(D) without regard to any other term or condition of such coverage (other than exclusion or coordination of benefits, or an affiliation or waiting period, permitted under section 2701 of the Public Health Service Act, section 701 of the Employee Retirement Income Security Act of 1974, or section 9801 of the Internal Revenue Code of 1986, and other than applicable cost-sharing).

(2) DEFINITIONS.—In this section:

(A) EMERGENCY MEDICAL CONDITION BASED ON PRUDENT LAYPERSON STANDARD.—The term ''emergency medical condition'' means a medical condition manifesting itself by acute symptoms of sufficient severity (including se-

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

(B) EMERGENCY SERVICES.—The term ''emergency services'' means—

(i) a medical screening examination (as required under section 1867 of the Social Security Act) that is within the capability of the emergency department of a hospital, including ancillary services routinely available to the emergency department to evaluate an emergency medical condition (as defined in subparagraph (A)); and

(ii) within the capabilities of the staff and facilities available at the hospital, such further medical examination and treatment as are required under section 1867 of such Act to stabilize the patient.

(C) STABILIZE.—The term ''to stabilize'' means, with respect to an emergency medical

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

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

SEC. 114. ACCESS TO SPECIALTY CARE.

(a) SPECIALTY CARE FOR COVERED SERVICES.—

(1) IN GENERAL.—If—

(A) an individual is a participant or beneficiary under a group health plan or an enrollee

who is covered under health insurance coverage offered by a health insurance issuer;

(B) the individual has a condition or disease of sufficient seriousness and complexity to require treatment by a specialist; and

(C) benefits for such treatment are provided under the plan or coverage,

the plan or issuer shall make or provide for a referral to a specialist who is available and accessible to provide the treatment for such condition or disease.

(2) SPECIALIST DEFINED.—For purposes of this subsection, the term ''specialist'' means, with respect to a condition, a health care practitioner, facility, or center that has adequate expertise through appropriate training and experience (including, in the case of a child, appropriate pediatric expertise) to provide high quality care in treating the condition.

(3) CARE UNDER REFERRAL.—A group health plan or health insurance issuer may require that the care provided to an individual pursuant to such referral under paragraph (1) be—

(A) pursuant to a treatment plan, only if the treatment plan is developed by the specialist and approved by the plan or issuer, in consulta-

tion with the designated primary care provider or specialist and the individual (or the individual's designee); and

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

Nothing in this subsection shall be construed as preventing such a treatment plan for an individual from requiring a specialist to provide the primary care provider with regular updates on the specialty care provided, as well as all necessary medical information.

(4) REFERRALS TO PARTICIPATING PROVIDERS.—A group health plan or health insurance issuer is not required under paragraph (1) to provide for a referral to a specialist that is not a participating provider, unless the plan or issuer does not have an appropriate specialist that is available and accessible to treat the individual's condition and that is a participating provider with respect to such treatment.

(5) TREATMENT OF NONPARTICIPATING PROVIDERS.—If a plan or issuer refers an individual to a nonparticipating specialist pursuant to paragraph (1), services provided pursuant to the approved

treatment plan (if any) shall be provided at no additional cost to the individual beyond what the individual would otherwise pay for services received by such a specialist that is a participating provider.

(b) SPECIALISTS AS GATEKEEPER FOR TREATMENT OF ONGOING SPECIAL CONDITIONS.—

(1) IN GENERAL.—A group health plan, or a health insurance issuer, in connection with the provision of health insurance coverage, shall have a procedure by which an individual who is a participant, beneficiary, or enrollee and who has an ongoing special condition (as defined in paragraph (3)) may request and receive a referral to a specialist for such condition who shall be responsible for and capable of providing and coordinating the individual's care with respect to the condition. Under such procedures if such an individual's care would most appropriately be coordinated by such a specialist, such plan or issuer shall refer the individual to such specialist.

(2) TREATMENT FOR RELATED REFERRALS.—Such specialists shall be permitted to treat the individual without a referral from the individual's primary care provider and may authorize such referrals, procedures, tests, and other medical services as the individual's primary care provider would other-

wise be permitted to provide or authorize, subject to the terms of the treatment (referred to in subsection (a)(3)(A)) with respect to the ongoing special condition.

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

(A) is life-threatening, degenerative, or disabling; and

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

(4) TERMS OF REFERRAL.—The provisions of paragraphs (3) through (5) of subsection (a) apply with respect to referrals under paragraph (1) of this subsection in the same manner as they apply to referrals under subsection (a)(1).

(c) STANDING REFERRALS.—

(1) IN GENERAL.—A group health plan, and a health insurance issuer in connection with the provision of health insurance coverage, shall have a procedure by which an individual who is a participant, beneficiary, or enrollee and who has a condition that requires ongoing care from a specialist may receive a standing referral to such specialist for treatment of such condition. If the plan or issuer, or if the pri-

mary care provider in consultation with the medical director of the plan or issuer and the specialist (if any), determines that such a standing referral is appropriate, the plan or issuer shall make such a referral to such a specialist if the individual so desires.

(2) TERMS OF REFERRAL.—The provisions of paragraphs (3) through (5) of subsection (a) apply with respect to referrals under paragraph (1) of this subsection in the same manner as they apply to referrals under subsection (a)(1).

SEC. 115. ACCESS TO OBSTETRICAL AND GYNECOLOGICAL CARE.

(a) IN GENERAL.—If a group health plan, or a health insurance issuer in connection with the provision of health insurance coverage, requires or provides for a participant, beneficiary, or enrollee to designate a participating primary care health care professional, the plan or issuer—

(1) may not require authorization or a referral by the individual's primary care health care professional or otherwise for coverage of gynecological care (including preventive women's health examinations) and pregnancy-related services provided by a participating health care professional, including a physician, who specializes in obstetrics and gynecology to the extent such care is otherwise covered; and

(2) shall treat the ordering of other obstetrical or gynecological care by such a participating professional as the authorization of the primary care health care professional with respect to such care under the plan or coverage.

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

(1) waive any exclusions of coverage under the terms of the plan or health insurance coverage with respect to coverage of obstetrical or gynecological care; or

(2) preclude the group health plan or health insurance issuer involved from requiring that the obstetrical or gynecological provider notify the primary care health care professional or the plan or issuer of treatment decisions.

SEC. 116. ACCESS TO PEDIATRIC CARE.

(a) PEDIATRIC CARE.—If a group health plan, or a health insurance issuer in connection with the provision of health insurance coverage, requires or provides for an enrollee to designate a participating primary care provider for a child of such enrollee, the plan or issuer shall permit the enrollee to designate a physician who specializes in pediatrics as the child's primary care provider.

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

SEC. 117. CONTINUITY OF CARE.

(a) IN GENERAL.—

(1) TERMINATION OF PROVIDER.—If a contract between a group health plan, or a health insurance issuer in connection with the provision of health insurance coverage, and a health care provider is terminated (as defined in paragraph (3)(B)), or benefits or coverage provided by a health care provider are terminated because of a change in the terms of provider participation in a group health plan, and an individual who is a participant, beneficiary, or enrollee in the plan or coverage is undergoing treatment from the provider for an ongoing special condition (as defined in paragraph (3)(A)) at the time of such termination, the plan or issuer shall—

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

(B) subject to subsection (c), permit the individual to elect to continue to be covered

with respect to treatment by the provider of such condition during a transitional period (provided under subsection (b)).

(2) TREATMENT OF TERMINATION OF CONTRACT WITH HEALTH INSURANCE ISSUER.—If a contract for the provision of health insurance coverage between a group health plan and a health insurance issuer is terminated and, as a result of such termination, coverage of services of a health care provider is terminated with respect to an individual, the provisions of paragraph (1) (and the succeeding provisions of this section) shall apply under the plan in the same manner as if there had been a contract between the plan and the provider that had been terminated, but only with respect to benefits that are covered under the plan after the contract termination.

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

(A) ONGOING SPECIAL CONDITION.—The term ''ongoing special condition'' has the meaning given such term in section 114(b)(3), and also includes pregnancy.

(B) TERMINATION.—The term ''terminated'' includes, with respect to a contract, the

expiration or nonrenewal of the contract, but does not include a termination of the contract by the plan or issuer for failure to meet applicable quality standards or for fraud.

(b) TRANSITIONAL PERIOD.—

(1) IN GENERAL.—Except as provided in paragraphs (2) through (4), the transitional period under this subsection shall extend up to 90 days (as determined by the treating health care professional) after the date of the notice described in subsection (a)(1)(A) of the provider's termination.

(2) SCHEDULED SURGERY AND ORGAN TRANSPLANTATION.—If surgery or organ transplantation was scheduled for an individual before the date of the announcement of the termination of the provider status under subsection (a)(1)(A) or if the individual on such date was on an established waiting list or otherwise scheduled to have such surgery or transplantation, the transitional period under this subsection with respect to the surgery or transplantation shall extend beyond the period under paragraph (1) and until the date of discharge of the individual after completion of the surgery or transplantation.

(3) PREGNANCY.—If—

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

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

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

(4) TERMINAL ILLNESS.—If—

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

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

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

(c) PERMISSIBLE TERMS AND CONDITIONS.—A group health plan or health insurance issuer may condition coverage of continued treatment by a provider under subsection (a)(1)(B) upon the individual notifying the plan

of the election of continued coverage and upon the provider agreeing to the following terms and conditions:

(1) The provider agrees to accept reimbursement from the plan or issuer and individual involved (with respect to cost-sharing) at the rates applicable prior to the start of the transitional period as payment in full (or, in the case described in subsection (a)(2), at the rates applicable under the replacement plan or issuer after the date of the termination of the contract with the health insurance issuer) and not to impose cost-sharing with respect to the individual in an amount that would exceed the cost-sharing that could have been imposed if the contract referred to in subsection (a)(1) had not been terminated.

(2) The provider agrees to adhere to the quality assurance standards of the plan or issuer responsible for payment under paragraph (1) and to provide to such plan or issuer necessary medical information related to the care provided.

(3) The provider agrees otherwise to adhere to such plan's or issuer's policies and procedures, including procedures regarding referrals and obtaining prior authorization and providing services pursuant

to a treatment plan (if any) approved by the plan or issuer.

(d) CONSTRUCTION.—Nothing in this section shall be construed to require the coverage of benefits which would not have been covered if the provider involved remained a participating provider.

SEC. 118. ACCESS TO NEEDED PRESCRIPTION DRUGS.

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

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

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

(3) in accordance with the applicable quality assurance and utilization review standards of the plan or issuer, provide for exceptions from the formulary limitation when a non-formulary alternative is medically necessary and appropriate and, in the case of such an exception, apply the same cost-sharing requirements that would have applied in the case of a drug covered under the formulary.

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

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

(A) in the case of a prescription drug—

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

(ii) is included in the labeling authorized by the application in effect for the drug under section 351 of the Public Health Service Act, without regard to any postmarketing requirements that may apply pursuant to such section; or

(B) in the case of a medical device, is included in the labeling authorized by a regulation under subsection (d) or (3) of section 513

of the Federal Food, Drug, and Cosmetic Act, an order under subsection (f) of such section, or an application approved under section 515 of such Act, without regard to any postmarketing requirements that may apply under such Act.

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

SEC. 119. COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CLINICAL TRIALS.

(a) COVERAGE.—

(1) IN GENERAL.—If a group health plan, or health insurance issuer that is providing health insurance coverage, provides coverage to a qualified individual (as defined in subsection (b)), the plan or issuer—

(A) may not deny the individual participation in the clinical trial referred to in subsection (b)(2);

(B) subject to subsection (c), may not deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and

services furnished in connection with participation in the trial; and

(C) may not discriminate against the individual on the basis of the enrollee's participation in such trial.

(2) EXCLUSION OF CERTAIN COSTS.—For purposes of paragraph (1)(B), routine patient costs do not include the cost of the tests or measurements conducted primarily for the purpose of the clinical trial involved.

(3) USE OF IN-NETWORK PROVIDERS.—If one or more participating providers is participating in a clinical trial, nothing in paragraph (1) shall be construed as preventing a plan or issuer from requiring that a qualified individual participate in the trial through such a participating provider if the provider will accept the individual as a participant in the trial.

(b) QUALIFIED INDIVIDUAL DEFINED.—For purposes of subsection (a), the term ''qualified individual'' means an individual who is a participant or beneficiary in a group health plan, or who is an enrollee under health insurance coverage, and who meets the following conditions:

(1)(A) The individual has a life-threatening or serious illness for which no standard treatment is effective.

(B) The individual is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of such illness.

(C) The individual's participation in the trial offers meaningful potential for significant clinical benefit for the individual.

(2) Either—

(A) the referring physician is a participating health care professional and has concluded that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1); or

(B) the participant, beneficiary, or enrollee provides medical and scientific information establishing that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1).

(c) PAYMENT.—

(1) IN GENERAL.—Under this section a group health plan or health insurance issuer shall provide

for payment for routine patient costs described in subsection (a)(2) but is not required to pay for costs of items and services that are reasonably expected (as determined by the Secretary) to be paid for by the sponsors of an approved clinical trial.

(2) PAYMENT RATE.—In the case of covered items and services provided by—

(A) a participating provider, the payment rate shall be at the agreed upon rate; or

(B) a nonparticipating provider, the payment rate shall be at the rate the plan or issuer would normally pay for comparable services under subparagraph (A).

(d) APPROVED CLINICAL TRIAL DEFINED.—

(1) IN GENERAL.—In this section, the term ''approved clinical trial'' means a clinical research study or clinical investigation approved and funded (which may include funding through in-kind contributions) by one or more of the following:

(A) The National Institutes of Health.

(B) A cooperative group or center of the National Institutes of Health.

(C) Either of the following if the conditions described in paragraph (2) are met:

(i) The Department of Veterans Affairs.

(ii) The Department of Defense.

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

(A) to be comparable to the system of peer review of studies and investigations used by the National Institutes of Health; and

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

(e) CONSTRUCTION.—Nothing in this section shall be construed to limit a plan's or issuer's coverage with respect to clinical trials.

Subtitle C—Access to Information

SEC. 121. PATIENT ACCESS TO INFORMATION.

(a) DISCLOSURE REQUIREMENT.—

(1) GROUP HEALTH PLANS.—A group health plan shall—

(A) provide to participants and beneficiaries at the time of initial coverage under

the plan (or the effective date of this section, in the case of individuals who are participants or beneficiaries as of such date), and at least annually thereafter, the information described in subsection (b) in printed form;

(B) provide to participants and beneficiaries, within a reasonable period (as specified by the appropriate Secretary) before or after the date of significant changes in the information described in subsection (b), information in printed form on such significant changes; and

(C) upon request, make available to participants and beneficiaries, the applicable authority, and prospective participants and beneficiaries, the information described in subsection (b) or (c) in printed form.

(2) HEALTH INSURANCE ISSUERS.—A health insurance issuer in connection with the provision of health insurance coverage shall—

(A) provide to individuals enrolled under such coverage at the time of enrollment, and at least annually thereafter, the information described in subsection (b) in printed form;

(B) provide to enrollees, within a reasonable period (as specified by the appropriate Secretary) before or after the date of significant changes in the information described in subsection (b), information in printed form on such significant changes; and

(C) upon request, make available to the applicable authority, to individuals who are prospective enrollees, and to the public the information described in subsection (b) or (c) in printed form.

(b) INFORMATION PROVIDED.—The information described in this subsection with respect to a group health plan or health insurance coverage offered by a health insurance issuer includes the following:

(1) SERVICE AREA.—The service area of the plan or issuer.

(2) BENEFITS.—Benefits offered under the plan or coverage, including—

(A) covered benefits, including benefit limits and coverage exclusions;

(B) cost sharing, such as deductibles, coinsurance, and copayment amounts, including any liability for balance billing, any maximum limitations on out of pocket expenses, and the max-

imum out of pocket costs for services that are provided by nonparticipating providers or that are furnished without meeting the applicable utilization review requirements;

(C) the extent to which benefits may be obtained from nonparticipating providers;

(D) the extent to which a participant, beneficiary, or enrollee may select from among participating providers and the types of providers participating in the plan or issuer network;

(E) process for determining experimental coverage; and

(F) use of a prescription drug formulary.

(3) ACCESS.—A description of the following:

(A) The number, mix, and distribution of providers under the plan or coverage.

(B) Out-of-network coverage (if any) provided by the plan or coverage.

(C) Any point-of-service option (including any supplemental premium or cost-sharing for such option).

(D) The procedures for participants, beneficiaries, and enrollees to select, access, and change participating primary and specialty providers.

(E) The rights and procedures for obtaining referrals (including standing referrals) to participating and nonparticipating providers.

(F) The name, address, and telephone number of participating health care providers and an indication of whether each such provider is available to accept new patients.

(G) Any limitations imposed on the selection of qualifying participating health care providers, including any limitations imposed under section 112(b)(2).

(H) How the plan or issuer addresses the needs of participants, beneficiaries, and enrollees and others who do not speak English or who have other special communications needs in accessing providers under the plan or coverage, including the provision of information described in this subsection and subsection (c) to such individuals.

(4) OUT-OF-AREA COVERAGE.—Out-of-area coverage provided by the plan or issuer.

(5) EMERGENCY COVERAGE.—Coverage of emergency services, including—

(A) the appropriate use of emergency services, including use of the 911 telephone system

or its local equivalent in emergency situations and an explanation of what constitutes an emergency situation;

(B) the process and procedures of the plan or issuer for obtaining emergency services; and

(C) the locations of (i) emergency departments, and (ii) other settings, in which plan physicians and hospitals provide emergency services and post-stabilization care.

(6) PERCENTAGE OF PREMIUMS USED FOR BENEFITS (LOSS-RATIOS).—In the case of health insurance coverage only (and not with respect to group health plans that do not provide coverage through health insurance coverage), a description of the overall loss-ratio for the coverage (as defined in accordance with rules established or recognized by the Secretary of Health and Human Services).

(7) PRIOR AUTHORIZATION RULES.—Rules regarding prior authorization or other review requirements that could result in noncoverage or nonpayment.

(8) GRIEVANCE AND APPEALS PROCEDURES.—All appeal or grievance rights and procedures under the plan or coverage, including the method for filing grievances and the time frames and circumstances

for acting on grievances and appeals, who is the applicable authority with respect to the plan or issuer.

(9) QUALITY ASSURANCE.—Any information made public by an accrediting organization in the process of accreditation of the plan or issuer or any additional quality indicators the plan or issuer makes available.

(10) INFORMATION ON ISSUER.—Notice of appropriate mailing addresses and telephone numbers to be used by participants, beneficiaries, and enrollees in seeking information or authorization for treatment.

(11) NOTICE OF REQUIREMENTS.—Notice of the requirements of this title.

(12) AVAILABILITY OF INFORMATION ON REQUEST.—Notice that the information described in subsection (c) is available upon request.

(c) INFORMATION MADE AVAILABLE UPON REQUEST.—The information described in this subsection is the following:

(1) UTILIZATION REVIEW ACTIVITIES.—A description of procedures used and requirements (including circumstances, time frames, and appeal rights) under any utilization review program under

section 101, including under any drug formulary program under section 118.

(2) GRIEVANCE AND APPEALS INFORMATION.—Information on the number of grievances and appeals and on the disposition in the aggregate of such matters.

(3) METHOD OF PHYSICIAN COMPENSATION.—A general description by category (including salary, fee-for-service, capitation, and such other categories as may be specified in regulations of the Secretary) of the applicable method by which a specified prospective or treating health care professional is (or would be) compensated in connection with the provision of health care under the plan or coverage.

(4) SPECIFIC INFORMATION ON CREDENTIALS OF PARTICIPATING PROVIDERS.—In the case of each participating provider, a description of the credentials of the provider.

(5) FORMULARY RESTRICTIONS.—A description of the nature of any drug formula restrictions.

(6) PARTICIPATING PROVIDER LIST.—A list of current participating health care providers.

(d) CONSTRUCTION.—Nothing in this section shall be construed as requiring public disclosure of individual con-

tracts or financial arrangements between a group health plan or health insurance issuer and any provider.

Subtitle D—Protecting the Doctor-Patient Relationship

SEC. 131. PROHIBITION OF INTERFERENCE WITH CERTAIN MEDICAL COMMUNICATIONS.

(a) GENERAL RULE.—The provisions of any contract or agreement, or the operation of any contract or agreement, between a group health plan or health insurance issuer in relation to health insurance coverage (including any partnership, association, or other organization that enters into or administers such a contract or agreement) and a health care provider (or group of health care providers) shall not prohibit or otherwise restrict a health care professional from advising such a participant, beneficiary, or enrollee who is a patient of the professional about the health status of the individual or medical care or treatment for the individual's condition or disease, regardless of whether benefits for such care or treatment are provided under the plan or coverage, if the professional is acting within the lawful scope of practice.

(b) NULLIFICATION.—Any contract provision or agreement that restricts or prohibits medical communications in violation of subsection (a) shall be null and void.

SEC. 132. PROHIBITION OF DISCRIMINATION AGAINST PROVIDERS BASED ON LICENSURE.

(a) IN GENERAL.—A group health plan and a health insurance issuer offering health insurance coverage shall not discriminate with respect to participation or indemnification as to any provider who is acting within the scope of the provider's license or certification under applicable State law, solely on the basis of such license or certification.

(b) CONSTRUCTION.—Subsection (a) shall not be construed—

(1) as requiring the coverage under a group health plan or health insurance coverage of particular benefits or services or to prohibit a plan or issuer from including providers only to the extent necessary to meet the needs of the plan's or issuer's participants, beneficiaries, or enrollees or from establishing any measure designed to maintain quality and control costs consistent with the responsibilities of the plan or issuer;

(2) to override any State licensure or scope-of-practice law; or

(3) as requiring a plan or issuer that offers network coverage to include for participation every willing provider who meets the terms and conditions of the plan or issuer.

SEC. 133. PROHIBITION AGAINST IMPROPER INCENTIVE ARRANGEMENTS.

(a) IN GENERAL.—A group health plan and a health insurance issuer offering health insurance coverage may not operate any physician incentive plan (as defined in subparagraph (B) of section 1876(i)(8) of the Social Security Act) unless the requirements described in clauses (i), (ii)(I), and (iii) of subparagraph (A) of such section are met with respect to such a plan.

(b) APPLICATION.—For purposes of carrying out paragraph (1), any reference in section 1876(i)(8) of the Social Security Act to the Secretary, an eligible organization, or an individual enrolled with the organization shall be treated as a reference to the applicable authority, a group health plan or health insurance issuer, respectively, and a participant, beneficiary, or enrollee with the plan or organization, respectively.

(c) CONSTRUCTION.—Nothing in this section shall be construed as prohibiting all capitation and similar arrangements or all provider discount arrangements.

SEC. 134. PAYMENT OF CLAIMS.

A group health plan, and a health insurance issuer offering group health insurance coverage, shall provide for prompt payment of claims submitted for health care services or supplies furnished to a participant, beneficiary, or enrollee with respect to benefits covered by the plan or

issuer, in a manner consistent with the provisions of sections 1816(c)(2) and 1842(c)(2) of the Social Security Act (42 U.S.C. 1395h(c)(2) and 42 U.S.C. 1395u(c)(2)), except that for purposes of this section, subparagraph (C) of section 1816(c)(2) of the Social Security Act shall be treated as applying to claims received from a participant, beneficiary, or enrollee as well as claims referred to in such subparagraph.

SEC. 135. PROTECTION FOR PATIENT ADVOCACY.

(a) PROTECTION FOR USE OF UTILIZATION REVIEW AND GRIEVANCE PROCESS.—A group health plan, and a health insurance issuer with respect to the provision of health insurance coverage, may not retaliate against a participant, beneficiary, enrollee, or health care provider based on the participant's, beneficiary's, enrollee's or provider's use of, or participation in, a utilization review process or a grievance process of the plan or issuer (including an internal or external review or appeal process) under this title.

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

(1) IN GENERAL.—A group health plan or health insurance issuer may not retaliate or discriminate against a protected health care professional because the professional in good faith—

(A) discloses information relating to the care, services, or conditions affecting one or more participants, beneficiaries, or enrollees of the plan or issuer to an appropriate public regulatory agency, an appropriate private accreditation body, or appropriate management personnel of the plan or issuer; or

(B) initiates, cooperates, or otherwise participates in an investigation or proceeding by such an agency with respect to such care, services, or conditions.

If an institutional health care provider is a participating provider with such a plan or issuer or otherwise receives payments for benefits provided by such a plan or issuer, the provisions of the previous sentence shall apply to the provider in relation to care, services, or conditions affecting one or more patients within an institutional health care provider in the same manner as they apply to the plan or issuer in relation to care, services, or conditions provided to one or more participants, beneficiaries, or enrollees; and for purposes of applying this sentence, any reference to a plan or issuer is deemed a reference to the institutional health care provider.

(2) GOOD FAITH ACTION.—For purposes of paragraph (1), a protected health care professional is considered to be acting in good faith with respect to disclosure of information or participation if, with respect to the information disclosed as part of the action—

(A) the disclosure is made on the basis of personal knowledge and is consistent with that degree of learning and skill ordinarily possessed by health care professionals with the same licensure or certification and the same experience;

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

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

(D) subject to subparagraphs (B) and (C) of paragraph (3), the professional has followed reasonable internal procedures of the plan, issuer, or institutional health care provider es-

tablished for the purpose of addressing quality concerns before making the disclosure.

(3) EXCEPTION AND SPECIAL RULE.—

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

(B) NOTICE OF INTERNAL PROCEDURES.—Subparagraph (D) of paragraph (2) shall not apply unless the internal procedures involved are reasonably expected to be known to the health care professional involved. For purposes of this subparagraph, a health care professional is reasonably expected to know of internal procedures if those procedures have been made available to the professional through distribution or posting.

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

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

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

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

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

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

(6) CONSTRUCTIONS.—

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

(B) ENFORCEMENT OF PEER REVIEW PROTOCOLS AND INTERNAL PROCEDURES.—Nothing in this subsection shall be construed to prohibit a plan, issuer, or provider from establishing and enforcing reasonable peer review or utilization review protocols or determining whether a protected health care professional has complied with those protocols or from establishing and enforcing internal procedures for the purpose of addressing quality concerns.

(C) RELATION TO OTHER RIGHTS.—Nothing in this subsection shall be construed to abridge rights of participants, beneficiaries, enrollees, and protected health care professionals under other applicable Federal or State laws.

(7) PROTECTED HEALTH CARE PROFESSIONAL DEFINED.—For purposes of this subsection, the term ''protected health care professional'' means an

individual who is a licensed or certified health care professional and who—

(A) with respect to a group health plan or health insurance issuer, is an employee of the plan or issuer or has a contract with the plan or issuer for provision of services for which benefits are available under the plan or issuer; or

(B) with respect to an institutional health care provider, is an employee of the provider or has a contract or other arrangement with the provider respecting the provision of health care services.

Subtitle E—Definitions

SEC. 151. DEFINITIONS.

(a) INCORPORATION OF GENERAL DEFINITIONS.—Except as otherwise provided, the provisions of section 2791 of the Public Health Service Act shall apply for purposes of this title in the same manner as they apply for purposes of title XXVII of such Act.

(b) SECRETARY.—Except as otherwise provided, the term ''Secretary'' means the Secretary of Health and Human Services, in consultation with the Secretary of Labor and the term ''appropriate Secretary'' means the Secretary of Health and Human Services in relation to carrying out this title under sections 2706 and 2751 of

the Public Health Service Act and the Secretary of Labor in relation to carrying out this title under section 713 of the Employee Retirement Income Security Act of 1974.

(c) ADDITIONAL DEFINITIONS.—For purposes of this title:

(1) ACTIVELY PRACTICING.—The term ''actively practicing'' means, with respect to a physician or other health care professional, such a physician or professional who provides professional services to individual patients on average at least two full days per week.

(2) APPLICABLE AUTHORITY.—The term ''applicable authority'' means—

(A) in the case of a group health plan, the Secretary of Health and Human Services and the Secretary of Labor; and

(B) in the case of a health insurance issuer with respect to a specific provision of this title, the applicable State authority (as defined in section 2791(d) of the Public Health Service Act), or the Secretary of Health and Human Services, if such Secretary is enforcing such provision under section 2722(a)(2) or 2761(a)(2) of the Public Health Service Act.

(3) CLINICAL PEER.—The term ''clinical peer'' means, with respect to a review or appeal, an actively practicing physician (allopathic or osteopathic) or other actively practicing health care professional who holds a nonrestricted license, and who is appropriately credentialed in the same or similar specialty or subspecialty (as appropriate) as typically handles the medical condition, procedure, or treatment under review or appeal and includes a pediatric specialist where appropriate; except that only a physician (allopathic or osteopathic) may be a clinical peer with respect to the review or appeal of treatment recommended or rendered by a physician.

(4) ENROLLEE.—The term ''enrollee'' means, with respect to health insurance coverage offered by a health insurance issuer, an individual enrolled with the issuer to receive such coverage.

(5) GROUP HEALTH PLAN.—The term ''group health plan'' has the meaning given such term in section 733(a) of the Employee Retirement Income Security Act of 1974 and in section 2791(a)(1) of the Public Health Service Act.

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

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

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

(8) NETWORK.—The term ''network'' means, with respect to a group health plan or health insurance issuer offering health insurance coverage, the participating health care professionals and providers through whom the plan or issuer provides health care items and services to participants, beneficiaries, or enrollees.

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

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

(11) PRIOR AUTHORIZATION.—The term ''prior authorization'' means the process of obtaining prior approval from a health insurance issuer or group health plan for the provision or coverage of medical services.

SEC. 152. PREEMPTION; STATE FLEXIBILITY; CONSTRUCTION.

(a) CONTINUED APPLICABILITY OF STATE LAW WITH RESPECT TO HEALTH INSURANCE ISSUERS.—

(1) IN GENERAL.—Subject to paragraph (2), this title shall not be construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers (in connection with group health insurance coverage or otherwise) except to the extent that such standard or re-

quirement prevents the application of a requirement of this title.

(2) CONTINUED PREEMPTION WITH RESPECT TO GROUP HEALTH PLANS.—Nothing in this title shall be construed to affect or modify the provisions of section 514 of the Employee Retirement Income Security Act of 1974 with respect to group health plans.

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

(1) STATE LAW.—The term ''State law'' includes all laws, decisions, rules, regulations, or other State action having the effect of law, of any State. A law of the United States applicable only to the District of Columbia shall be treated as a State law rather than a law of the United States.

(2) STATE.—The term ''State'' includes a State, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, any political subdivisions of such, or any agency or instrumentality of such.

SEC. 153. EXCLUSIONS.

(a) NO BENEFIT REQUIREMENTS.—Nothing in this title shall be construed to require a group health plan or a health insurance issuer offering health insurance coverage to include specific items and services under the

terms of such a plan or coverage, other than those that are provided for under the terms of such plan or coverage.

(b) EXCLUSION FROM ACCESS TO CARE MANAGED CARE PROVISIONS FOR FEE-FOR-SERVICE COVERAGE.—

(1) IN GENERAL.—The provisions of sections 111 through 117 shall not apply to a group health plan or health insurance coverage if the only coverage offered under the plan or coverage is fee-for-service coverage (as defined in paragraph (2)).

(2) FEE-FOR-SERVICE COVERAGE DEFINED.—For purposes of this subsection, the term ''fee-for-service coverage'' means coverage under a group health plan or health insurance coverage that—

(A) reimburses hospitals, health professionals, and other providers on the basis of a rate determined by the plan or issuer on a fee-for-service basis without placing the provider at financial risk;

(B) does not vary reimbursement for such a provider based on an agreement to contract terms and conditions or the utilization of health care items or services relating to such provider;

(C) does not restrict the selection of providers among those who are lawfully authorized to provide the covered services and agree to ac-

cept the terms and conditions of payment established under the plan or by the issuer; and

(D) for which the plan or issuer does not require prior authorization before providing coverage for any services.

SEC. 154. COVERAGE OF LIMITED SCOPE PLANS.

Only for purposes of applying the requirements of this title under sections 2707 and 2753 of the Public Health Service Act and section 714 of the Employee Retirement Income Security Act of 1974, section 2791(c)(2)(A), and section 733(c)(2)(A) of the Employee Retirement Income Security Act of 1974 shall be deemed not to apply.

SEC. 155. REGULATIONS.

The Secretaries of Health and Human Services and Labor shall issue such regulations as may be necessary or appropriate to carry out this title. Such regulations shall be issued consistent with 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.

TITLE II—APPLICATION OF QUALITY CARE STANDARDS TO GROUP HEALTH PLANS AND HEALTH INSURANCE COVERAGE UNDER THE PUBLIC HEALTH SERVICE ACT

SEC. 201. APPLICATION TO GROUP HEALTH PLANS AND GROUP HEALTH INSURANCE COVERAGE.

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

"SEC. 2707. PATIENT PROTECTION STANDARDS.

''(a) IN GENERAL.—Each group health plan shall comply with patient protection requirements under title I of the Patients' Bill of Rights Act, and each health insurance issuer shall comply with patient protection requirements under such title with respect to group health insurance coverage it offers, and such requirements shall be deemed to be incorporated into this subsection.

''(b) NOTICE.—A group health plan shall comply with the notice requirement under section 711(d) of the Employee Retirement Income Security Act of 1974 with respect to the requirements referred to in subsection (a) and a health insurance issuer shall comply with such notice

requirement as if such section applied to such issuer and such issuer were a group health plan.''.

(b) CONFORMING AMENDMENT.—Section 2721(b)(2)(A) of such Act (42 U.S.C. 300gg–21(b)(2)(A)) is amended by inserting ''(other than section 2707)'' after ''requirements of such subparts''.

SEC. 202. APPLICATION TO INDIVIDUAL HEALTH INSURANCE COVERAGE.

Part B of title XXVII of the Public Health Service Act is amended by inserting after section 2752 the following new section:

''SEC. 2753. PATIENT PROTECTION STANDARDS.

''(a) IN GENERAL.—Each health insurance issuer shall comply with patient protection requirements under title I of the Patients' Bill of Rights Act with respect to individual health insurance coverage it offers, and such requirements shall be deemed to be incorporated into this subsection.

''(b) NOTICE.—A health insurance issuer under this part shall comply with the notice requirement under section 711(d) of the Employee Retirement Income Security Act of 1974 with respect to the requirements of such title as if such section applied to such issuer and such issuer were a group health plan.''.

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

SEC. 301. APPLICATION OF PATIENT PROTECTION STANDARDS TO GROUP HEALTH PLANS AND GROUP HEALTH INSURANCE COVERAGE UNDER THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974.

Subpart B of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 is amended by adding at the end the following new section:

"SEC. 714. PATIENT PROTECTION STANDARDS.

"(a) IN GENERAL.—Subject to subsection (b), a group health plan (and a health insurance issuer offering group health insurance coverage in connection with such a plan) shall comply with the requirements of title I of the Patients' Bill of Rights Act (as in effect as of the date of the enactment of such Act), and such requirements shall be deemed to be incorporated into this subsection.

"(b) PLAN SATISFACTION OF CERTAIN REQUIREMENTS.—

"(1) SATISFACTION OF CERTAIN REQUIREMENTS THROUGH INSURANCE.—For purposes of subsection (a), insofar as a group health plan pro-

vides benefits in the form of health insurance coverage through a health insurance issuer, the plan shall be treated as meeting the following requirements of title I of the Patients' Bill of Rights 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 112 (relating to choice of providers).

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

"(C) Section 114 (relating to access to specialty care).

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

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

"(F) Section 117(a)(1) (relating to continuity in case of termination of provider contract) and section 117(a)(2) (relating to continuity in case of termination of issuer contract), but only insofar as a replacement issuer assumes the obligation for continuity of care.

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

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

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

''(2) INFORMATION.—With respect to information required to be provided or made available under section 121, in the case of a group health plan that provides benefits in the form of health insurance coverage through a health insurance issuer, the Secretary shall determine the circumstances under which the plan is not required to provide or make available the information (and is not liable for the issuer's failure to provide or make available the information), if the issuer is obligated to provide and make available (or provides and makes available) such information.

''(3) GRIEVANCE AND INTERNAL APPEALS.—With respect to the internal appeals process and the grievance system required to be established under sections 102 and 104, in the case of a group health plan that provides benefits in the form of health insurance coverage through a health insurance issuer,

the Secretary shall determine the circumstances under which the plan is not required to provide for such process and system (and is not liable for the issuer's failure to provide for such process and system), if the issuer is obligated to provide for (and provides for) such process and system.

''(4) EXTERNAL APPEALS.—Pursuant to rules of the Secretary, insofar as a group health plan enters into a contract with a qualified external appeal entity for the conduct of external appeal activities in accordance with section 103, the plan shall be treated as meeting the requirement of such section and is not liable for the entity's failure to meet any requirements under such section.

''(5) APPLICATION TO PROHIBITIONS.—Pursuant to rules of the Secretary, if a health insurance issuer offers health insurance coverage in connection with a group health plan and takes an action in violation of any of the following sections, the group health plan shall not be liable for such violation unless the plan caused such violation:

''(A) Section 131 (relating to prohibition of interference with certain medical communications).

''(B) Section 132 (relating to prohibition of discrimination against providers based on licensure).

''(C) Section 133 (relating to prohibition against improper incentive arrangements).

''(D) Section 135 (relating to protection for patient advocacy).

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

''(7) APPLICATION TO CERTAIN PROHIBITIONS AGAINST RETALIATION.—With respect to compliance with the requirements of section 135(b)(1) of the Patients' Bill of Rights Act, for purposes of this subtitle the term 'group health plan' is deemed to include a reference to an institutional health care provider.

''(c) ENFORCEMENT OF CERTAIN REQUIREMENTS.—

''(1) COMPLAINTS.—Any protected health care professional who believes that the professional has been retaliated or discriminated against in violation of section 135(b)(1) of the Patients' Bill of Rights 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 may issue regulations to coordinate the requirements on group health plans under this section with the requirements imposed under the other provisions of this title.''.

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

''(b) In the case of a group health plan (as defined in section 733) compliance with the requirements of subtitle A of title I of the Patients Bill of Rights Act in the case of a claims denial shall be deemed compliance with subsection (a) with respect to such claims denial.''.

(c) CONFORMING AMENDMENTS.—(1) Section 732(a) of such Act (29 U.S.C. 1185(a)) is amended by striking ''section 711'' and inserting ''sections 711 and 714''.

(2) The table of contents in section 1 of such Act is amended by inserting after the item relating to section 713 the following new item:

''Sec. 714. Patient protection standards.''.

(3) Section 502(b)(3) of such Act (29 U.S.C. 1132(b)(3)) is amended by inserting ''(other than section 135(b))'' after ''part 7''.

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

(a) IN GENERAL.—Section 514 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1144) (as amended by section 301(b)) is amended further by adding at the end the following subsections:

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

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

''(A) IN GENERAL.—Except as provided in this subsection, nothing in this title shall be construed to invalidate, impair, or supersede any cause of action by a participant or bene-

ficiary (or the estate of a participant or beneficiary) under State law to recover damages resulting from personal injury or for wrongful death against any person—

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

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

"(B) LIMITATION ON PUNITIVE DAMAGES.—

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

"(I) it relates to an externally appealable decision (as defined in subsection (a)(2) of section 103 of the Patients' Bill of Rights Act);

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

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

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

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

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

''(C) PERSONAL INJURY DEFINED.—For purposes of this subsection, the term 'personal injury' means a physical injury and includes an injury arising out of the treatment (or failure to treat) a mental illness or disease.

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

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

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

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

''(B) SPECIAL RULE.—Subparagraph (A) shall not preclude any cause of action described in paragraph (1) against group health plan or an employer or other plan sponsor (or against

an employee of such a plan, employer, or sponsor acting within the scope of employment) if—

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

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

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

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

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

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

"(3) FUTILITY OF EXHAUSTION.—An individual bringing an action under this subsection is required to exhaust administrative processes under sections

102 and 103 of the Patients' Bill of Rights Act, unless the injury to or death of such individual has occurred before the completion of such processes.

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

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

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

"(C) permitting a cause of action or remedy under State law in connection with the provision or arrangement of excepted benefits (as defined in section 733(c)), other than those described in section 733(c)(2)(A).

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

"(1) permitting the application of State laws that are otherwise superseded by this title and that mandate the provision of specific benefits by a group health plan (as defined in section 733(a)) or a mul-

tiple employer welfare arrangement (as defined in section 3(40)), or

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

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

SEC. 303. LIMITATIONS ON ACTIONS.

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

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

''(2) An action may be brought under subsection (a)(1)(B), (a)(2), or (a)(3) by a participant or beneficiary seeking relief based on the application of section 101, 113, 114, 115, 116, 117, 119, or 118(3) of the Patients' Bill of Rights 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) Nothing in this subsection shall be construed as affecting any action brought by the Secretary.''.

TITLE IV—APPLICATION TO GROUP HEALTH PLANS UNDER THE INTERNAL REVENUE CODE OF 1986

SEC. 401. AMENDMENTS TO THE INTERNAL REVENUE CODE OF 1986.

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

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

''Sec. 9813. Standard relating to patient freedom of choice.'';

and

(2) by inserting after section 9812 the following:

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

"A group health plan shall comply with the requirements of title I of the Patients' Bill of Rights 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 section.".

TITLE V—EFFECTIVE DATES; COORDINATION IN IMPLEMENTATION

SEC. 501. EFFECTIVE DATES.

(a) GROUP HEALTH COVERAGE.—

(1) IN GENERAL.—Subject to paragraph (2), the amendments made by sections 201(a), 301, 303, and 401 (and title I insofar as it relates to such sections) shall apply with respect to group health plans, and health insurance coverage offered in connection with group health plans, for plan years beginning on or after January 1, 2002 (in this section referred to as the "general effective date") and also shall apply to portions of plan years occurring on and after such date.

(2) TREATMENT OF COLLECTIVE BARGAINING AGREEMENTS.—In the case of a group health plan maintained pursuant to 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), 301, 303, and 401 (and title I insofar as it relates to such sections) shall not apply to plan years beginning before the later of—

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

(B) the general effective date.

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

(b) INDIVIDUAL HEALTH INSURANCE COVERAGE.—The amendments made by section 202 shall apply with respect to individual health insurance coverage offered,

sold, issued, renewed, in effect, or operated in the individual market on or after the general effective date.

SEC. 502. COORDINATION IN IMPLEMENTATION.

The Secretary of Labor, the Secretary of Health and Human Services, and the Secretary of the Treasury shall ensure, through the execution of an interagency memorandum of understanding among such Secretaries, that—

(1) regulations, rulings, and interpretations issued by such Secretaries relating to the same matter over which such Secretaries have responsibility under the provisions of this Act (and the amendments made thereby) are administered so as to have the same effect at all times; and

(2) coordination of policies relating to enforcing the same requirements through such Secretaries in order to have a coordinated enforcement strategy that avoids duplication of enforcement efforts and assigns priorities in enforcement.

TITLE VI—MISCELLANEOUS PROVISIONS

SEC. 601. HEALTH CARE PAPERWORK SIMPLIFICATION.

(a) ESTABLISHMENT OF PANEL.—

(1) ESTABLISHMENT.—There is established a panel to be known as the Health Care Panel to De-

vise a Uniform Explanation of Benefits (in this section referred to as the ''Panel'').

(2) DUTIES OF PANEL.—

(A) IN GENERAL.—The Panel shall devise a single form for use by third-party health care payers for the remittance of claims to providers.

(B) DEFINITION.—For purposes of this section, the term ''third-party health care payer'' means any entity that contractually pays health care bills for an individual.

(3) MEMBERSHIP.—

(A) SIZE AND COMPOSITION.—The Secretary of Health and Human Services shall determine the number of members and the composition of the Panel. Such Panel shall include equal numbers of representatives of private insurance organizations, consumer groups, State insurance commissioners, State medical societies, State hospital associations, and State medical specialty societies.

(B) TERMS OF APPOINTMENT.—The members of the Panel shall serve for the life of the Panel.

(C) VACANCIES.—A vacancy in the Panel shall not affect the power of the remaining

members to execute the duties of the Panel, but any such vacancy shall be filled in the same manner in which the original appointment was made.

(4) PROCEDURES.—

(A) MEETINGS.—The Panel shall meet at the call of a majority of its members.

(B) FIRST MEETING.—The Panel shall convene not later than 60 days after the date of the enactment of the Patients' Bill of Rights Act.

(C) QUORUM.—A quorum shall consist of a majority of the members of the Panel.

(D) HEARINGS.—For the purpose of carrying out its duties, the Panel may hold such hearings and undertake such other activities as the Panel determines to be necessary to carry out its duties.

(5) ADMINISTRATION.—

(A) COMPENSATION.—Except as provided in subparagraph (B), members of the Panel shall receive no additional pay, allowances, or benefits by reason of their service on the Panel.

(B) TRAVEL EXPENSES AND PER DIEM.—Each member of the Panel who is not an officer

or employee of the Federal Government shall receive travel expenses and per diem in lieu of subsistence in accordance with sections 5702 and 5703 of title 5, United States Code.

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

(D) USE OF MAILS.—The Panel may use the United States mails in the same manner and under the same conditions as Federal agencies and shall, for purposes of the frank, be considered a commission of Congress as described in section 3215 of title 39, United States Code.

(E) ADMINISTRATIVE SUPPORT SERVICES.—Upon the request of the Panel, the Secretary of Health and Human Services shall provide to the Panel on a reimbursable basis such administrative support services as the Panel may request.

(6) SUBMISSION OF FORM.—Not later than 2 years after the first meeting, the Panel shall submit

a form to the Secretary of Health and Human Services for use by third-party health care payers.

(7) TERMINATION.—The Panel shall terminate on the day after submitting the form under paragraph (6).

(b) REQUIREMENT FOR USE OF FORM BY THIRD-PARTY CARE PAYERS.—A third-party health care payer shall be required to use the form devised under subsection (a) for plan years beginning on or after 5 years following the date of the enactment of this Act.

SEC. 602. NO IMPACT ON SOCIAL SECURITY TRUST FUND.

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

(b) TRANSFERS.—

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

(2) TRANSFER OF FUNDS.—If, under paragraph (1), the Secretary of the Treasury estimates that the enactment of this Act has a negative impact

on the income and balances of the trust funds 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.

○