AMENDMENT IN THE NATURE OF A SUBSTITUTE TO H.R. 2327 OFFERED BY MR BOEHNER OF OHIO

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE AND TABLE OF CONTENTS.

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

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

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

Subtitle A—Patient Protections

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

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

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

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

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

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

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

clinical nurse specialist, certified registered nurse anesthetist, and certified nurse-midwife), licensed certified social worker, registered respiratory therapist, and certified respiratory therapy technician.

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

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

''(1) COVERAGE OF EMERGENCY SERVICES.—

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

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

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

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

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

''(B) DEFINITIONS.—In this subsection:

''(i) EMERGENCY MEDICAL CONDITION.—The term 'emergency medical condition' means—

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

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

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

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

''(I) with respect to an emergency medical condition described in clause (i)(I), a medical screening examination (as required under section

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

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

''(iii) EMERGENCY AMBULANCE SERVICES.—The term 'emergency ambulance

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

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

occur during the transfer of the individual from a facility.

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

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

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

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

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

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

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

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

''(B) requires or provides for designation by a participant or beneficiary of a participating primary care provider,

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

''(2) REQUIREMENTS.—A group health plan (or a health insurance issuer offering health insurance coverage in connection with the plan) meets the requirements of this paragraph, in connection with

benefits described in paragraph (1) consisting of care described in clause (i) or (ii) of paragraph (1)(A) (or consisting of payment therefor), if the plan (or issuer)—

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

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

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

''(4) CONSTRUCTION.—Nothing in paragraph (1) shall be construed as preventing a plan from offering (but not requiring a participant or beneficiary

to accept) a health care professional trained, credentialed, and operating within the scope of their licensure to perform obstetric and gynecological health care services. Nothing in paragraph (2)(B) shall waive any requirements of coverage relating to medical necessity or appropriateness with respect to coverage of gynecological or obstetric care so ordered.

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

''(d) PATIENT RIGHT TO PEDIATRIC CARE.—

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

available, by a parent or guardian of any beneficiary under the plan is who under 18 years of age, as the primary care provider with respect to any such benefits.

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

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

''(4) TREATMENT OF MULTIPLE COVERAGE OPTIONS.—In the case of a plan providing benefits under two or more coverage options, the require-

ments of this subsection shall apply separately with respect to each coverage option.

''(e) CONTINUITY OF CARE.—

''(1) IN GENERAL.—

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

''(i) notify the individual on a timely basis of such termination and of the right to elect continuation of coverage of treat-

ment by the provider under this subsection; and

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

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

''(C) TERMINATION DEFINED.—For purposes of this subsection, the term 'terminated'

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

''(2) TRANSITIONAL PERIOD.—

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

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

''(C) PREGNANCY.—If—

''(i) a participant or beneficiary was determined to be pregnant at the time of

a provider's termination of participation, and

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

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

''(D) TERMINAL ILLNESS.—If—

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

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

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

''(3) PERMISSIBLE TERMS AND CONDITIONS.—A group health plan or health insurance issuer may

condition coverage of continued treatment by a provider under paragraph (1)(A)(i) upon the individual notifying the plan of the election of continued coverage and upon the provider agreeing to the following terms and conditions:

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

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

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

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

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

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

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

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

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

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

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

''(1) COVERAGE.—

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

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

''(ii) subject to paragraphs (2), (3), and (4), may not deny (or limit or impose additional conditions on) the coverage of

routine patient costs for items and services furnished in connection with participation in the trial; and

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

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

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

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

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

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

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

''(B) Either—

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

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

''(3) PAYMENT.—

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

''(B) ROUTINE PATIENT CARE COSTS.—

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

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

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

''(ii) EXCLUSION.—For purposes of this paragraph, 'routine patient care costs'

shall not include the costs associated with the provision of—

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

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

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

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

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

''(4) APPROVED CLINICAL TRIAL DEFINED.—

''(A) IN GENERAL.—For purposes of this subsection, the term 'approved clinical trial'

means a cancer clinical research study or cancer clinical investigation approved by an Institutional Review Board.

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

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

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

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

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

''(A) IN GENERAL.—For purposes of this subsection, insofar as a group health plan provides benefits in the form of health insurance

coverage through a health insurance issuer, the plan shall be treated as meeting the requirements of this subsection with respect to such benefits and not be considered as failing to meet such requirements because of a failure of the issuer to meet such requirements so long as the plan sponsor or its representatives did not cause such failure by the issuer.

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

''(7) STUDY AND REPORT.—

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

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

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

''(iii) research outcomes;

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

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

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

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

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

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

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

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

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

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

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

''(iv) recommendations regarding action on other diseases.''.

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

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

SEC. 102. REQUIRED DISCLOSURE TO NETWORK PROVIDERS.

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

''SEC. 715. REQUIRED DISCLOSURE TO NETWORK PROVIDERS.

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

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

''(2) The existence of any substantial benefit differentials established for the purpose of actively

encouraging participants or beneficiaries under the plan to utilize the providers in that network.

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

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

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

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

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

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

''(2) among health care providers.

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

''(1) BENEFIT DIFFERENTIAL.—The term 'benefit differential' means, with respect to a group

health plan, differences in the case of any participant or beneficiary, in the financial responsibility for payment of coinsurance, copayments, deductibles, balance billing requirements, or any other charge, based upon whether a health care provider from whom covered items or services are obtained is a network provider.

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

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

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

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

''Sec. 715. Required disclosure to network providers.''.

SEC. 103. EFFECTIVE DATE AND RELATED RULES.

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

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

(c) SPECIAL RULE FOR COLLECTIVE BARGAINING AGREEMENTS.—In the case of a group health plan maintained pursuant to one or more collective bargaining agreements between employee representatives and one or

more employers ratified before the date of the enactment of this Act, the amendments made by this subtitle shall not apply with respect to plan years beginning before the later of—

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

(2) January 1, 2002.

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

Subtitle B—Patient Access to Information

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

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

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

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

''DISCLOSURE BY GROUP HEALTH PLANS

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

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

''(1) COVERED ITEMS AND SERVICES.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

''(1) descriptions thereof relating specifically to—

''(A) coverage decisions;

''(B) internal review of coverage decisions; and

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

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

''(e) INFORMATION ON PLAN PERFORMANCE.—Any information required under subsection (a) shall include information concerning the number of external reviews under section 503 that have been completed during the prior plan year and the number of such reviews in which

a recommendation is made for modification or reversal of an internal review decision under the plan.

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

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

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

''(g) INFORMATION AVAILABLE ON REQUEST.—

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

''(A) IN GENERAL.—In addition to the information required to be provided under section

104(b)(4), a group health plan may, upon written request (made not more frequently than annually), make available to participants and beneficiaries, in a generally recognized electronic format—

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

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

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

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

readily accessible to participants and beneficiaries.

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

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

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

''(i) CARE MANAGEMENT INFORMATION.—A description of the circumstances under which, and the extent to which, the plan has special disease management programs or programs for persons with disabilities, indicating whether these programs are voluntary or mandatory and

whether a significant benefit differential results from participation in such programs.

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

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

''(iv) QUALITY PERFORMANCE MEASURES.—The latest information (if any) maintained by the plan relating to quality of performance of the delivery of medical care with respect to coverage options of-

fered under the plan and of health care professionals and facilities providing medical care under the plan.

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

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

''(ii) COST OF PROCEDURES.—Any health care professional who recommends an elective procedure or treatment while

treating a participant or beneficiary under a group health plan that requires a participant or beneficiary to share in the cost of treatment shall inform such participant or beneficiary of each cost associated with the procedure or treatment and an estimate of the magnitude of such costs.

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

''(h) ACCESS TO INFORMATION RELEVANT TO THE COVERAGE OPTIONS UNDER WHICH THE PARTICIPANT OR BENEFICIARY IS ELIGIBLE TO ENROLL.—In addition to information otherwise required to be made available under this section, a group health plan shall, upon written request (made not more frequently than annually), make available to a participant (and an employee who, under the terms of the plan, is eligible for coverage but not en-

rolled) in connection with a period of enrollment the summary plan description for any coverage option under the plan under which the participant is eligible to enroll and any information described in clauses (i), (ii), (iii), (vi), (vii), and (viii) of subsection (e)(2)(B).

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

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

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

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

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

''(j) DEFINITIONS AND RELATED RULES.—

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

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

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

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

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

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

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

''(B) INCLUDED GROUP HEALTH PLAN BENEFIT.—For purposes of subparagraph (A),

the term 'included group health plan benefit' means a benefit which is not an excepted benefit (as defined in section 733(c)).''.

(b) CONFORMING AMENDMENTS.—

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

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

''Sec. 111. Disclosure by group health plans.
''Sec. 112. Repeal and effective date.''.

SEC. 112. EFFECTIVE DATE AND RELATED RULES.

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

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

Subtitle C—Group Health Plan Review Standards

SEC. 121. SPECIAL RULES FOR GROUP HEALTH PLANS.

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

(1) by inserting ''(a) IN GENERAL.—'' after ''SEC. 503.'';

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

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

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

''(b) SPECIAL RULES FOR GROUP HEALTH PLANS.—

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

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

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

''(C) afford a reasonable opportunity to any participant or beneficiary who is in receipt of the notice of such adverse coverage decision, and who files a written request for review of the initial coverage decision within 90 days after receipt of the notice of the initial decision, for a

full and fair review of the decision by an appropriate named fiduciary who did not make the initial decision; and

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

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

''(A) TIME LIMITS FOR DECIDING REQUESTS FOR BENEFIT PAYMENTS, REQUESTS FOR ADVANCE DETERMINATION OF COVERAGE, AND REQUESTS FOR REQUIRED DETERMINATION OF MEDICAL NECESSITY.—Except as provided in subparagraph (B)—

''(i) INITIAL DECISIONS.—If a request for benefit payments, a request for advance determination of coverage, or a request for required determination of medical necessity is submitted to a group health plan in such reasonable form as may be required under the plan, the plan shall issue in writing an initial coverage decision on the request before the end of the initial decision period under paragraph (10)(I) following the fil-

ing completion date. Failure to issue a coverage decision on such a request before the end of the period required under this clause shall be treated as an adverse coverage decision for purposes of internal review under clause (ii).

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

clause shall be treated as a final decision affirming the initial coverage decision.

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

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

''(ii) INTERNAL REVIEWS OF INITIAL DENIALS.—Upon the written request of a participant or beneficiary for review of an

initial adverse coverage decision under clause (i), a review by an appropriate named fiduciary (subject to paragraph (3)) of the initial coverage decision shall be completed, including issuance by the plan of a written decision affirming, reversing, or modifying the initial converge decision, setting forth the grounds for the decision before the end of the accelerated need decision period under paragraph (10)(K) following the review filing date. Such decision shall be treated as the final decision of the plan, subject to any applicable reconsideration under paragraph (4). Failure to issue before the end of the applicable decision period such a written decision requested under this clause shall be treated as a final decision affirming the initial coverage decision.

''(3) PHYSICIANS MUST REVIEW INITIAL COVERAGE DECISIONS INVOLVING MEDICAL APPROPRIATENESS OR NECESSITY OR INVESTIGATIONAL ITEMS OR EXPERIMENTAL TREATMENT.—If an initial coverage decision under paragraph (2)(A)(i) or (2)(B)(i) is based on a determination that provision

of a particular item or service is excluded from coverage under the terms of the plan because the provision of such item or service does not meet the requirements for medical appropriateness or necessity or would constitute provision of investigational items or experimental treatment or technology, the review under paragraph (2)(A)(ii) or (2)(B)(ii), to the extent that it relates to medical appropriateness or necessity or to investigational items or experimental treatment or technology, shall be conducted by a physician who is selected by the plan and who did not make the initial denial.

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

''(A) IN GENERAL.—In any case in which a participant or beneficiary, who has received an adverse coverage decision which is not reversed upon review conducted pursuant to paragraph (1)(C) (including review under paragraph (2)(A)(ii) or (2)(B)(ii)) and who has not commenced review of the coverage decision under section 502, makes a request in writing, within 30 days after the date of such review decision, for reconsideration of such review decision, the

requirements of subparagraphs (B), (C), (D) and (E) shall apply in the case of such adverse coverage decision, if the requirements of clause (i) or (ii) are met, subject to clause (iii).

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

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

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

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

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

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

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

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

''(I) a determination of eligibility for benefits,

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

''(III) a limitation on the amount of any benefit payment or a require-

ment to make copayments under the terms of the plan.

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

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

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

''(ii) $25,

with such dollar amount subject to compounded annual adjustments in the same manner and to the same extent as apply under section 215(i) of the Social Security Act, except that, for any calendar year, such amount as so adjusted shall be deemed, solely for such calendar year, to be equal to such amount rounded to the nearest

$10. No such payment may be required in the case of any participant or beneficiary whose enrollment under the plan is paid for, in whole or in part, under a State plan under title XIX or XXI of the Social Security Act. Any such advance payment shall be subject to reimbursement if the recommendation of the independent medical expert (or panel of such experts) under subparagraph (D)(ii)(IV) is to reverse or modify the coverage decision.

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

''(i) IN GENERAL.—In the case of a request for review made by a participant or beneficiary as described in subparagraph (A), if the requirements of subparagraph (A)(ii) are met (and review is not otherwise precluded under subparagraph (A)(iii)), the terms of the plan shall provide for a procedure for initial review by an independent contract expert selected in accordance with subparagraph (H) under

which the expert will determine whether the coverage decision requires the evaluation of medical facts or evidence by a health professional. If the expert determines that the coverage decision requires such evaluation, reconsideration of such adverse decision shall proceed under this paragraph. If the expert determines that the coverage decision does not require such evaluation, the adverse decision shall remain the final decision of the plan.

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

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

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

''(III) who is selected in accordance with subparagraph (H)(i) and

meets the requirements of subparagraph (H)(iii).

''(D) RECONSIDERATION OF INITIAL REVIEW DECISION.—

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

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

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

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

''(III) Such expert (or panel) will reconsider the initial review decision to determine whether such decision was in accordance with the terms of the plan and this title. The expert (or panel) in its reconsideration will take into account the medical condition of the patient, the recommendation of the treating physician, the initial coverage decision (including the reasons for such decision) and the decision upon review conducted pursuant to paragraph (1)(C) (including review under paragraph (2)(A)(ii) or (2)(B)(ii)) , any guidelines adopted by the plan through a process involving medical practitioners and peer-re-

viewed medical literature identified as such under criteria established by the Food and Drug Administration, and any other valid, relevant, scientific or clinical evidence the expert (or panel) determines appropriate for its review. The expert (or panel) may consult the participant or beneficiary, the treating physician, the medical director of the plan, or any other party who, in the opinion of the expert (or panel), may have relevant information for consideration.

''(E) ISSUANCE OF BINDING FINAL DECISION.—Upon completion of the procedure for review under subparagraph (D), the independent medical expert (or panel of such experts) shall issue a written decision affirming, modifying, or reversing the initial review decision, setting forth the grounds for the decision. Such decision shall be the final decision of the plan and shall be binding on the plan. Such decision shall set forth specifically the determination of the expert (or panel) of the appro-

priate period for timely compliance by the plan with the decision. Such decision shall be issued concurrently to the participant or beneficiary, to the treating physician, and to the plan, shall constitute conclusive, written authorization for the provision of benefits under the plan in accordance with the decision, and shall be treated as terms of the plan for purposes of any action by the participant or beneficiary under section 502.

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

''(G) INDEPENDENT MEDICAL EXPERTS.—

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

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

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

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

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

''(V) who is selected in accordance with subparagraph (H)(i) and

meets the requirements of subparagraph (H)(iii).

''(H) SELECTION OF EXPERTS.—

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

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

''(II) the expert is selected by an appropriately credentialed panel of

physicians meeting the requirements of clauses (ii) and (iii) established by a fully accredited teaching hospital meeting such requirements;

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

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

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

''(VI) the expert is selected, by an intermediary or otherwise, in a manner that is, under regulations issued pursuant to negotiated rule-

making, sufficient to ensure the expert's independence, and the method of selection is devised to reasonably ensure that the expert selected meets the requirements of clauses (ii) and (iii).

''(ii) STANDARDS OF PERFORMANCE FOR INTERMEDIARIES.—The Secretary shall prescribe by regulation standards (in addition to the requirements of clause (iii)) which entities making selections under subclause (I), (II), (III), (IV), (V), or (VI) of clause (ii) must meet in order to be eligible for making such selections. Such standards shall include (but are not limited to)—

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

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

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

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

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

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

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

''(III) under the terms of the plan and any health insurance coverage offered in connection with the

plan, the plan and the issuer (if any) have no recourse against the expert or entity in connection with the external review; and

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

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

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

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

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

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

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

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

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

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

''(ii) demonstrates failure to adhere to the standards for selection set forth in subparagraph (H)(iii),

shall be treated as a failure to meet the requirements of this paragraph and therefore as a cause of action which may be brought by a fiduciary under section 502(a)(3).

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

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

''(A) IN GENERAL.—In accordance with such regulations (if any) as may be prescribed by the Secretary for purposes of this paragraph, in the case of any initial coverage decision or any decision upon review thereof under paragraph (2)(A)(ii) or (2)(B)(ii), a group health plan may provide an alternative dispute resolution procedure meeting the requirements of subparagraph (B) for use in lieu of the procedures set forth under the preceding provisions of this subsection relating review of such decision. Such procedure may be provided in one form

for all participants and beneficiaries or in a different form for each group of similarly situated participants and beneficiaries. Upon voluntary election of such procedure by the plan and by the aggrieved participant or beneficiary in connection with the decision, the plan may provide under such procedure (in a manner consistent with such regulations as the Secretary may prescribe to ensure equitable procedures) for waiver of the review of the decision under paragraph (3) or waiver of further review of the decision under paragraph (4) or section 502 or for election by such parties of an alternative means of external review (other than review under paragraph (4)).

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

''(i) such procedure is utilized solely—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

''(B) REQUIRED DETERMINATION OF MEDICAL NECESSITY.—The term 'required determination of medical necessity' means a determination required under a group health plan solely that proposed medical care meets, under the facts and circumstances at the time of the determination, the requirements for medical appropriateness or necessity (which may be subject to exceptions under the plan for fraud or misrepresentation), irrespective of whether the proposed medical care otherwise meets other terms and conditions of coverage, but only if such determination does not constitute an advance determination of coverage (as defined in subparagraph (C)).

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

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

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

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

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

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

''(i) that failure to immediately provide the care to the participant or bene-

ficiary could reasonably be expected to result in—

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

''(II) serious impairment to bodily functions; or

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

''(ii) that immediate provision of the care is necessary because the participant or beneficiary has made or is at serious risk of making an attempt to harm himself or herself or another individual.

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

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

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

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

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

''(N) REVIEW FILING DATE.—The term 'review filing date' means, in connection with a group health plan, the date as of which the appropriate named fiduciary (or the independent medical expert or panel of such experts in the case of a review under paragraph (4)) is in re-

ceipt of all information reasonably required (in writing or in such other reasonable form as may be specified by the plan) to make a decision to affirm, modify, or reverse a coverage decision.

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

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

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

''(R) WRITTEN OR IN WRITING.—

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

''(ii) MEDICAL APPROPRIATENESS OR INVESTIGATIONAL ITEMS OR EXPERIMENTAL TREATMENT DETERMINATIONS.—For purposes of this subparagraph, in the case of a request for advance determination of coverage, a request for expedited advance determination of coverage, a request for required determination of medical necessity, or a request for expedited required determination of medical necessity, if the decision on such request is conveyed to the provider of medical care or to the participant or beneficiary by means of telephonic or other electronic communications, such decision shall be treated as a written decision.

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

(b) CIVIL PENALTIES.—

(1) IN GENERAL.—Section 502(c) of such Act (29 U.S.C. 1132(c)) is amended by redesignating paragraphs (6) and (7) as paragraphs (7) and (8),

respectively, and by inserting after paragraph (5) the following new paragraph:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

''(II) $100,000.

''(iii) Any person acting in the capacity of a fiduciary of a group health plan or plans who has engaged in any such pattern or practice in connection with included group health plan benefits, upon the petition of the Secretary, may be removed by the court from that position, and from

any other involvement, with respect to such plan or plans, and may be precluded from returning to any such position or involvement for a period determined by the court.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

''(B) SPECIALIST.—For purposes of this paragraph, the term 'specialist' means, with respect to a condition, a physician who has a high level of expertise through appropriate training

and experience (including, in the case of a patient who is a child, appropriate pediatric expertise) to treat the condition.''.

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

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

(1) Peer review.

(2) Utilization review.

(3) Quality management or improvement.

(4) Quality control.

(5) Risk management.

(6) Internal review for purposes of reducing mortality, morbidity, or for improving patient care or safety.

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

(1) the development of such information in connection with a request or requirement of an accrediting body; or

(2) the transfer of such information to an accrediting body.

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

(1) The term ''accrediting body'' means a national, not-for-profit organization that—

(A) accredits health care providers; and

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

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

(3) The term ''health care response information'' means information (including any data, report, record, memorandum, analysis, statement, or other

communication) developed by, or on behalf of, a health care provider in response to a serious, adverse, patient-related event—

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

(B) for purposes of—

(i) reducing mortality or morbidity; or

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

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

SEC. 124. EFFECTIVE DATE.

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

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

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

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

SEC. 131. ESTABLISHMENT OF COMMISSION.

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

''SEC. 518. HEALTH POLICY COMMISSION.

''(a) ESTABLISHMENT.—There is hereby established a commission to be known as the Health Care Access, Affordability, and Quality Commission (hereinafter in this Act referred to as the ''Commission'').

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

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

''(A) Independent expert external review programs.

''(B) Consumer friendly information programs.

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

''(i) health plan enrollees' attitudes based on surveys;

''(ii) outcomes measurements; and

''(iii) accreditation by private organizations.

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

''(2) ESTABLISHMENT OF FORM FOR REMITTANCE OF CLAIMS TO PROVIDERS.—Not later than 2 years after the date of the first meeting of the Commission, the Commission shall develop and

transmit to the Secretary a proposed form for use by health insurance issuers (as defined in section 733(b)(2)) for the remittance of claims to health care providers. Effective for plan years beginning after 5 years after the date of the Comprehensive Access and Responsibility in Health Care Act of 1999, a health insurance issuer offering health insurance coverage in connection with a group health plan shall use such form for the remittance of all claims to providers.

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

''(4) COMMENTS ON CERTAIN SECRETARIAL REPORTS.—If the Secretary submits to Congress (or a committee of Congress) a report that is required by law and that relates to policies under this section, the Secretary shall transmit a copy of the report to the Commission. The Commission shall review the report and, not later than 6 months after the date

of submittal of the Secretary's report to Congress, shall submit to the appropriate committees of Congress written comments on such report. Such comments may include such recommendations as the Commission deems appropriate.

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

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

''(c) MEMBERSHIP.—

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

''(2) QUALIFICATIONS.—

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

''(i) physicians and other health professionals;

''(ii) representatives of employers, including multiemployer plans;

''(ii) representatives of insured employees;

''(iv) third-party payers; and

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

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

''(3) TERMS.—

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

''(B) VACANCIES.—Any member appointed to fill a vacancy occurring before the expiration

of the term for which the member's predecessor was appointed shall be appointed only for the remainder of that term. A member may serve after the expiration of that member's term until a successor has taken office. A vacancy in the Commission shall be filled in the manner in which the original appointment was made.

''(4) BASIC PAY.—

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

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

''(5) TRAVEL EXPENSES.—Each member shall receive travel expenses, including per diem in lieu of

subsistence, in accordance with sections 5702 and 5703 of title 5, United States Code.

''(6) CHAIRPERSON.—The Chairperson of the Commission shall be designated by the Comptroller at the time of the appointment. The term of office of the Chairperson shall be 3 years.

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

''(d) DIRECTOR AND STAFF OF COMMISSION.—

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

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

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

''(e) POWERS OF COMMISSION.—

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

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

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

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

''(5) ADMINISTRATIVE SUPPORT SERVICES.—Upon the request of the Commission, the Administrator of General Services shall provide to the Com-

mission, on a reimbursable basis, the administrative support services necessary for the Commission to carry out its responsibilities under this Act.

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

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

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

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

''(g) DEFINITION OF APPROPRIATE COMMITTEES OF CONGRESS.—For purposes of this section the term 'appropriate committees of Congress' means any committee in

the Senate or House of Representatives having jurisdiction over the Employee Retirement Income Security Act of 1974.

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

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

SEC. 132. EFFECTIVE DATE.

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

TITLE II—AMENDMENTS TO THE PUBLIC HEALTH SERVICE ACT

Subtitle A—Patient Protections and Point of Service Coverage Requirements

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

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

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

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

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

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

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

clinical nurse specialist, certified registered nurse anesthetist, and certified nurse-midwife), licensed certified social worker, registered respiratory therapist, and certified respiratory therapy technician.

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

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

''(1) COVERAGE OF EMERGENCY SERVICES.—

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

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

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

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

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

''(B) DEFINITIONS.—In this subsection:

''(i) EMERGENCY MEDICAL CONDITION.—The term 'emergency medical condition' means—

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

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

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

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

''(I) with respect to an emergency medical condition described in clause (i)(I), a medical screening examination (as required under section

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

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

''(iii) EMERGENCY AMBULANCE SERVICES.—The term 'emergency ambulance

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

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

occur during the transfer of the individual from a facility.

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

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

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

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

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

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

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

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

''(B) requires or provides for designation by a participant or beneficiary of a participating primary care provider,

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

''(1) REQUIREMENTS.—A group health plan (or a health insurance issuer offering health insurance coverage in connection with the plan) meets the requirements of this paragraph, in connection with

benefits described in paragraph (1) consisting of care described in clause (i) or (ii) of paragraph (1)(A) (or consisting of payment therefor), if the plan (or issuer)—

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

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

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

''(4) CONSTRUCTION.—Nothing in paragraph (1) shall be construed as preventing a plan from offering (but not requiring a participant or beneficiary

to accept) a health care professional trained, credentialed, and operating within the scope of their licensure to perform obstetric and gynecological health care services. Nothing in paragraph (2)(B) shall waive any requirements of coverage relating to medical necessity or appropriateness with respect to coverage of gynecological or obstetric care so ordered.

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

''(d) PATIENT RIGHT TO PEDIATRIC CARE.—

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

available, by a parent or guardian of any beneficiary under the plan is who under 18 years of age, as the primary care provider with respect to any such benefits.

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

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

''(4) TREATMENT OF MULTIPLE COVERAGE OPTIONS.—In the case of a plan providing benefits under two or more coverage options, the require-

ments of this subsection shall apply separately with respect to each coverage option.

''(e) CONTINUITY OF CARE.—

''(1) IN GENERAL.—

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

''(i) notify the individual on a timely basis of such termination and of the right to elect continuation of coverage of treat-

ment by the provider under this subsection; and

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

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

''(C) TERMINATION DEFINED.—For purposes of this subsection, the term 'terminated'

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

''(2) TRANSITIONAL PERIOD.—

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

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

''(C) PREGNANCY.—If—

''(i) a participant or beneficiary was determined to be pregnant at the time of

a provider's termination of participation, and

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

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

''(D) TERMINAL ILLNESS.—If—

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

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

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

''(3) PERMISSIBLE TERMS AND CONDITIONS.—A group health plan or health insurance issuer may

condition coverage of continued treatment by a provider under paragraph (1)(A)(i) upon the individual notifying the plan of the election of continued coverage and upon the provider agreeing to the following terms and conditions:

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

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

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

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

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

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

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

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

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

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

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

''(1) COVERAGE.—

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

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

''(ii) subject to paragraphs (2), (3), and (4), may not deny (or limit or impose additional conditions on) the coverage of

routine patient costs for items and services furnished in connection with participation in the trial; and

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

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

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

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

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

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

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

''(B) Either—

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

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

''(3) PAYMENT.—

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

''(B) ROUTINE PATIENT CARE COSTS.—

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

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

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

''(ii) EXCLUSION.—For purposes of this paragraph, 'routine patient care costs'

shall not include the costs associated with the provision of—

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

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

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

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

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

''(4) APPROVED CLINICAL TRIAL DEFINED.—

''(A) IN GENERAL.—For purposes of this subsection, the term 'approved clinical trial'

means a cancer clinical research study or cancer clinical investigation approved by an Institutional Review Board.

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

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

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

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

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

''(A) IN GENERAL.—For purposes of this subsection, insofar as a group health plan provides benefits in the form of health insurance

coverage through a health insurance issuer, the plan shall be treated as meeting the requirements of this subsection with respect to such benefits and not be considered as failing to meet such requirements because of a failure of the issuer to meet such requirements so long as the plan sponsor or its representatives did not cause such failure by the issuer.

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

''(7) STUDY AND REPORT.—

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

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

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

''(iii) research outcomes;

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

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

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

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

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

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

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

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

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

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

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

''(iv) recommendations regarding action on other diseases.''.

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

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

''SEC. 2714. REQUIRING OFFERING OF OPTION OF POINT-OF-SERVICE COVERAGE.

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

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

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

the issuer shall make available to the plan sponsor in connection with such a plan a coverage option which provides for coverage of such services which are furnished through

such class (or classes) of health care professionals regardless of whether or not the professionals are members of such panel.

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

''(c) EXCEPTIONS.—

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

graph shall be applied separately to distinguishable groups of employees under the plan.

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

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

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

''(B) the State requires the organization to receive or qualify for a separate license, as an

indemnity insurer or otherwise, in order to offer such coverage option or supplemental coverage, respectively.

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

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

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

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

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

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

bursed for or provided only within a limited network of such professionals.

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

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

SEC. 203. EFFECTIVE DATE AND RELATED RULES.

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

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

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

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

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

(2) January 1, 2002.

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

Subtitle B—Patient Access to Information

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

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

"SEC. 2708. DISCLOSURE BY GROUP HEALTH PLANS.

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

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

''(1) COVERED ITEMS AND SERVICES.—

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

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

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

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

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

''(D) DRUG FORMULARIES.—A description of the extent to which covered benefits are determined by the use or application of a drug

formulary and a summary of the process for determining what is included in such formulary.

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

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

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

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

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

''(D) CUSTODIAL CARE.—A description of the circumstances under which, and the extent to which, the coverage of benefits for custodial

care is limited or excluded, and a statement of the definition used by the plan for custodial care.

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

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

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

''(H) SPECIALTY CARE.—A description of the circumstances under which, and the extent

to which, coverage of benefits for specialty care is conditioned on referral from a primary care provider.

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

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

''(3) NETWORK CHARACTERISTICS.—If the plan (or issuer) utilizes a defined set of providers under contract with the plan (or issuer), a detailed list of the names of such providers and their geographic lo-

cation, set forth separately with respect to primary care providers and with respect to specialists.

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

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

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

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

''(1) descriptions thereof relating specifically to—

''(A) coverage decisions;

''(B) internal review of coverage decisions; and

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

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

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

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

''(1) PREAUTHORIZATION AND UTILIZATION REVIEW PROCEDURES.—A description of the basis on which any preauthorization requirement or any utili-

zation review requirement has resulted in the adverse coverage decision.

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

''(g) INFORMATION AVAILABLE ON REQUEST.—

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

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

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

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

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

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

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

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

''(B) INFORMATION REQUIRED FROM PLANS AND ISSUERS ON REQUEST.—In addition to information otherwise required to be provided under this subsection, a health insurance issuer offering health insurance coverage in connection with a group health plan shall provide the following information to a participant or beneficiary on request:

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

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

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

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

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

''(i) QUALIFICATIONS, PRIVILEGES, AND METHOD OF COMPENSATION.—Any health care professional treating a participant or beneficiary under a group health plan shall provide to the participant or

beneficiary, on request, a description of his or her professional qualifications (including board certification status, licensing status, and accreditation status, if any), privileges, and experience and a general description by category (including salary, fee-for-service, capitation, and such other categories as may be specified in regulations of the Secretary) of the applicable method by which such professional is compensated in connection with the provision of such medical care.

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

''(D) INFORMATION REQUIRED FROM HEALTH CARE FACILITIES ON REQUEST.—Any health care facility from which a participant or

beneficiary has sought treatment under a group health plan shall provide to the participant or beneficiary, on request, a description of the facility's corporate form or other organizational form and all forms of licensing and accreditation status (if any) assigned to the facility by standard-setting organizations.

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

''(i) ADVANCE NOTICE OF CHANGES IN DRUG FORMULARIES.—Not later than 30 days before the effective of date of any exclusion of a specific drug or biological from any drug formulary under health insurance coverage

offered by a health insurance issuer in connection with a group health plan that is used in the treatment of a chronic illness or disease, the issuer shall take such actions as are necessary to reasonably ensure that plan participants are informed of such exclusion. The requirements of this subsection may be satisfied—

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

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

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

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

''(j) DEFINITIONS AND RELATED RULES.—

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

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

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

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

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

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

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

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

SEC. 212. EFFECTIVE DATE AND RELATED RULES.

(a) IN GENERAL.—The amendments made by section 211 shall apply with respect to plan years beginning on or after January 1 of the second calendar year following the date of the enactment of this Act. The Secretary of

Labor shall first issue all regulations necessary to carry out the amendments made by this title before such date.

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

TITLE III—AMENDMENTS TO THE INTERNAL REVENUE CODE OF 1986

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

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

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

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

(2) by inserting after section 9812 the following:

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

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

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

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

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

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

''(1) COVERAGE OF EMERGENCY SERVICES.—

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

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

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

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

''(iv) without regard to any other term or condition of such plan (other than exclusion or coordination of benefits, or an affiliation or waiting period, permitted

under section 701 and other than applicable cost sharing).

''(B) DEFINITIONS.—In this subsection:

''(i) EMERGENCY MEDICAL CONDITION.—The term 'emergency medical condition' means—

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

''(II) a medical condition manifesting itself in a neonate by acute symptoms of sufficient severity (including severe pain) such that a prudent health care professional could reasonably expect the absence of immediate medical attention to result in

a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act.

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

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

''(II) with respect to an emergency medical condition described in clause (i)(II), medical treatment for

such condition rendered by a health care provider in a hospital to a neonate, including available hospital ancillary services in response to an urgent request of a health care professional and to the extent necessary to stabilize the neonate.

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

serious dysfunction of any bodily organ or part.

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

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

''(vi) PARTICIPATING.—The term 'participating' means, with respect to a health care provider that provides health care items and services to a participant or beneficiary under group health plan, a health care provider that furnishes such

items and services under a contract or other arrangement with the plan.

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

''(1) IN GENERAL.—In any case in which a group health plan—

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

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

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

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

''(B) requires or provides for designation by a participant or beneficiary of a participating primary care provider,

if the primary care provider designated by such a participant or beneficiary is not such a health care professional, then the plan shall meet the requirements of paragraph (2).

''(2) REQUIREMENTS.—A group health plan meets the requirements of this paragraph, in connec-

tion with benefits described in paragraph (1) consisting of care described in clause (i) or (ii) of paragraph (1)(A) (or consisting of payment therefor), if the plan—

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

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

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

''(4) CONSTRUCTION.—Nothing in paragraph (1) shall be construed as preventing a plan from offering (but not requiring a participant or beneficiary

to accept) a health care professional trained, credentialed, and operating within the scope of their licensure to perform obstetric and gynecological health care services. Nothing in paragraph (2)(B) shall waive any requirements of coverage relating to medical necessity or appropriateness with respect to coverage of gynecological or obstetric care so ordered.

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

''(d) PATIENT RIGHT TO PEDIATRIC CARE.—

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

primary care provider with respect to any such benefits.

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

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

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

''(e) CONTINUITY OF CARE.—

''(1) IN GENERAL.—

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

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

''(ii) subject to paragraph (3), permit the individual to elect to continue to be covered with respect to treatment by the

provider for such surgery, pregnancy, or illness during a transitional period (provided under paragraph (2)).

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

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

''(2) TRANSITIONAL PERIOD.—

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

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

''(C) PREGNANCY.—If—

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

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

the transitional period under this paragraph with respect to provider's treatment of the pregnancy shall extend through the provision of

post-partum care directly related to the delivery.

''(D) TERMINAL ILLNESS.—If—

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

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

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

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

''(A) The provider agrees to accept reimbursement from the plan and individual involved (with respect to cost-sharing) at the

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

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

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

''(D) The provider agrees to provide transitional care to all participants and beneficiaries

who are eligible for and elect to have coverage of such care from such provider.

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

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

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

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

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

''(B) prohibit a group health plan from conditioning a provider's participation on the provider's agreement to provide transitional

care to all participants and beneficiaries eligible to obtain coverage of such care furnished by the provider as set forth under this subsection.

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

''(1) COVERAGE.—

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

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

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

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

''(B) EXCLUSION OF CERTAIN COSTS.—For purposes of subparagraph (A)(ii), routine patient costs do not include the cost of the tests

or measurements conducted primarily for the purpose of the clinical trial involved.

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

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

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

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

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

''(B) Either—

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

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

''(3) PAYMENT.—

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

''(B) ROUTINE PATIENT CARE COSTS.—

''(i) IN GENERAL.—For purposes of this paragraph, the term 'routine patient care costs' shall include the costs associ-

ated with the provision of items and services that—

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

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

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

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

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

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

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

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

''(4) APPROVED CLINICAL TRIAL DEFINED.—

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

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

''(i) to be comparable to the system of peer review of studies and investigations

used by the National Institutes of Health, and

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

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

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

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

''(B) CONSTRUCTION.—Nothing in this subsection shall be construed to affect or modify the responsibilities of the fiduciaries of a

group health plan under part 4 of subtitle B of title I of the Employee Retirement Income Security Act of 1974.

''(7) STUDY AND REPORT.—

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

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

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

''(iii) research outcomes;

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

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

''(vi) patient cost sharing or copyament costs realized in different sites of service;

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

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

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

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

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

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

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

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

''(iv) recommendations regarding action on other diseases.''.

SEC. 302. EFFECTIVE DATE AND RELATED RULES.

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

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

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

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

(2) January 1, 2002.

For purposes of this subsection, any plan amendment made pursuant to a collective bargaining agreement relating to the plan which amends the plan solely to conform

to any requirement added by this title shall not be treated as a termination of such collective bargaining agreement.

TITLE IV—HEALTH CARE LAWSUIT REFORM

Subtitle A—General Provisions

SEC. 401. FEDERAL REFORM OF HEALTH CARE LIABILITY ACTIONS.

(a) APPLICABILITY.—This title shall apply with respect to any health care liability action brought in any State or Federal court, except that this title shall not apply to—

(1) an action for damages arising from a vaccine-related injury or death to the extent that title XXI of the Public Health Service Act applies to the action;

(2) an action under the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1001 et seq.); or

(3) an action in connection with benefits which are not included group health plan benefits (as defined in section 402(14)).

(b) PREEMPTION.—This title shall preempt any State law to the extent such law is inconsistent with the limitations contained in this title. This title shall not preempt any State law that provides for defenses or places limita-

tions on a person's liability in addition to those contained in this title or otherwise imposes greater restrictions than those provided in this title.

(c) EFFECT ON SOVEREIGN IMMUNITY AND CHOICE OF LAW OR VENUE.—Nothing in subsection (b) shall be construed to—

(1) waive or affect any defense of sovereign immunity asserted by any State under any provision of law;

(2) waive or affect any defense of sovereign immunity asserted by the United States;

(3) affect the applicability of any provision of the Foreign Sovereign Immunities Act of 1976;

(4) preempt State choice-of-law rules with respect to claims brought by a foreign nation or a citizen of a foreign nation; or

(5) affect the right of any court to transfer venue or to apply the law of a foreign nation or to dismiss a claim of a foreign nation or of a citizen of a foreign nation on the ground of inconvenient forum.

(d) AMOUNT IN CONTROVERSY.—In an action to which this title applies and which is brought under section 1332 of title 28, United States Code, the amount of noneconomic damages or punitive damages, and attorneys'

fees or costs, shall not be included in determining whether the matter in controversy exceeds the sum or value of $50,000.

(e) FEDERAL COURT JURISDICTION NOT ESTABLISHED ON FEDERAL QUESTION GROUNDS.—Nothing in this title shall be construed to establish any jurisdiction in the district courts of the United States over health care liability actions on the basis of section 1331 or 1337 of title 28, United States Code.

SEC. 402. DEFINITIONS.

As used in this title:

(1) ACTUAL DAMAGES.—The term ''actual damages'' means damages awarded to pay for economic loss.

(2) ALTERNATIVE DISPUTE RESOLUTION SYSTEM; ADR.—The term ''alternative dispute resolution system'' or ''ADR'' means a system established under Federal or State law that provides for the resolution of health care liability claims in a manner other than through health care liability actions.

(3) CLAIMANT.—The term ''claimant'' means any person who brings a health care liability action and any person on whose behalf such an action is brought. If such action is brought through or on behalf of an estate, the term includes the claimant's

decedent. If such action is brought through or on behalf of a minor or incompetent, the term includes the claimant's legal guardian.

(4) CLEAR AND CONVINCING EVIDENCE.—The term ''clear and convincing evidence'' is that measure or degree of proof that will produce in the mind of the trier of fact a firm belief or conviction as to the truth of the allegations sought to be established. Such measure or degree of proof is more than that required under preponderance of the evidence but less than that required for proof beyond a reasonable doubt.

(5) COLLATERAL SOURCE PAYMENTS.—The term ''collateral source payments'' means any amount paid or reasonably likely to be paid in the future to or on behalf of a claimant, or any service, product, or other benefit provided or reasonably likely to be provided in the future to or on behalf of a claimant, as a result of an injury or wrongful death, pursuant to—

(A) any State or Federal health, sickness, income-disability, accident or workers' compensation Act;

(B) any health, sickness, income-disability, or accident insurance that provides health benefits or income-disability coverage;

(C) any contract or agreement of any group, organization, partnership, or corporation to provide, pay for, or reimburse the cost of medical, hospital, dental, or income disability benefits; and

(D) any other publicly or privately funded program.

(6) DRUG.—The term ''drug'' has the meaning given such term in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)).

(7) ECONOMIC LOSS.—The term ''economic loss'' means any pecuniary loss resulting from injury (including the loss of earnings or other benefits related to employment, medical expense loss, replacement services loss, loss due to death, burial costs, and loss of business or employment opportunities), to the extent recovery for such loss is allowed under applicable State law.

(8) HARM.—The term ''harm'' means any legally cognizable wrong or injury for which punitive damages may be imposed.

(9) HEALTH BENEFIT PLAN.—The term ''health benefit plan'' means—

(A) a hospital or medical expense incurred policy or certificate;

(B) a hospital or medical service plan contract;

(C) a health maintenance subscriber contract; or

(D) a Medicare+Choice plan (offered under part C of title XVIII of the Social Security Act),

that provides benefits with respect to health care services.

(10) HEALTH CARE LIABILITY ACTION.—The term ''health care liability action'' means a civil action brought in a State or Federal court against—

(A) a health care provider;

(B) an entity which is obligated to provide or pay for health benefits under any health benefit plan (including any person or entity acting under a contract or arrangement to provide or administer any health benefit); or

(C) the manufacturer, distributor, supplier, marketer, promoter, or seller of a medical product,

in which the claimant alleges a claim (including third party claims, cross claims, counter claims, or contribution claims) based upon the provision of (or the failure to provide or pay for) health care services or the use of a medical product, regardless of the theory of liability on which the claim is based or the number of plaintiffs, defendants, or causes of action.

(11) HEALTH CARE LIABILITY CLAIM.—The term ''health care liability claim'' means a claim in which the claimant alleges that injury was caused by the provision of (or the failure to provide) health care services.

(12) HEALTH CARE PROVIDER.—The term ''health care provider'' means any person that is engaged in the delivery of health care services in a State and that is required by the laws or regulations of the State to be licensed or certified by the State to engage in the delivery of such services in the State.

(13) HEALTH CARE SERVICE.—The term ''health care service'' means any service eligible for payment under a health benefit plan, including services related to the delivery or administration of such service.

(14) INCLUDED GROUP HEALTH PLAN BENEFIT.—The term 'included group health plan benefit' means a benefit under a group health plan which is not an excepted benefit (as defined in section 733(c) of the Employee Retirement Income Security Act of 1974).

(15) MEDICAL DEVICE.—The term ''medical device'' has the meaning given such term in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)).

(16) NON-ECONOMIC DAMAGES.—The term ''non-economic damages'' means damages paid to an individual for pain and suffering, inconvenience, emotional distress, mental anguish, loss of consortium, injury to reputation, humiliation, and other nonpecuniary losses.

(17) PERSON.—The term ''person'' means any individual, corporation, company, association, firm, partnership, society, joint stock company, or any other entity, including any governmental entity.

(18) PRODUCT SELLER.—

(A) IN GENERAL.—Subject to subparagraph (B), the term ''product seller'' means a person who, in the course of a business conducted for that purpose—

(i) sells, distributes, rents, leases, prepares, blends, packages, labels, or is otherwise involved in placing, a product in the stream of commerce; or

(ii) installs, repairs, or maintains the harm-causing aspect of a product.

(B) EXCLUSION.—Such term does not include—

(i) a seller or lessor of real property;

(ii) a provider of professional services in any case in which the sale or use of a product is incidental to the transaction and the essence of the transaction is the furnishing of judgment, skill, or services; or

(iii) any person who—

(I) acts in only a financial capacity with respect to the sale of a product; or

(II) leases a product under a lease arrangement in which the selection, possession, maintenance, and operation of the product are controlled by a person other than the lessor.

(19) PUNITIVE DAMAGES.—The term ''punitive damages'' means damages awarded against any per-

son not to compensate for actual injury suffered, but to punish or deter such person or others from engaging in similar behavior in the future.

(20) STATE.—The term ''State'' means each of the several States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, and any other territory or possession of the United States.

SEC. 403. EFFECTIVE DATE.

This title will apply to—

(1) any health care liability action brought in a Federal or State court; and

(2) any health care liability claim subject to an alternative dispute resolution system,

that is initiated on or after the date of enactment of this title, except that any health care liability claim or action arising from an injury occurring before the date of enactment of this title shall be governed by the applicable statute of limitations provisions in effect at the time the injury occurred.

Subtitle B—Uniform Standards for Health Care Liability Actions

SEC. 411. STATUTE OF LIMITATIONS.

A health care liability action may not be brought after the expiration of the 2-year period that begins on

the date on which the alleged injury that is the subject of the action was discovered or should reasonably have been discovered, but in no case after the expiration of the 5-year period that begins on the date the alleged injury occurred.

SEC. 412. CALCULATION AND PAYMENT OF DAMAGES.

(a) TREATMENT OF NON-ECONOMIC DAMAGES.—

(1) LIMITATION ON NON-ECONOMIC DAMAGES.—The total amount of non-economic damages that may be awarded to a claimant for losses resulting from the injury which is the subject of a health care liability action may not exceed $250,000, regardless of the number of parties against whom the action is brought or the number of actions brought with respect to the injury. The limitation under this paragraph shall not apply to an action for damages based solely on intentional denial of medical treatment necessary to preserve a patient's life that the patient is otherwise qualified to receive, against the wishes of a patient, or if the patient is incompetent, against the wishes of the patient's guardian, on the basis of the patient's present or predicated age, disability, degree of medical dependency, or quality of life.

(2) LIMIT.—If, after the date of the enactment of this Act, a State enacts a law which prescribes the amount of non-economic damages which may be awarded in a health care liability action which is different from the amount prescribed by section 412(a)(1), the State amount shall apply in lieu of the amount prescribed by such section. If, after the date of the enactment of this Act, a State enacts a law which limits the amount of recovery in a health care liability action without delineating between economic and non-economic damages, the State amount shall apply in lieu of the amount prescribed by such section.

(3) JOINT AND SEVERAL LIABILITY.—In any health care liability action brought in State or Federal court, a defendant shall be liable only for the amount of non-economic damages attributable to such defendant in direct proportion to such defendant's share of fault or responsibility for the claimant's actual damages, as determined by the trier of fact. In all such cases, the liability of a defendant for non-economic damages shall be several and not joint and a separate judgment shall be rendered against each defendant for the amount allocated to such defendant.

(b) TREATMENT OF PUNITIVE DAMAGES.—

(1) GENERAL RULE.—Punitive damages may, to the extent permitted by applicable State law, be awarded in any health care liability action for harm in any Federal or State court against a defendant if the claimant establishes by clear and convincing evidence that the harm suffered was the result of conduct—

(A) specifically intended to cause harm; or

(B) conduct manifesting a conscious, flagrant indifference to the rights or safety of others.

(2) APPLICABILITY.—This subsection shall apply to any health care liability action brought in any Federal or State court on any theory where punitive damages are sought. This subsection does not create a cause of action for punitive damages.

(3) LIMITATION ON PUNITIVE DAMAGES.—The total amount of punitive damages that may be awarded to a claimant for losses resulting from the injury which is the subject of a health care liability action may not exceed the greater of—

(A) 2 times the amount of economic damages, or

(B) $250,000,

regardless of the number of parties against whom the action is brought or the number of actions brought with respect to the injury. This subsection does not preempt or supersede any State or Federal law to the extent that such law would further limit the award of punitive damages.

(4) BIFURCATION.—At the request of any party, the trier of fact shall consider in a separate proceeding whether punitive damages are to be awarded and the amount of such award. If a separate proceeding is requested, evidence relevant only to the claim of punitive damages, as determined by applicable State law, shall be inadmissible in any proceeding to determine whether actual damages are to be awarded.

(4) DRUGS AND DEVICES.—

(A) IN GENERAL.—

(i) PUNITIVE DAMAGES.—Punitive damages shall not be awarded against a manufacturer or product seller of a drug or medical device which caused the claimant's harm where—

(I) such drug or device was subject to premarket approval by the Food and Drug Administration with

respect to the safety of the formulation or performance of the aspect of such drug or device which caused the claimant's harm, or the adequacy of the packaging or labeling of such drug or device which caused the harm, and such drug, device, packaging, or labeling was approved by the Food and Drug Administration; or

(II) the drug is generally recognized as safe and effective pursuant to conditions established by the Food and Drug Administration and applicable regulations, including packaging and labeling regulations.

(ii) APPLICATION.—Clause (i) shall not apply in any case in which the defendant, before or after premarket approval of a drug or device—

(I) intentionally and wrongfully withheld from or misrepresented to the Food and Drug Administration information concerning such drug or device required to be submitted under the Federal Food, Drug, and Cos-

metic Act (21 U.S.C. 301 et seq.) or section 351 of the Public Health Service Act (42 U.S.C. 262) that is material and relevant to the harm suffered by the claimant; or

(II) made an illegal payment to an official or employee of the Food and Drug Administration for the purpose of securing or maintaining approval of such drug or device.

(B) PACKAGING.—In a health care liability action for harm which is alleged to relate to the adequacy of the packaging or labeling of a drug which is required to have tamper-resistant packaging under regulations of the Secretary of Health and Human Services (including labeling regulations related to such packaging), the manufacturer or product seller of the drug shall not be held liable for punitive damages unless such packaging or labeling is found by the court by clear and convincing evidence to be substantially out of compliance with such regulations.

(c) PERIODIC PAYMENTS FOR FUTURE LOSSES.—

(1) GENERAL RULE.—In any health care liability action in which the damages awarded for future

economic and non-economic loss exceeds $50,000, a person shall not be required to pay such damages in a single, lump-sum payment, but shall be permitted to make such payments periodically based on when the damages are likely to occur, as such payments are determined by the court.

(2) FINALITY OF JUDGMENT.—The judgment of the court awarding periodic payments under this subsection may not, in the absence of fraud, be re-opened at any time to contest, amend, or modify the schedule or amount of the payments.

(3) LUMP-SUM SETTLEMENTS.—This subsection shall not be construed to preclude a settlement providing for a single, lump-sum payment.

(d) TREATMENT OF COLLATERAL SOURCE PAYMENTS.—

(1) INTRODUCTION INTO EVIDENCE.—In any health care liability action, any defendant may introduce evidence of collateral source payments. If any defendant elects to introduce such evidence, the claimant may introduce evidence of any amount paid or contributed or reasonably likely to be paid or contributed in the future by or on behalf of the claimant to secure the right to such collateral source payments.

(2) NO SUBROGATION.—No provider of collateral source payments shall recover any amount against the claimant or receive any lien or credit against the claimant's recovery or be equitably or legally subrogated to the right of the claimant in a health care liability action.

(3) APPLICATION TO SETTLEMENTS.—This subsection shall apply to an action that is settled as well as an action that is resolved by a fact finder.

SEC. 413. ALTERNATIVE DISPUTE RESOLUTION.

Any ADR used to resolve a health care liability action or claim shall contain provisions relating to statute of limitations, non-economic damages, joint and several liability, punitive damages, collateral source rule, and periodic payments which are consistent with the provisions relating to such matters in this title.

SEC. 414. REPORTING ON FRAUD AND ABUSE ENFORCEMENT ACTIVITIES.

The General Accounting Office shall—

(1) monitor—

(A) the compliance of the Department of Justice and all United States Attorneys–with the guideline entitled ''Guidance on the Use of the False Claims Act in Civil Health Care Matters'' issued by the Department on June 3,

1998, including any revisions to that guideline; and

(B) the compliance of the Office of the Inspector General of the Department of Health and Human Services with the protocols and guidelines entitled ''National Project Protocols—Best Practice Guidelines'' issued by the Inspector General on June 3, 1998, including any revisions to such protocols and guidelines; and

(2) submit a report on such compliance to the Committee on Commerce, the Committee on the Judiciary, and the Committee on Ways and Means of the House of Representatives and the Committee on the Judiciary and the Committee on Finance of the Senate not later than February 1, 2000, and every year thereafter for a period of 4 years ending February 1, 2003.