I

105TH CONGRESS
1ST SESSION

H. R. 3009

To amend the Public Health Service Act and the Employee Retirement Income Security Act of 1974 to establish standards for managed care plans.

IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 9, 1997

Mr. PALLONE (for himself, Mr. GILMAN, Mr. BROWN of Ohio, Mr. FOX of Pennsylvania, Ms. SANCHEZ, Mr. HORN, Ms. ESHOO, Mr. GREEN, Mr. FROST, Mr. ANDREWS, Mr. FILNER, Mr. ACKERMAN, Mr. WEXLER, Mr. BROWN of California, Mrs. MALONEY of New York, Mr. HASTINGS of Florida, Mr. PASCRELL, Mr. MASCARA, Mr. DAVIS of Illinois, Ms. MILLENDER-MCDONALD, Ms. CARSON, Mrs. CLAYTON, Mr. LAMPSON, Mr. NADLER, Ms. JACKSON-LEE of Texas, Mr. ROTHMAN, Mr. ENGEL, Mr. PAYNE, Mr. MCCOLLUM, Mr. SHERMAN, Mr. CRAMER, and Mrs. MORELLA) introduced the following bill; which was referred to the Committee on Commerce, and in addition to the Committees on Ways and Means, and Education and the Workforce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To amend the Public Health Service Act and the Employee Retirement Income Security Act of 1974 to establish standards for managed care plans.

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

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Health Care Consumer Protection Act of 1997''.

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

TITLE I—PATIENT CHOICE; ACCESS; QUALITY OF CARE

SEC. 101. PATIENT CHOICE.

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

(1) by redesignating part C as part D, and

(2) by inserting after part B the following new part:

''PART C—CONSUMER PROTECTIONS UNDER MANAGED CARE

''SEC. 2770. PATIENT CHOICE OF HEALTH PROFESSIONALS AND PROVIDERS.

''(a) CHOICE OF PERSONAL HEALTH PROFESSIONAL.—A health insurance issuer shall permit each enrollee under network coverage to—

''(1) select a personal health professional from among the participating health professionals of the issuer, and

''(2) change that selection as appropriate.

''(b) POINT-OF-SERVICE OPTION.—

''(1) IN GENERAL.—If a health insurance issuer offers to enrollees health insurance coverage which provides for coverage of services only if such services are furnished through health professionals and providers who are members of a network of health pro-

fessionals and providers who have entered into a contract with the issuer to provide such services, the issuer shall also offer to such enrollees (at the time of enrollment) the option of health insurance coverage which provides for coverage of such services which are not furnished through health professionals and providers who are members of such a network.

''(2) FAIR PREMIUMS.—The amount of any additional premium required for the option described in paragraph (1) may not exceed an amount that is fair and reasonable, as established by the applicable State authority, in consultation with the National Association of Insurance Commissioners, based on the nature of the additional coverage provided.

''(3) COST-SHARING.—Under the option described in paragraph (1)—

''(A) the health insurance coverage shall provide for reimbursement rates for covered services offered by health professionals and providers who are not participating health professionals or providers that are not less than the reimbursement rates for covered services offered by participating health professionals and providers; and

''(B) the issuer shall disclose to enrollees their potential liability for cost-sharing and other out-of-pocket expenses.

''(c) CONTINUITY OF CARE.—A health insurance issuer offering network coverage shall—

''(1) ensure that any process established by the issuer to coordinate care and control costs does not create an undue burden, as defined by the applicable State authority, for enrollees with special health care needs or chronic conditions;

''(2) ensure direct access to relevant specialists for the continued care of such enrollees when medically or clinically indicated in the judgment of the treating health professional, in consultation with the enrollee;

''(3) in the case of an enrollee with special health care needs or a chronic condition, determine whether, based on the judgment of the treating health professional, in consultation with the enrollee, it is medically or clinically necessary to use a specialist or a care coordinator from an interdisciplinary team to ensure continuity of care; and

''(4) in circumstances under which a change of health professional or provider might disrupt the continuity of care for an enrollee, such as—

''(A) hospitalization, or

''(B) dependency on high-technology home medical equipment,

provide for continued coverage of items and services furnished by the health professional or provider that was treating the enrollee before such change for a reasonable period of time.

For purposes of paragraph (4), a change of health professional or provider may be due to changes in the membership of an issuer's health professional and provider network, changes in the health coverage made available by an employer, or other similar circumstances.

''(d) NO REQUIREMENT FOR ANY WILLING PROVIDER.—Nothing in this part shall be construed as requiring a health insurance issuer that offers network coverage to include for participation every willing provider or health professional who meets the terms and conditions of the plan or issuer.

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

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

''(2) HEALTH PROFESSIONAL.—The term 'health professional' means a physician or other

health care practitioner licensed, accredited, or certified to perform specified health services consistent with State law.

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

''(4) NETWORK COVERAGE.—The term 'network coverage' means health insurance coverage offered by a health insurance issuer that provides or arranges for the provision of health care items and services to enrollees through participating health professionals and providers.

''(5) PARTICIPATING.—The term 'participating' means, with respect to a health professional or provider, a health professional or provider that provides health care items and services to enrollees under network coverage under an agreement with the health insurance issuer offering the coverage.

''(6) PRIOR AUTHORIZATION.—The term 'prior authorization' means the process of obtaining prior approval from a health insurance issuer as to the necessity or appropriateness of receiving medical or

clinical services for treatment of a medical or clinical condition.

''(7) PROVIDER.—The term 'provider' means a health organization, health facility, or health agency that is licensed, accredited, or certified to provide health care items and services under applicable State law.

''(8) SERVICE AREA.—The term 'service area' means, with respect to a health insurance issuer with respect to health insurance coverage, the geographic area served by the issuer with respect to the coverage.

''(9) UTILIZATION REVIEW.—The term 'utilization review' means prospective, concurrent, or retrospective review of health care items and services for medical necessity, appropriateness, or quality of care that includes prior authorization requirements for coverage of such items and services.''.

(b) REQUIRING MEDICARE+CHOICE ORGANIZATIONS TO OFFER COVERAGE FOR OUT-OF-NETWORK SERVICES.—

(1) IN GENERAL.—Section 1852(a)(3) of the Social Security Act (42 U.S.C. 1395w–22(a)(3)), as added by section 4001 of the Balanced Budget Act of 1997, is amended by redesignating subparagraph

(C) as subparagraph (D) and by inserting after subparagraph (B) the following new subparagraph:

''(C) REQUIRING OUT-OF-NETWORK SERVICE OPTION.—If a Medicare+Choice organization offers to members enrolled under this part a plan which provides for coverage of services covered under parts A and B of this title only if such services are furnished through providers and other persons who are members of a network of providers and other persons who have entered into a contract with the organization to provide such services, the contract with the organization under section 1857 shall provide that the organization shall also offer to members enrolled under this part (at the time of enrollment) a plan which provides for coverage of such services which are not furnished through providers and other persons who are members of such a network.''.

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to contracts for years beginning with 1999.

SEC. 102. ACCESS TO CARE.

(a) IN GENERAL.—Part C of title XVIII of the Public Health Service Act, as inserted by section 101, is amended by adding at the end the following:

"SEC. 2771. ACCESS TO CARE.

"(a) GENERAL ACCESS.—

"(1) IN GENERAL.—Subject to paragraphs (2), and (3), a health insurance issuer shall establish and maintain adequate arrangements, as defined by the applicable State authority, with a sufficient number, mix, and distribution of health professionals and providers to assure that covered items and services are available and accessible to each enrollee under health insurance coverage—

"(A) in the service area of the issuer;

"(B) in a variety of sites of service;

"(C) with reasonable promptness (including reasonable hours of operation and after-hours services);

"(D) with reasonable proximity to the residences and workplaces of enrollees; and

"(E) in a manner that—

"(i) takes into account the diverse needs of enrollees, and

"(ii) reasonably assures continuity of care.

For a health insurance issuer that serves a rural or medically underserved area, the issuer shall be treated as meeting the requirement of this subsection if the issuer has arrangements with a sufficient number, mix, and distribution of health professionals and providers having a history of serving such areas. The use of telemedicine and other innovative means to provide covered items and services by a health insurance issuer that serves a rural or medically underserved area shall also be considered in determining whether the requirement of this subsection is met.

''(2) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed as requiring a health insurance issuer to have arrangements that conflict with its responsibilities to establish measures designed to maintain quality and control costs.

''(3) DEFINITIONS.—For purposes of paragraph (1):

''(A) MEDICALLY UNDERSERVED AREA.—The term 'medically underserved area' means an area that is designated as a health professional shortage area under section 332 of the Public Health Service Act or as a medically underserved area for purposes of section 330 or 1302(7) of such Act.

"(B) RURAL AREA.—The term 'rural area' means an area that is not within a Standard Metropolitan Statistical Area or a New England County Metropolitan Area (as defined by the Office of Management and Budget).

"(b) EMERGENCY AND URGENT CARE.—

"(1) IN GENERAL.—A health insurance issuer shall—

"(A) assure the availability and accessibility of medically or clinically necessary emergency services and urgent care services within the service area of the issuer 24 hours a day, 7 days a week;

"(B) require no prior authorization for items and services furnished in a hospital emergency department to an enrollee (without regard to whether the health professional or hospital has a contractual or other arrangement with the issuer) with symptoms that would reasonably suggest to a prudent layperson an emergency medical condition (including items and services described in subparagraph (C)(iii));

"(C) cover (and make reasonable payments for)—

"(i) emergency services,

"(ii) services that are not emergency services but are described in subparagraph (B),

"(iii) medical screening examinations and other ancillary services necessary to diagnose, treat, and stabilize an emergency medical condition, and

"(iv) urgent care services, without regard to whether the health professional or provider furnishing such services has a contractual (or other) arrangement with the issuer; and

"(D) make prior authorization determinations for—

"(i) services that are furnished in a hospital emergency department (other than services described in clauses (i) and (iii) of subparagraph (C)), and

"(ii) urgent care services, within the time periods specified in (or pursuant to) section 2781(a)(8).

"(2) DEFINITIONS.—For purposes of this subsection:

"(A) EMERGENCY MEDICAL CONDITION.—The term 'emergency medical condition' means a medical condition (including emergency labor and delivery) 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 could reasonably be expected to result in—

"(i) placing the patient's health in serious jeopardy,

"(ii) serious impairment to bodily functions, or

"(iii) serious dysfunction of any bodily organ or part.

"(B) EMERGENCY SERVICES.—The term 'emergency services' means health care items and services that are necessary for the diagnosis, treatment, and stabilization of an emergency medical condition.

"(C) URGENT CARE SERVICES.—The term 'urgent care services' means health care items and services that are necessary for the treatment of a condition that—

''(i) is not an emergency medical condition,

''(ii) requires prompt medical or clinical treatment, and

''(iii) poses a danger to the patient if not treated in a timely manner, as defined by the applicable State authority in consultation with relevant treating health professionals or providers.

''(c) OBSTETRICAL AND GYNECOLOGICAL CARE.—

''(1) IN GENERAL.—If a health insurance issuer, in connection with the provision of health insurance coverage, requires or provides for an enrollee to designate a participating primary care provider—

''(A) the issuer shall permit a female enrollee to designate a physician who specializes in obstetrics and gynecology as the enrollee's primary care provider; and

''(B) if such an enrollee has not designated such a provider as a primary care provider, the issuer—

''(i) may not require prior authorization by the enrollee's primary care provider or otherwise for coverage of routine gyne-

cological care (such as preventive women's health examinations) and pregnancy-related services provided by a participating physician who specializes in obstetrics and gynecology to the extent such care is otherwise covered, and

"(ii) may treat the ordering of other gynecological care by such a participating physician as the prior authorization of the primary care provider with respect to such care under the coverage.

"(2) CONSTRUCTION.—Nothing in paragraph (1)(B)(ii) shall waive any requirements of coverage relating to medical necessity or appropriateness with respect to coverage of gynecological care so ordered.

"(d) REFERRAL TO SPECIALTY CARE FOR ENROLLEES REQUIRING TREATMENT BY SPECIALISTS.—

"(1) IN GENERAL.—In the case of an enrollee who is covered under health insurance coverage offered by a health insurance issuer and who has a condition or disease of sufficient seriousness and complexity to require treatment by a specialist, the issuer shall make or provide for a referral to a specialist who is available and accessible to provide the treatment for such condition or disease.

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

''(3) CARE UNDER REFERRAL.—Care provided pursuant to such referral under paragraph (1) shall be—

''(A) pursuant to a treatment plan (if any) developed by the specialist and approved by the issuer, in consultation with the designated primary care provider or specialist and the enrollee (or the enrollee's designee), and

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

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

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

''(5) TREATMENT OF NONPARTICIPATING PROVIDERS.—If an issuer refers an enrollee to a nonparticipating specialist, services provided pursuant to the approved treatment plan shall be provided at no additional cost to the enrollee beyond what the enrollee would otherwise pay for services received by such a specialist that is a participating provider.

''(e) CONTINUITY OF CARE.—

''(1) IN GENERAL.—A health insurance issuer offering network coverage shall—

''(A) ensure that any process established by the issuer to coordinate care and control costs does not create an undue burden, as defined by the applicable State authority, for enrollees with special health care needs or chronic conditions;

"(B) ensure direct access to relevant specialists for the continued care of such enrollees when medically or clinically indicated in the judgment of the treating health professional, in consultation with the enrollee;

"(C) in the case of an enrollee with special health care needs or a chronic condition, determine whether, based on the judgment of the treating health professional, in consultation with the enrollee, it is medically or clinically necessary to use a specialist or a care coordinator from an interdisciplinary team to ensure continuity of care; and

"(D) in circumstances under which a change of health professional or provider might disrupt the continuity of care for an enrollee, such as—

"(i) hospitalization, or

"(ii) dependency on high-technology home medical equipment,

provide for continued coverage of items and services furnished by the health professional or provider that was treating the enrollee before such change for a reasonable period of time.

For purposes of subparagraph (D), a change of health professional or provider may be due to changes in the membership of an issuer's health professional and provider network, changes in the health coverage made available by an employer, or other similar circumstances.

"(2) CONTINUED COURSE OF TREATMENT.—

"(A) IN GENERAL.—If a contract between a health insurance issuer, in connection with the provision of health insurance coverage, and a health care provider is terminated (other than by the issuer for failure to meet applicable quality standards or for fraud) and an enrollee is described in subparagraph (B)(i), (B)(ii), or (B)(iii) and is undergoing a course of treatment from the provider at the time of such termination, the issuer shall—

"(i) notify the enrollee of such termination, and

"(ii) subject to subparagraph (C), permit the enrollee to continue the course of treatment with the provider during a transitional period (provided under subparagraph (B)).

"(B) TRANSITIONAL PERIODS.—

''(ii) TRANSITIONAL PERIOD FOR INSTITUTIONAL CARE.—The transitional period under this clause for institutional or inpatient care from a provider shall extend until the discharge or termination of the period of institutionalization and shall include reasonable follow-up care related to the institutionalization and shall also include institutional care scheduled prior to the date of termination of the provider status.

''(iii) PREGNANCY.—If—

''(I) an enrollee has entered the second trimester of pregnancy 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 clause with respect to provider's treatment of the pregnancy shall extend through the provision of post-partum care directly related to the delivery.

''(iv) TERMINAL ILLNESS.—If—

"(I) an enrollee was determined to be terminally ill 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 clause shall extend for the remainder of the enrollee's life for care directly related to the treatment of the terminal illness. In subclause (I), an enrollee is considered to be 'terminally ill' if the enrollee has a medical prognosis that the enrollee's life expectancy is 6 months or less.

"(C) PERMISSIBLE TERMS AND CONDITIONS.—An issuer may condition coverage of continued treatment by a provider under subparagraph (A)(ii) upon the provider agreeing to the following terms and conditions:

"(i) The provider agrees to continue to accept reimbursement from the issuer at the rates applicable prior to the start of the transitional period as payment in full.

''(ii) The provider agrees to adhere to the issuer's quality assurance standards and to provide to the issuer necessary medical information related to the care provided.

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

''(e) NONDISCRIMINATION AGAINST ENROLLEES.—No health insurance issuer may discriminate (directly or through contractual arrangements) in any activity that has the effect of discriminating against an individual on the basis of race, national origin, genetic makeup, gender, language, socioeconomic status, sexual orientation, age, disability, health status, or anticipated need for health services.

SEC. 103. QUALITY OF CARE.

(a) QUALITY IMPROVEMENT PROGRAM.—Such part is further amended by adding at the end the following:

''SEC. 2772. QUALITY IMPROVEMENT PROGRAM.

''(a) IN GENERAL.—A health insurance issuer shall establish a quality improvement program (consistent with

subsection (b)) that systematically and continuously assesses and improves—

''(1) enrollee health status, patient outcomes, processes of care, and enrollee satisfaction associated with health care provided by the issuer; and

''(2) the administrative and funding capacity of the issuer to support and emphasize preventive care, utilization, access and availability, cost effectiveness, acceptable treatment modalities, specialists referrals, the peer review process, and the efficiency of the administrative process.

''(b) FUNCTIONS.—A quality improvement program established pursuant to subsection (a) shall—

''(1) assess the performance of the issuer and its participating health professionals and providers and report the results of such assessment to purchasers, participating health professionals and providers, and administrative personnel;

''(2) demonstrate measurable improvements in clinical outcomes and plan performance measured by identified criteria, including those specified in subsection (a)(1); and

''(3) analyze quality assessment data to determine specific interactions in the delivery system (both the design and funding of the health insurance

coverage and the clinical provision of care) that have an adverse impact on the quality of care.''.

''(c) INCENTIVE PLANS.—

''(1) IN GENERAL.—In the case of a health insurance issuer that offers network coverage, any health professional or provider incentive plan operated by the issuer with respect to such coverage shall meet the following requirements:

''(A) No specific payment is made directly or indirectly under the plan to a professional or provider or group of professionals or providers as an inducement to reduce or limit medically necessary services provided with respect to a specific enrollee.

''(B) If the plan places such a professional, provider, or group at substantial financial risk (as determined by the Secretary) for services not provided by the professional, provider, or group, the issuer—

''(i) provides stop-loss protection for the professional, provider, or group that is adequate and appropriate, based on standards developed by the Secretary that take into account the number of professionals or providers placed at such substantial fi-

nancial risk in the group or under the coverage and the number of individuals enrolled with the issuer who receive services from the professional, provider, or group, and

''(ii) conducts periodic surveys of both individuals enrolled and individuals previously enrolled with the issuer to determine the degree of access of such individuals to services provided by the issuer and satisfaction with the quality of such services.

''(C) The issuer provides the Secretary with descriptive information regarding the plan, sufficient to permit the Secretary to determine whether the plan is in compliance with the requirements of this paragraph.

''(2) In this subsection, the term 'health professional or provider incentive plan' means any compensation arrangement between a health insurance issuer and a health professional or provider or professional or provide group that may directly or indirectly have the effect of reducing or limiting services provided with respect to individuals enrolled with the issuer.''.

(b) OFFICE OF MEDICARE ADVOCACY.—Title XVIII of the Social Security Act is amended by inserting after section 1804 the following new section:

''OFFICE OF MEDICARE ADVOCACY

''SEC. 1805. (a) ESTABLISHMENT.—The Secretary shall establish, within the Health Care Financing Administration, an office of medicare advocacy (in this section referred to as the 'office'), to be headed by a director appointed by the Secretary.

''(b) PURPOSE.—The office shall provide, in accordance with this section, independent review of problems and concerns of medicare beneficiaries in relation to the programs under this title, including, but not limited to, complaints concerning plans offered under part C or section 1876.

''(c) ACCESS.—In order to carry out its functions, the office shall provide for a toll-free telephone number through which medicare beneficiaries can obtain assistance in the programs under this title, including providing comparative information on plans offered under part C or section 1876. The office also shall undertake such additional outreach activities, such as the use of town meetings and development of an appropriate Internet site, as most effectively and efficiently promotes dissemination of information to medicare beneficiaries.

''(d) RECEIPT AND DISPOSITION OF COMPLAINTS.—The office shall provide for a record of the types of complaints and problems received and shall submit to the Secretary and publish an annual report on the nature of such complaints and problems, the disposition with respect to such complaints and problems, and such other additional information as the Secretary may specify.

''(e) EXPEDITED REVIEW PROCESS FOR COMPLAINTS UNDER EMERGENCY CIRCUMSTANCES.—

''(1) IN GENERAL.—Under regulations of the Secretary, the office shall have authority to provide for an expedited review and resolution of complaints under emergency circumstances, including those described in paragraph (2). Such reviews and resolutions shall be conducted to the greatest extent practicable through regional and local agencies.

''(2) EMERGENCY CIRCUMSTANCES DESCRIBED.—The emergency circumstances described in this paragraph are cases in which—

''(A) a delay in treatment resulting from application of the usual hearing and appeals process may endanger the life of the beneficiary, result in a loss of function or a significant worsening of a condition, or render treatment ineffective; or

''(B) an advanced directive (as defined in section 1866(f)(3)) or other end-of-life preference is involved.''.

(c) STATE HEALTH INSURANCE OMBUDSMEN.—Part C of title XVIII of the Public Health Service Act, as previously inserted and amended, is further amended by adding at the end the following:

''SEC. 2773. STATE HEALTH INSURANCE OMBUDSMEN.

''(a) IN GENERAL.—Each State that obtains a grant under subsection (c) shall establish and maintain a Health Insurance Ombudsman. Such Ombudsman may be part of a independent, nonprofit entity, and shall be responsible for at least the following:

''(1) To assist consumers in the State in choosing among health insurance coverage.

''(2) To provide counseling and assistance to enrollees dissatisfied with their treatment by health insurance issuers in regard to such coverage and in the filing of complaints and appeals regarding determinations under such coverage.

''(3) To investigate instances of poor quality or improper treatment of enrollees by health insurance issuers in regard to such coverage and to bring such instances to the attention of the applicable State authority.

''(b) FEDERAL ROLE.—In the case of any State that does not establish and maintain such an Ombudsman under subsection (a), the Secretary shall provide for the establishment and maintenance of such an official as will carry out with respect to that State the functions otherwise provided under subsection (a) by a Health Insurance Ombudsman.

''(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Secretary such amounts as may be necessary to provide for grants to States to establish and operate Health Insurance Ombudsmen under subsection (a) or for the operation of Ombudsmen under subsection (b).''.

SEC. 104. PATIENT CONFIDENTIALITY.

Part C of title XVIII of the Public Health Service Act, as previously inserted and amended, is further amended by adding at the end the following:

''SEC. 2774. PROTECTION OF PATIENT CONFIDENTIALITY.

''(a) IN GENERAL.—A health insurance issuer that offers health insurance coverage shall establish appropriate written policies and procedures to ensure that all applicable State and Federal laws to protect the confidentiality of individually identifiable medical information are followed.

''(b) DETAILS.—Such policies and procedures shall provide that individually identifiable medical information should not be disclosed except under the following circumstances:

''(1) For purposes necessary to perform required quality assurance functions, to meet requirements of purchasers and providers (in order to determine entitlement to coverage and to administer payments), and to conduct approved, bona fide clinical or health services research. The disclosure of information in such circumstances should not contain patient identifiers which could lead to violation of individual privacy and harm patients.

''(2) Upon the express consent of the covered person.

''(3) Pursuant to law or court order for the production of evidence or the discovery thereof or other legally mandated disclosure.

''(4) In the event of claim or litigation between the covered person and the issuer.''.

SEC. 105. COVERAGE UNDER APPROVED CLINICAL TRIALS.

Such part is further amended by adding at the end the following new section:

"SEC. 2775. COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CLINICAL TRIALS.

''(a) IN GENERAL.—If a health insurance issuer offers health insurance coverage to a qualified enrollee (as defined in subsection (b)), the issuer—

''(1) may not deny the enrollee participation in the clinical trial referred to in subsection (b)(2);

''(2) subject to subsection (c), may not deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and services furnished in connection with participation in the trial; and

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

''(b) QUALIFIED ENROLLEE DEFINED.—For purposes of subsection (a), the term 'qualified enrollee' means an enrollee under health insurance coverage who meets the following conditions:

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

''(2) The enrollee is eligible to participate in an approved clinical trial with respect to treatment of such illness.

''(3) The enrollee and the referring physician conclude that the enrollee's participation in such trial would be appropriate.

''(4) The enrollee's participation in the trial offers potential for significant clinical benefit for the enrollee.

''(c) PAYMENT.—

''(1) IN GENERAL.—Under this section an issuer shall provide for payment for routine patient costs described in subsection (a)(2) but is not required to pay for costs of items and services that are reasonably expected (as determined by the Secretary) to be paid for by the sponsors of an approved clinical trial.

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

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

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

''(d) APPROVED CLINICAL TRIAL DEFINED.—In this section, the term 'approved clinical trial' means a clinical

research study or clinical investigation approved and funded by one or more of the following:

''(1) The National Institutes of Health.

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

''(3) The Department of Veterans Affairs.

''(4) The Department of Defense.''.

SEC. 106. ACCESS TO NEEDED PRESCRIPTION DRUGS; DRUG UTILIZATION PROGRAM.

Such part is further amended by adding at the end the following new section:

''SEC. 2776. ACCESS TO NEEDED PRESCRIPTION DRUGS; DRUG UTILIZATION PROGRAM.

''(a) ACCESS.—If a health insurance issuer offers health insurance coverage (whether directly or through any agent) that provides benefits with respect to prescription drugs but the coverage limits such benefits to drugs included in a formulary, the issuer shall—

''(1) ensure participation of participating physicians in the development of the formulary;

''(2) disclose the nature of the formulary restrictions; and

''(3) provide for exceptions from the formulary limitation when medical necessity, as determined by the enrollee's physician subject to reasonable review

by the issuer, dictates that a non-formulary alternative is indicated.

''(b) DRUG UTILIZATION PROGRAM.—A health insurance issuer that provides health insurance coverage that includes benefits for prescription drugs shall establish and maintain a drug utilization program which—

''(1) encourages appropriate use of prescription drugs by enrollees and providers,

''(2) monitors illnesses arising from improper drug use or from adverse drug reactions or interactions, and

''(3) takes appropriate action to reduce the incidence of improper drug use and adverse drug reactions and interactions.''.

TITLE II—CONTRACTING AND TERMINATION RIGHTS

SEC. 201. NONDISCRIMINATION AGAINST PROVIDERS.

Part C of title XXVII of the Public Health Service Act is amended by adding at the end the following:

''SEC. 2777. NONDISCRIMINATION IN THE SELECTION OF HEALTH PROFESSIONALS; EQUITABLE ACCESS TO NETWORKS.

''(a) NONDISCRIMINATION IN SELECTION OF NETWORK HEALTH PROFESSIONALS.—A health insurance issuer offering network coverage shall not discriminate in

selecting the members of its health professional network (or in establishing the terms and conditions for membership in such network) on the basis of the race, national origin, genetic makeup, gender, sexual orientation, age, place or institution in which received health professional education, or disability (other than a disability that impairs the ability of an individual to provide health care services or that may threaten the health of enrollees) of the health professional.

''(b) NONDISCRIMINATION IN ACCESS TO HEALTH PLANS.—While nothing in this section shall be construed as an 'any willing provider' requirement (as referred to in section 2770(d)), a health insurance issuer shall not discriminate in participation, reimbursement, or indemnification against a health professional, who is acting within the scope of the health professional's license or certification under applicable State law, solely on the basis of such license or certification.''.

SEC. 202. DEVELOPMENT OF PLAN POLICIES.

Such part is further amended by adding at the end the following:

''SEC. 2778. DEVELOPMENT OF PLAN POLICIES.

''A health insurance issuer that offers network coverage shall establish mechanisms to consider the recommendations, suggestions, and views of enrollees and

participating health professionals and providers regarding—

''(1) the medical policies of the issuer (including policies relating to coverage of new technologies, treatments, and procedures);

''(2) the utilization review criteria and procedures of the issuer;

''(3) the quality and credentialing criteria of the issuer; and

''(4) the medical management procedures of the issuer.''.

SEC. 203. DUE PROCESS.

Such part is further amended by adding at the end the following:

''SEC. 2779. DUE PROCESS FOR HEALTH PROFESSIONALS AND PROVIDERS.

''(a) IN GENERAL.—A health insurance issuer with respect to its offering of network coverage shall—

''(1) allow all health professionals and providers in its service area to apply to become a participating health professional or provider during at least one period in each calendar year;

''(2) provide reasonable notice to such health professionals and providers of the opportunity to

apply and of the period during which applications are accepted;

''(3) provide for review of each application by a credentialing committee with appropriate representation of the category or type of health professional or provider;

''(4) select participating health professionals and providers based on objective standards of quality developed with the suggestions and advice of professional associations, health professionals, and providers;

''(5) make such selection standards available to—

''(A) those applying to become a participating provider or health professional;

''(B) health plan purchasers, and

''(C) enrollees;

''(6) when economic considerations are taken into account in selecting participating health professionals and providers, use objective criteria that are available to those applying to become a participating provider or health professional and enrollees;

''(7) adjust any economic profiling to take into account patient characteristics (such as severity of

illness) that may result in atypical utilization of services;

''(8) make the results of such profiling available to insurance purchasers, enrollees, and the health professional or provider involved;

''(9) notify any health professional or provider being reviewed under the process referred to in paragraph (3) of any information indicating that the health professional or provider fails to meet the standards of the issuer;

''(10) offer a health professional or provider receiving notice pursuant to the requirement of paragraph (9) with an opportunity to—

''(A) review the information referred to in such paragraph, and

''(B) submit supplemental or corrected information;

''(11) not include in its contracts with participating health professionals and providers a provision permitting the issuer to terminate the contract 'without cause';

''(12) provide a due process appeal that conforms to the process specified in section 412 of the Health Care Quality Improvement Act of 1986 (42

U.S.C. 11112) for all determinations that are adverse to a health professional or provider; and

''(13) unless a health professional or provider poses an imminent harm to enrollees or an adverse action by a governmental agency effectively impairs the ability to provide health care items and services, provide—

''(A) reasonable notice of any decision to terminate a health professional or provider 'for cause' (including an explanation of the reasons for the determination),

''(B) an opportunity to review and discuss all of the information on which the determination is based, and

''(C) an opportunity to enter into a corrective action plan, before the determination becomes subject to appeal under the process referred to in paragraph (12).

''(b) RULE OF CONSTRUCTION.—The requirements of subsection (a) shall not be construed as preempting or superseding any other reviews and appeals a health insurance issuer is required by law to make available.''.

SEC. 204. NON-PREEMPTION OF STATE LAW RESPECTING LIABILITY OF GROUP HEALTH PLANS.

(a) IN GENERAL.—Section 514(b) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1144(b)) is amended by redesignating paragraph (9) as paragraph (10) and inserting the following new paragraph:

''(9) Subsection (a) of this section shall not be construed to preclude any State cause of action to recover damages for personal injury or wrongful death against any person that provides insurance or administrative services to or for an employee welfare benefit plan maintained to provide health care benefits.''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to causes of action arising on or after the date of the enactment of this Act.

TITLE III—INFORMATION REPORTING

SEC. 301. INFORMATION REPORTING.

Part C of title XXVII of the Public Health Service Act is further amended by adding at the end the following:

''SEC. 2780. INFORMATION REPORTING AND DISCLOSURE.

''(a) IN GENERAL.—A health insurance issuer offering health insurance coverage shall provide enrollees and prospective enrollees with information about—

''(1) coverage provisions, benefits, and any exclusions—

''(A) by category of service,

''(B) by category or type of health professional or provider, and

''(C) if applicable, by specific service, including experimental treatments;

''(2) the percentage of the premium charged by the issuer that is set aside for administration and marketing of the issuer;

''(3) the percentage of the premium charged by the issuer that is expended directly for patient care;

''(4) the number, mix, and distribution of participating health professionals and providers;

''(5) the ratio of enrollees to participating health professionals and providers by category and type of health professional and provider;

''(6) the expenditures and utilization per enrollee by category and type of health professional and provider;

''(7) the financial obligations of the enrollee and the issuer, including premiums, copayments, deductibles, and established aggregate maximums on out-of-pocket costs, for all items and services, including—

''(A) those furnished by health professionals and providers that are not participating health professionals and providers, and

''(B) those furnished to an enrollee who is outside the service area of the coverage;

''(8) utilization review requirements of the issuer (including prior authorization review, concurrent review, post-service review, post-payment review, and any other procedures that may lead to denial of coverage or payment for a service);

''(9) financial arrangements and incentives that may—

''(A) limit the items and services furnished to an enrollee,

''(B) restrict referral or treatment options, or

''(C) negatively affect the fiduciary responsibility of a health professional or provider to an enrollee;

''(10) other incentives for health professionals and providers to deny or limit needed items or services;

''(11) quality indicators for the issuer and participating health professionals and providers, including performance measures such as appropriate refer-

rals and prevention of secondary complications following treatment;

''(12) grievance procedures and appeals rights under the coverage, and summary information about the number and disposition of grievances and appeals in the most recent period for which complete and accurate information is available; and

''(13) the percentage of utilization review determinations made by the issuer that disagree with the judgment of the treating health professional or provider and the percentage of such determinations that are reversed on appeal.

''(b) REGULATIONS.—The Secretary, in collaboration with the Secretary of Labor, shall issue regulations to establish—

''(1) the styles and sizes of type to be used with respect to the appearance of the publication of the information required under subsection (a);

''(2) standards for the publication of information to ensure that such publication is—

''(A) readily accessible, and

''(B) in common language easily understood,

by individuals with little or no connection to or understanding of the language employed by health pro-

fessionals and providers, health insurance issuers, or other entities involved in the payment or delivery of health care services, and

''(3) the placement and positioning of information in health plan marketing materials.''.

SEC. 302. AUTOMATIC EXCLUSION FROM MEDICARE AND MEDICAID FOR HEALTH PLANS THAT LIE ABOUT QUALITY DATA.

Notwithstanding any other provision of law, in the case of a Medicare+Choice organization, an eligible organization, health maintenance organizations, or other entity that is receiving payment on a prepaid basis for items and services provided under title XVIII or XIX of the Social Security Act and that submits information relating to the quality of such services provided that is material and false, the Secretary of Health and Human Services shall take such steps as may be necessary to assure the exclusion of the entity from continuing to qualify for such payments under such title and shall provide for the imposition of any intermediate sanctions in lieu of such exclusion.

TITLE IV—PATIENT-PROVIDER COMMUNICATION

SEC. 401. SHORT TITLE; FINDINGS.

(a) SHORT TITLE.—This title may be cited as the ''Patient Right to Know Act''.

(b) FINDINGS.—Congress finds the following:

(1) Patients need access to all relevant information to make appropriate decisions about their health care.

(2) Open medical communications between health care providers and their patients is a key to prevention and early diagnosis and treatment, as well as to informed consent and quality, cost-effective care.

(3) Open medical communications are in the best interests of patients.

(4) Open medical communications must meet applicable legal and ethical standards of care.

(5) It is critical that health care providers continue to exercise their best medical, ethical, and moral judgment in advising patients without interference from health plans.

(6) The offering and operation of health plans affect commerce among the States.

(c) PURPOSE.—It is the purpose of this title to establish a Federal standard that protects medical communications between health care providers and patients.

SEC. 402. PROHIBITION OF INTERFERENCE WITH CERTAIN MEDICAL COMMUNICATIONS.

(a) PROHIBITION.—

(1) GENERAL RULE.—The provisions of any contract or agreement, or the operation of any contract or agreement, between an entity operating a health plan (including any partnership, association, or other organization that enters into or administers such a contract or agreement) and a health care provider (or group of health care providers) shall not prohibit or restrict the provider from engaging in medical communications with his or her patient.

(2) NULLIFICATION.—Any contract provision or agreement described in paragraph (1) shall be null and void.

(3) PROHIBITION ON PROVISIONS.—Effective on the date described in section 404, a contract or agreement described in paragraph (1) shall not include a provision that violates paragraph (1).

(b) RULES OF CONSTRUCTION.—Nothing in this title shall be construed—

(1) to prohibit the enforcement, as part of a contract or agreement to which a health care provider is a party, of any mutually agreed upon terms and conditions, including terms and conditions requiring a health care provider to participate in, and cooperate with, all programs, policies, and procedures developed or operated by a health plan to as-

sure, review, or improve the quality and effective utilization of health care services (if such utilization is according to guidelines or protocols that are based on clinical or scientific evidence and the professional judgment of the provider) but only if the guidelines or protocols under such utilization do not prohibit or restrict medical communications between providers and their patients; or

(2) to permit a health care provider to misrepresent the scope of benefits covered under a health plan or to otherwise require the plan to reimburse providers for benefits not covered under the plan

(c) ENFORCEMENT.—

(1) STATE AUTHORITY.—Except as otherwise provided in this subsection, each State shall enforce the provisions of this title with respect to health insurance issuers that issue, sell, renew, or offer health plans in the State.

(2) ENFORCEMENT BY SECRETARY.—

(A) IN GENERAL.—Effective on January 1, 1998, if the Secretary, after consultation with the chief executive officer of a State and the insurance commissioner or chief insurance regulatory official of the State, determines that the

State has failed to substantially enforce the requirements of this title with respect to health insurance issuers in the State, the Secretary shall enforce the requirements of this title with respect to such State.

(B) ENFORCEMENT THROUGH IMPOSITION OF CIVIL MONEY PENALTY.—

(i) IN GENERAL.—With respect to a State in which the Secretary is enforcing the requirements of this title, an entity operating a health plan in that State that violates subsection (a) shall be subject to a civil money penalty of up to $25,000 for each such violation.

(ii) PROCEDURES.—For purposes of imposing a civil money penalty under clause (i), the provisions of subparagraphs (C) through (G) of section 2722(b)(2) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 300gg–22(b)(2)) shall apply except that the provisions of clause (i) of subparagraph (C) of such section shall not apply.

(3) SELF-INSURED PLANS.—Effective on January 1, 1998, the Secretary of Labor shall enforce the

requirements of this section in the case of a health plan not subject to State regulation by reason of section 514(b) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1144(b)).

(4) RULE OF CONSTRUCTION.—Nothing in this title shall be construed to affect or modify the provisions of section 514 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1144).

(d) NO PREEMPTION OF MORE PROTECTIVE LAWS.—A State may establish or enforce requirements with respect to the protection of medical communications, but only if such requirements are equal to or more protective of such communications than the requirements established under this section.

SEC. 403. DEFINITIONS.

In this title:

(1) HEALTH CARE PROVIDER.—The term ''health care provider'' means anyone licensed or certified under State law to provide health care services who is operating within the scope of such license.

(2) HEALTH INSURANCE ISSUER.—The term ''health insurance issuer'' has the meaning given such term in section 2791(b)(2) of the Public Health Service Act (as added by the Health Insurance Portability and Accountability Act of 1996).

(3) HEALTH PLAN.—The term ''health plan'' means a group health plan (as defined in section 2791(a) of the Public Health Service Act (as added by the Health Insurance Portability and Accountability Act of 1996)) and any individual health insurance (as defined in section 2791(b)(5)) operated by a health insurance issuer and includes any other health care coverage provided through a private or public entity. In the case of a health plan that is an employee welfare benefit plan (as defined in section 3(1) of the Employee Retirement Income Security Act of 1974), any third party administrator or other person with responsibility for contracts with health care providers under the plan shall be considered, for purposes of enforcement under this section, to be a health insurance issuer operating such health plan.

(4) MEDICAL COMMUNICATION.—

(A) IN GENERAL.—The term ''medical communication'' means any communication made by a health care provider with a patient of the health care provider (or the guardian or legal representative of such patient) with respect to—

(i) the patient's health status, medical care, or treatment options;

(ii) any utilization review requirements that may affect treatment options for the patient; or

(iii) any financial incentives that may affect the treatment of the patient.

(B) MISREPRESENTATION.—The term ''medical communication'' does not include a communication by a health care provider with a patient of the health care provider (or the guardian or legal representative of such patient) if the communication involves a knowing or willful misrepresentation by such provider.

(5) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

SEC. 404. EFFECTIVE DATE.

This title shall take effect on the date of enactment of this Act, except that section 402(a)(3) shall take effect 180 days after such date of enactment.

TITLE V—UTILIZATION REVIEW AND MANAGEMENT

SEC. 501. UTILIZATION REVIEW DUE PROCESS FOR ENROLLEES.

Part C of title XXVII of the Public Health Service Act, as previously inserted and amended, is further amended by adding at the end the following new section:

"SEC. 2781. DUE PROCESS FOR ENROLLEES.

''(a) UTILIZATION REVIEW.—The utilization review program of a health insurance issuer shall—

''(1) be developed (including any screening criteria used by such program) with the involvement of participating health professionals and providers;

''(2) to the extent consistent with the protection of proprietary business information (as defined for purposes of section 552 of title 5, United States Code) release, upon request, to affected health professionals, providers, and enrollees the screening criteria, weighting elements, and computer algorithms used in reviews and a description of the method by which they were developed;

''(3) uniformly apply review criteria that are based on sound scientific principles and the most recent medical evidence;

''(4) use licensed, accredited, or certified health professionals to make review determinations (and for services requiring specialized training for their delivery, use a health professional who is qualified through equivalent specialized training and experience);

''(5) subject to reasonable safeguards, disclose to health professionals and providers, upon request,

the names and credentials of individuals conducting utilization review;

''(6) not compensate individuals conducting utilization review for denials of payment or coverage of benefits;

''(7) comply with the requirement of section 2771 that prior authorization not be required for emergency and related services furnished in a hospital emergency department;

''(8) make prior authorization determinations—

''(A) in the case of services that are urgent care services described in section 2771(b)(2)(C), within 30 minutes of a request for such determination, and

''(B) in the case of other services, within 24 hours after the time of a request for determination;

''(9) include in any notice of such determination an explanation of the basis of the determination and the right to an immediate appeal;

''(10) treat a favorable prior authorization review determination as a final determination for purposes of making payment for a claim submitted for the item or service involved unless such determina-

tion was based on false information knowingly supplied by the person requesting the determination;

''(11) provide timely access, as defined by the applicable State authority, to utilization review personnel and, if such personnel are not available, waives any prior authorization that would otherwise be required;

''(12) provide notice of an initial determination on payment of a claim within 30 days after the date the claim is submitted for such item or service, and include in such notice an explanation of the reasons for such determination and of the right to an immediate appeal; and

''(13) take into consideration guidelines established by the medical societies relating to necessary health care.

''(b) RIGHT OF APPEAL.—

''(1) IN GENERAL.—An enrollee in health insurance coverage offered by a health insurance issuer, and any provider acting on behalf of the enrollee with the enrollee's consent, may appeal any appealable decision (as defined in paragraph (2)) under the procedures described in the succeeding subsections in this section and (to the extent applicable) subsection (a). Such enrollees and providers shall be

provided with a written explanation of the appeal process upon the conclusion of each stage in the appeal process.

''(2) APPEALABLE DECISION DEFINED.—In this section, the term 'appealable decision' means any of the following:

''(A) An adverse determination under a utilization review program under subsection (a).

''(B) A denial of patient choice of health care professionals under section 2770.

''(C) A denial of access to care under section 2771.

''(D) Denial of coverage of routine patient costs in connection with an approved clinical trial under section 2775.

''(E) Denial of access to needed drugs under section 2776(a)(3).

''(F) Denial of payment for a benefit,

''(c) INFORMAL INTERNAL APPEAL PROCESS (STAGE 1).—

''(1) IN GENERAL.—Each issuer shall establish and maintain an informal internal appeal process (an appeal under such process in this section referred to as a 'stage 1 appeal') under which any enrollee or any provider acting on behalf of an enrollee

with the enrollee's consent, who is dissatisfied with any appealable decision has the opportunity to discuss and appeal that decision with the medical director of the issuer or the health care professional who made the decision.

''(2) TIMING.—All appeals under this paragraph shall be concluded as soon as possible in accordance with the medical exigencies of the cases, and in no event later than 72 hours in the case of appeals from decisions regarding urgent care and 5 days in the case of all other appeals.

''(3) FURTHER REVIEW.—If the appeal is not resolved to the satisfaction of the enrollee at this level by the deadline under paragraph (2), the issuer shall provide the enrollee and provider (if any) with a written explanation of the decision and the right to proceed to a stage 2 appeal under subsection (d).

''(d) FORMAL INTERNAL APPEAL PROCESS (STAGE 2).—

''(1) IN GENERAL.—Each issuer shall establish and maintain a formal internal appeal process (an appeal under such process in this section referred to as a 'stage 2 appeal') under which any enrollee or provider acting on behalf of an enrollee with the enrollee's consent, who is dissatisfied with the results

of a stage 1 appeal has the opportunity to appeal the results before a panel that includes a physician or other health care professional (or professionals) selected by the issuer who have not been involved in the appealable decision at issue in the appeal.

''(2) AVAILABILITY OF CLINICAL PEERS.—The panel under subparagraph (A) shall have available either clinical peers who have not been involved in the appealable decision at issue in the appeal or others who are mutually agreed upon by the parties. If requested by the enrollee or enrollee's provider with the enrollee's consent, such a peer shall participate in the panel's review of the case. In this paragraph, the term 'clinical peer' means, with respect to a review, a physician or other health care professional who holds a non-restricted license in a State and in the same or similar specialty as typically manages the medical condition, procedure, or treatment under review.

''(3) TIMELY ACKNOWLEDGMENT.—The issuer shall acknowledge the enrollee or provider involved of the receipt of a stage 2 appeals upon receipt of the appeal.

''(4) DEADLINE.—

"(A) IN GENERAL.—The issuer shall conclude each stage 2 appeal as soon as possible after the date of the receipt of the appeal in accordance with medical exigencies of the case involved, but in no event later than 72 hours in the case of appeals from decisions regarding urgent care and (except as provided in subparagraph (B)) 20 business days in the case of all other appeals.

"(B) EXTENSION.—An issuer may extend the deadline for an appeal that does not relate to a decision regarding urgent or emergency care up to an additional 20 business days where it can demonstrate to the applicable State authority reasonable cause for the delay beyond its control and where it provides, within the original deadline under subparagraph (A), a written progress report and explanation for the delay to such authority and to the enrollee and provider involved.

"(5) NOTICE.—If an issuer denies a stage 2 appeal, the issuer shall provide the enrollee and provider involved with written notification of the denial and the reasons therefore, together with a written notification of rights to any further appeal.

''(e) DIRECT USE OF FURTHER APPEALS.—In the event that the issuer fails to comply with any of the deadlines for completion of appeals under this section or in the event that the issuer for any reason expressly waives its rights to an internal review of an appeal under subsection (c) or (d), the enrollee and provider involved shall be relieved of any obligation to complete the appeal stage involved and may, at the enrollee's or provider's option, proceed directly to seek further appeal through any applicable external appeals process.

''(f) EXTERNAL APPEAL PROCESS IN CASE OF USE OF EXPERIMENTAL TREATMENT TO SAVE LIFE OF PATIENT.—

''(1) IN GENERAL.—In the case of an enrollee described in paragraph (2), the health insurance issuer shall provide for an external independent review process respecting the issuer's decision not to cover the experimental therapy (described in paragraph (2)(B)(ii)).

''(2) ENROLLEE DESCRIBED.—An enrollee described in this paragraph is an enrollee who meets the following requirements:

''(A) The enrollee has a terminal condition that is highly likely to cause death within 2 years.

"(B) The enrollee's physician certifies that—

"(i) there is no standard, medically appropriate therapy for successfully treating such terminal condition, but

"(ii) based on medical and scientific evidence, there is a drug, device, procedure, or therapy (in this section referred to as the 'experimental therapy') that is more beneficial than any available standard therapy.

"(C) The issuer has denied coverage of the experimental therapy on the basis that it is experimental or investigational.

"(3) DESCRIPTION OF PROCESS AND DECISION.—The process under this subsection shall provide for a determination on a timely basis, by a panel of independent, impartial physicians appointed by a State authority or by an independent review organization certified by the State, of the medical appropriateness of the experimental therapy. The decision of the panel shall be in writing and shall be accompanied by an explanation of the basis for the decision. A decision of the panel that is favorable to the enrollee may not be appealed by the issuer ex-

cept in the case of misrepresentation of a material fact by the enrollee or a provider. A decision of the panel that is not favorable to the enrollee may be appealed by the enrollee.

''(4) ISSUER COVERING PROCESS COSTS.—Direct costs of the process under this subsection shall be borne by the issuer, and not by the enrollee.

''(g) OTHER INDEPENDENT OR EXTERNAL REVIEW.—

''(1) IN GENERAL.—In the case of appealable decision described in paragraph (2), the health insurance issuer shall provide for—

''(A) an external review process for such decisions consistent with the requirements of paragraph (3), or

''(B) an internal independent review process for such decisions consistent with the requirements of paragraph (4).

''(2) APPEALABLE DECISION DESCRIBED.—An appealable decision described in this paragraph is a decision that does not involve a decision a described in subsection (f)(1) but involves—

''(A) a claim for benefits involving costs over a significant threshold, or

"(B) assuring access to care for a serious condition.

"(3) EXTERNAL REVIEW PROCESS.—The requirements of this subsection for an external review process are as follows:

"(A) The process is established under State law and provides for review of decisions on stage 2 appeals by an independent review organization certified by the State.

"(B) If the process provides that decisions in such process are not binding on issuers, the process must provide for public methods of disclosing frequency of noncompliance with such decisions and for sanctioning issuers that consistently refuse to take appropriate actions in response to such decisions.

"(C) Results of all such reviews under the process are disclosed to the public, along with at least annual disclosure of information on issuer compliance.

"(D) All decisions under the process shall be in writing and shall be accompanied by an explanation of the basis for the decision.

"(E) Direct costs of the process shall be borne by the issuer, and not by the enrollee.

"(F) The issuer shall provide for publication at least annually of information on the numbers of appeals and decisions considered under the process.

"(4) INTERNAL, INDEPENDENT REVIEW PROCESS.—The requirements of this subsection for an internal, independent review process are as follows:

"(A)(i) The process must provide for the participation of persons who are independent of the issuer in conducting reviews and (ii) the Secretary must have found (through reviews conducted no less often than biannually) the process to be fair and impartial.

"(B) If the process provides that decisions in such process are not binding on issuers, the process must provide for public methods of disclosing frequency of noncompliance with such decisions and for sanctioning issuers that consistently refuse to take appropriate actions in response to such decisions.

"(C) Results of all such reviews under the process are disclosed to the public, along with at least annual disclosure of information on issuer compliance.

''(D) All decisions under the process shall be in writing and shall be accompanied by an explanation of the basis for the decision.

''(E) Direct costs of the process shall be borne by the issuer, and not by the enrollee.

''(F) The issuer shall provide for publication at least annually of information on the numbers of appeals and decisions considered under the process.

The Secretary may delegate the authority under subparagraph (A)(ii) to applicable State authorities.

''(5) OVERSIGHT.—The Secretary (and applicable State authorities in the case of delegation of Secretarial authority under paragraph (4)) shall conduct reviews not less often than biannually of the fairness and impartiality issuers who desired to use an internal, independent review process described in paragraph (4) to satisfy the requirement of paragraph (1).

''(6) REPORT.—The Secretary shall provide for periodic reports on the effectiveness of this subsection in assuring fair and impartial reviews of stage 2 appeals. Such reports shall include information on the number of stage 2 appeals (and decisions), for each of the types of review processes de-

scribed in paragraph (2), by health insurance coverage.

''(h) CONSTRUCTION.—Nothing in this part shall be construed as removing any legal rights of enrollees under State or Federal law, including the right to file judicial actions to enforce rights.''.

TITLE VI—ADDITIONAL AMENDMENTS; EFFECTIVE DATES.

SEC. 601. APPLICATION TO GROUP AND INDIVIDUAL HEALTH INSURANCE COVERAGE.

(a) GROUP HEALTH INSURANCE COVERAGE.—(1) 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. 2706. CONSUMER PROTECTION STANDARDS.

''(a) IN GENERAL.—Each health insurance issuer shall comply with consumer protection requirements under part C with respect to group health insurance coverage it offers.

''(b) ASSURING COORDINATION.—The Secretary of Health and Human Services and the Secretary of Labor shall ensure, through the execution of an interagency memorandum of understanding between such Secretaries, that—

''(1) regulations, rulings, and interpretations issued by such Secretaries relating to the same matter over which such Secretaries have responsibility under part C (and this section) and section 713 of the Employee Retirement Income Security Act of 1974 are administered so as to have the same effect at all times; and

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

(2) Section 2792 of such Act (42 U.S.C. 300gg–92) is amended by inserting ''and section 2706(b)'' after ''of 1996''.

(b) APPLICATION TO INDIVIDUAL HEALTH INSURANCE COVERAGE.—Part B of title XXVII of the Public Health Service Act is amended by inserting after section 2751 the following new section:

''SEC. 2752. CONSUMER PROTECTION STANDARDS.

''Each health insurance issuer shall comply with consumer protection requirements under part C with respect to individual health insurance coverage it offers.''.

(c) APPLICATION UNDER MEDICARE AND MEDICAID PROGRAMS.—

(1) MEDICARE PROGRAM.—Section 1852 of the Social Security Act (42 U.S.C. 1395w–22), as inserted by section 4001 of the Balanced Budget Act of 1997 (Public Law 105–33) is amended by adding at the end the following new subsection:

''(l) ADDITIONAL BENEFICIARY PROTECTIONS.—

''(1) IN GENERAL.—Each Medicare+Choice plan shall comply with consumer protection requirements under part C of title XXVII of the Public Health Service Act.

''(2) CONSTRUCTION.—Paragraph (1) shall not be construed as superseding any requirements of this part to the extent such requirements are more stringent than the requirements under part C of title XXVII of the Public Health Service Act.'',

(2) MEDICAID PROGRAM.—Section 1932(b) of the Social Security Act (42 U.S.C. 1396u–2(b)), as added by section 4704(a) of the Balanced Budget Act of 1997 (Public Law 105–33) is amended by adding at the end the following new paragraph:

''(9) ADDITIONAL ENROLLEE PROTECTIONS.—

''(A) IN GENERAL.—A medicaid managed care organization shall comply with consumer protection requirements under part C of title XXVII of the Public Health Service Act with

respect to individuals enrolled with the organization under a contract under section 1903(m) or 1905(t)(3).

''(B) CONSTRUCTION.—Paragraph (1) shall not be construed as superseding any requirements of this title to the extent such requirements are more stringent than the requirements under part C of title XXVII of the Public Health Service Act.'',

(d) MODIFICATION OF PREEMPTION STANDARDS.—

(1) GROUP HEALTH INSURANCE COVERAGE.—Section 2723 of such Act (42 U.S.C. 300gg–23) is amended—

(A) in subsection (a)(1), by striking ''subsection (b)'' and inserting ''subsections (b) and (c)'';

(B) by redesignating subsections (c) and (d) as subsections (d) and (e), respectively; and

(C) by inserting after subsection (b) the following new subsection:

''(c) SPECIAL RULES IN CASE OF CONSUMER PROTECTION REQUIREMENTS.—Subject to subsection (a)(2), the provisions of section 2706 and part C, and part D insofar as it applies to section 2706 or part C, shall not be construed to preempt any State law, or the enactment

or implementation of such a State law, that provides protections for individuals that are equivalent to or stricter than the protections provided under such provisions.''.

(2) INDIVIDUAL HEALTH INSURANCE COVERAGE.—Section 2762 of such Act (42 U.S.C. 300gg–62), as added by section 605(b)(3)(B) of Public Law 104–204, is amended—

(A) in subsection (a), by striking ''subsection (b), nothing in this part'' and inserting ''subsections (b) and (c)'', and

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

''(c) SPECIAL RULES IN CASE OF CONSUMER PROTECTION REQUIREMENTS.—Subject to subsection (b), the provisions of section 2752 and part C, and part D insofar as it applies to section 2752 or part C, shall not be construed to preempt any State law, or the enactment or implementation of such a State law, that provides protections for individuals that are equivalent to or stricter than the protections provided under such provisions.''.

(e) ADDITIONAL CONFORMING AMENDMENTS.—

(1) Section 2723(a)(1) of such Act (42 U.S.C. 300gg–23(a)(1)) is amended by striking ''part C'' and inserting ''parts C and D''.

(2) Section 2762(b)(1) of such Act (42 U.S.C. 300gg–62(b)(1)) is amended by striking ''part C'' and inserting ''part D''.

(f) EFFECTIVE DATES.—(1)(A) Subject to subparagraph (B), the amendments made by this Act shall apply with respect to group health insurance coverage for group health plan years beginning on or after July 1, 1998 (in this subsection referred to as the ''general effective date'') and also shall apply to portions of plan years occurring on and after January 1, 1999.

(B) In the case of group health insurance coverage provided pursuant to a group health plan maintained pursuant to 1 or more collective bargaining agreements between employee representatives and 1 or more employers ratified before the date of enactment of this Act, the amendments made by this Act shall not apply to plan years beginning before the later of—

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

(ii) the general effective date.

For purposes of clause (i), any plan amendment made pursuant to a collective bargaining agreement relating to the

plan which amends the plan solely to conform to any requirement added by this Act shall not be treated as a termination of such collective bargaining agreement.

(2) The amendments made by this Act shall apply with respect to individual health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market on or after the general effective date.

(3) The amendments made by this Act shall apply under the medicare and medicaid programs under titles XVIII and XIX of the Social Security Act on and after the general effective date.

SEC. 602. CONSUMER PROTECTION STANDARDS UNDER THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974.

(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. 713. CONSUMER PROTECTION STANDARDS.

''(a) IN GENERAL.—Subject to subsection (b), a group health plan (and a health insurance issuer offering group health insurance coverage in connection with such a plan) shall comply with the requirements of part C of title XXVII of the Public Health Service Act.

''(b) REFERENCES IN APPLICATION.—In applying subsection (a) under this part, any reference in such part C—

''(1) to a health insurance issuer and health insurance coverage offered by such an issuer is deemed to include a reference to a group health plan and coverage under such plan, respectively;

''(2) to the Secretary is deemed a reference to the Secretary of Labor;

''(3) to an applicable State authority is deemed a reference to the Secretary of Labor; and

''(4) to an enrollee with respect to health insurance coverage is deemed to include a reference to a participant or beneficiary with respect to a group health plan.

''(c) ASSURING COORDINATION.—The Secretary of Health and Human Services and the Secretary of Labor shall ensure, through the execution of an interagency memorandum of understanding between such Secretaries, that—

''(1) regulations, rulings, and interpretations issued by such Secretaries relating to the same matter over which such Secretaries have responsibility under such part C (and section 2706 of the Public

Health Service Act) and this section are administered so as to have the same effect at all times; and

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

(b) MODIFICATION OF PREEMPTION STANDARDS.—Section 731 of such Act (42 U.S.C. 1191) is amended—

(1) in subsection (a)(1), by striking ''subsection (b)'' and inserting ''subsections (b) and (c)'';

(2) by redesignating subsections (c) and (d) as subsections (d) and (e), respectively; and

(3) by inserting after subsection (b) the following new subsection:

''(c) SPECIAL RULES IN CASE OF CONSUMER PROTECTION REQUIREMENTS.—Subject to subsection (a)(2), the provisions of section 713 and part C of title XXVII of the Public Health Service Act, and subpart C insofar as it applies to section 713 or such part, shall not be construed to preempt any State law, or the enactment or implementation of such a State law, that provides protections for individuals that are equivalent to or stricter than the protections provided under such provisions.''.

(c) CONFORMING AMENDMENTS.—(1) Section 732(a) of such Act (29 U.S.C. 1185(a)) is amended by striking ''section 711'' and inserting ''sections 711 and 713''.

(2) The table of contents in section 1 of such Act is amended by inserting after the item relating to section 712 the following new item:

''Sec. 713. Consumer protection standards.''.

(3) Section 734 of such Act (29 U.S.C. 1187) is amended by inserting ''and section 713(d)'' after ''of 1996''.

(d) EFFECTIVE DATE.—(1) Subject to paragraph (2), the amendments made by this section shall apply with respect to group health plans for plan years beginning on or after July 1, 1998 (in this subsection referred to as the ''general effective date'') and also shall apply to portions of plan years occurring on and after January 1, 1999.

(2) In the case of a group health plan maintained pursuant to 1 or more collective bargaining agreements between employee representatives and 1 or more employers ratified before the date of enactment of this Act, the amendments made by this section shall not apply to plan years beginning before the later of—

(A) the date on which the last collective bargaining agreements relating to the plan terminates (determined without regard to any extension thereof

agreed to after the date of enactment of this Act), or

(B) the general effective date.

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

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