105TH CONGRESS
1ST SESSION

S. 373

To amend title XXVII of the Public Health Service Act and part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 to establish standards for protection of consumers in managed care plans and other health plans.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 27, 1997

Mr. KENNEDY introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

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A BILL

To amend title XXVII of the Public Health Service Act and part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 to establish standards for protection of consumers in managed care plans and other health plans.

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

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Health Insurance Bill of Rights Act of 1997''.

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

Sec. 1. Short title; table of contents.
Sec. 2. Amendments to the Public Health Service Act.

"PART C—PATIENT PROTECTION STANDARDS

"Sec. 2770. Notice; additional definitions.

"SUBPART 1—ACCESS TO CARE

"Sec. 2771. Access to emergency care.
"Sec. 2772. Access to specialty care.
"Sec. 2773. Continuity of care.
"Sec. 2774. Choice of provider.
"Sec. 2775. Coverage for individuals participating in approved clinical trials.
"Sec. 2776. Access to needed prescription drugs.

"SUBPART 2—QUALITY ASSURANCE

"Sec. 2777. Internal quality assurance program.
"Sec. 2778. Collection of standardized data.
"Sec. 2779. Process for selection of providers.
"Sec. 2780. Drug utilization program.
"Sec. 2781. Standards for utilization review activities.

"SUBPART 3—PATIENT INFORMATION

"Sec. 2782. Patient information.
"Sec. 2783. Protection of patient confidentiality.

"SUBPART 4—GRIEVANCE PROCEDURES

"Sec. 2784. Establishment of complaint and appeals process.
"Sec. 2785. Provisions relating to appeals of utilization review determinations and similar determinations.
"Sec. 2786. State health insurance ombudsmen.

"SUBPART 5—PROTECTION OF PROVIDERS AGAINST INTERFERENCE WITH MEDICAL COMMUNICATIONS AND IMPROPER INCENTIVE ARRANGEMENTS

"Sec. 2787. Prohibition of interference with certain medical communications.
"Sec. 2788. Prohibition against transfer of indemnification or improper incentive arrangements.

"SUBPART 6—PROMOTING GOOD MEDICAL PRACTICE AND PROTECTING THE DOCTOR-PATIENT RELATIONSHIP

"Sec. 2789. Promoting good medical practice.
Sec. 3. Amendments to the Employee Retirement Income Security Act of 1974.
"Sec. 713. Patient protection standards.

SEC. 2. AMENDMENTS TO THE PUBLIC HEALTH SERVICE ACT.

(a) PATIENT PROTECTION STANDARDS.—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—PATIENT PROTECTION STANDARDS

''SEC. 2770. NOTICE; ADDITIONAL DEFINITIONS.

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

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

''(1) NONPARTICIPATING PHYSICIAN OR PROVIDER.—The term 'nonparticipating physician or provider' means, with respect to health care items and services furnished to an enrollee under health insurance coverage, a physician or provider that is not a participating physician or provider for such services.

''(2) PARTICIPATING PHYSICIAN OR PROVIDER.—The term 'participating physician or provider' means, with respect to health care items and services furnished to an enrollee under health insurance coverage, a physician or provider that furnishes such items and services under a contract or other arrangement with the health insurance issuer offering such coverage.

''SUBPART 1—ACCESS TO CARE

''SEC. 2771. ACCESS TO EMERGENCY CARE.

''(a) PROHIBITION OF CERTAIN RESTRICTIONS ON COVERAGE OF EMERGENCY SERVICES.

''(1) IN GENERAL.—If health insurance coverage provides any benefits with respect to emergency services (as defined in paragraph (2)(B)), the health insurance issuer offering such coverage shall cover emergency services furnished to an enrollee—

''(A) without the need for any prior authorization determination,

''(B) subject to paragraph (3), whether or not the physician or provider furnishing such services is a participating physician or provider with respect to such services, and

"(C) subject to paragraph (3), without regard to any other term or condition of such coverage (other than an exclusion of benefits, or an affiliation or waiting period, permitted under section 2701).

"(2) EMERGENCY SERVICES; EMERGENCY MEDICAL CONDITION.—For purposes of this section—

"(A) EMERGENCY MEDICAL CONDITION BASED ON PRUDENT LAYPERSON.—The term 'emergency medical condition' means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in—

"(i) placing the health of the individual (or, with respect to 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.

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

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

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

"(C) TRAUMA AND BURN CENTERS.—The provisions of clause (ii) of subparagraph (B) apply to a trauma or burn center, in a hospital, that—

"(i) is designated by the State, a regional authority of the State, or by the designee of the State, or

"(ii) is in a State that has not made such designations and meets medically recognized national standards.

"(3) APPLICATION OF NETWORK RESTRICTION PERMITTED IN CERTAIN CASES.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), if a health insurance issuer in relation to health insurance coverage denies, limits, or otherwise differentiates in coverage or payment for benefits other than emergency services on the basis that the physician or provider of such services is a nonparticipating physician or provider, the issuer may deny, limit, or differentiate in coverage or payment for emergency services on such basis.

"(B) NETWORK RESTRICTIONS NOT PERMITTED IN CERTAIN EXCEPTIONAL CASES.—The denial or limitation of, or differentiation in, coverage or payment of benefits for emergency services under subparagraph (A) shall not apply in the following cases:

"(i) CIRCUMSTANCES BEYOND CONTROL OF ENROLLEE.—The enrollee is unable to go to a participating hospital for such services due to circumstances beyond

the control of the enrollee (as determined consistent with guidelines and subparagraph (C)).

''(ii) LIKELIHOOD OF AN ADVERSE HEALTH CONSEQUENCE BASED ON LAYPERSON'S JUDGMENT.—A prudent layperson possessing an average knowledge of health and medicine could reasonably believe that, under the circumstances and consistent with guidelines, the time required to go to a participating hospital for such services could result in any of the adverse health consequences described in a clause of subsection (a)(2)(A).

''(iii) PHYSICIAN REFERRAL.—A participating physician or other person authorized by the plan refers the enrollee to an emergency department of a hospital and does not specify an emergency department of a hospital that is a participating hospital with respect to such services.

''(C) APPLICATION OF 'BEYOND CONTROL' STANDARDS.—For purposes of applying subparagraph (B)(i), receipt of emergency services

from a nonparticipating hospital shall be treated under the guidelines as being 'due to circumstances beyond the control of the enrollee' if any of the following conditions are met:

"(i) UNCONSCIOUS.—The enrollee was unconscious or in an otherwise altered mental state at the time of initiation of the services.

"(ii) AMBULANCE DELIVERY.—The enrollee was transported by an ambulance or other emergency vehicle directed by a person other than the enrollee to the nonparticipating hospital in which the services were provided.

"(iii) NATURAL DISASTER.—A natural disaster or civil disturbance prevented the enrollee from presenting to a participating hospital for the provision of such services.

"(iv) NO GOOD FAITH EFFORT TO INFORM OF CHANGE IN PARTICIPATION DURING A CONTRACT YEAR.—The status of the hospital changed from a participating hospital to a nonparticipating hospital with respect to emergency services during a contract year and the plan or issuer failed to

make a good faith effort to notify the enrollee involved of such change.

''(v) OTHER CONDITIONS.—There were other factors (such as those identified in guidelines) that prevented the enrollee from controlling selection of the hospital in which the services were provided.

''(b) ASSURING COORDINATED COVERAGE OF MAINTENANCE CARE AND POST-STABILIZATION CARE.—

''(1) IN GENERAL.—In the case of an enrollee who is covered under health insurance coverage issued by a health insurance issuer and who has received emergency services pursuant to a screening evaluation conducted (or supervised) by a treating physician at a hospital that is a nonparticipating provider with respect to emergency services, if—

''(A) pursuant to such evaluation, the physician identifies post-stabilization care (as defined in paragraph (3)(B)) that is required by the enrollee,

''(B) the coverage provides benefits with respect to the care so identified and the coverage requires (but for this subsection) an affirmative prior authorization determination as a condition of coverage of such care, and

"(C) the treating physician (or another individual acting on behalf of such physician) initiates, not later than 30 minutes after the time the treating physician determines that the condition of the enrollee is stabilized, a good faith effort to contact a physician or other person authorized by the issuer (by telephone or other means) to obtain an affirmative prior authorization determination with respect to the care,

then, without regard to terms and conditions specified in paragraph (2) the issuer shall cover maintenance care (as defined in paragraph (3)(A)) furnished to the enrollee during the period specified in paragraph (4) and shall cover post-stabilization care furnished to the enrollee during the period beginning under paragraph (5) and ending under paragraph (6).

"(2) TERMS AND CONDITIONS WAIVED.—The terms and conditions (of coverage) described in this paragraph that are waived under paragraph (1) are as follows:

"(A) The need for any prior authorization determination.

"(B) Any limitation on coverage based on whether or not the physician or provider furnishing the care is a participating physician or provider with respect to such care.

"(C) Any other term or condition of the coverage (other than an exclusion of benefits, or an affiliation or waiting period, permitted under section 2701 and other than a requirement relating to medical necessity for coverage of benefits).

"(3) MAINTENANCE CARE AND POST-STABILIZATION CARE DEFINED.—In this subsection:

"(A) MAINTENANCE CARE.—The term 'maintenance care' means, with respect to an individual who is stabilized after provision of emergency services, medically necessary items and services (other than emergency services) that are required by the individual to ensure that the individual remains stabilized during the period described in paragraph (4).

"(B) POST-STABILIZATION CARE.—The term 'post-stabilization care' means, with respect to an individual who is determined to be

stable pursuant to a medical screening examination or who is stabilized after provision of emergency services, medically necessary items and services (other than emergency services and other than maintenance care) that are required by the individual.

''(4) PERIOD OF REQUIRED COVERAGE OF MAINTENANCE CARE.—The period of required coverage of maintenance care of an individual under this subsection begins at the time of the request (or the initiation of the good faith effort to make the request) under paragraph (1)(C) and ends when—

''(A) the individual is discharged from the hospital;

''(B) a physician (designated by the issuer involved) and with privileges at the hospital involved arrives at the emergency department of the hospital and assumes responsibility with respect to the treatment of the individual; or

''(C) the treating physician and the issuer agree to another arrangement with respect to the care of the individual.

''(5) WHEN POST-STABILIZATION CARE REQUIRED TO BE COVERED.—

"(A) WHEN TREATING PHYSICIAN UNABLE TO COMMUNICATE REQUEST.—If the treating physician or other individual makes the good faith effort to request authorization under paragraph (1)(C) but is unable to communicate the request directly with an authorized person referred to in such paragraph within 30 minutes after the time of initiating such effort, then post-stabilization care is required to be covered under this subsection beginning at the end of such 30-minute period.

"(B) WHEN ABLE TO COMMUNICATE REQUEST, AND NO TIMELY RESPONSE.—

"(i) IN GENERAL.—If the treating physician or other individual under paragraph (1)(C) is able to communicate the request within the 30-minute period described in subparagraph (A), the post-stabilization care requested is required to be covered under this subsection beginning 30 minutes after the time when the issuer receives the request unless a person authorized by the plan or issuer involved communicates (or makes a good faith effort to communicate) a denial of the request for

the prior authorization determination within 30 minutes of the time when the issuer receives the request and the treating physician does not request under clause (ii) to communicate directly with an authorized physician concerning the denial.

''(ii) REQUEST FOR DIRECT PHYSICIAN-TO-PHYSICIAN COMMUNICATION CONCERNING DENIAL.—If a denial of a request is communicated under clause (i), the treating physician may request to communicate respecting the denial directly with a physician who is authorized by the issuer to deny or affirm such a denial.

''(C) WHEN NO TIMELY RESPONSE TO REQUEST FOR PHYSICIAN-TO-PHYSICIAN COMMUNICATION.—If a request for physician-to-physician communication is made under subparagraph (B)(ii), the post-stabilization care requested is required to be covered under this subsection beginning 30 minutes after the time when the issuer receives the request from a treating physician unless a physician, who is authorized by the issuer to reverse or affirm the initial denial of the care, communicates (or

makes a good faith effort to communicate) directly with the treating physician within such 30-minute period.

"(D) DISAGREEMENTS OVER POST-STABILIZATION CARE.—If, after a direct physician-to-physician communication under subparagraph (C), the denial of the request for the post-stabilization care is not reversed and the treating physician communicates to the issuer involved a disagreement with such decision, the post-stabilization care requested is required to be covered under this subsection beginning as follows:

"(i) DELAY TO ALLOW FOR PROMPT ARRIVAL OF PHYSICIAN ASSUMING RESPONSIBILITY.—If the issuer communicates that a physician (designated by the plan or issuer) with privileges at the hospital involved will arrive promptly (as determined under guidelines) at the emergency department of the hospital in order to assume responsibility with respect to the treatment of the enrollee involved, the required coverage of the post-stabilization care begins after the passage of such time

period as would allow the prompt arrival of such a physician.

"(ii) OTHER CASES.—If the issuer does not so communicate, the required coverage of the post-stabilization care begins immediately.

"(6) NO REQUIREMENT OF COVERAGE OF POST-STABILIZATION CARE IF ALTERNATE PLAN OF TREATMENT.—

"(A) IN GENERAL.—Coverage of post-stabilization care is not required under this subsection with respect to an individual when—

"(i) subject to subparagraph (B), a physician (designated by the plan or issuer involved) and with privileges at the hospital involved arrives at the emergency department of the hospital and assumes responsibility with respect to the treatment of the individual; or

"(ii) the treating physician and the issuer agree to another arrangement with respect to the post-stabilization care (such as an appropriate transfer of the individual

involved to another facility or an appointment for timely followup treatment for the individual).

"(B) SPECIAL RULE WHERE ONCE CARE INITIATED.—Required coverage of requested post-stabilization care shall not end by reason of subparagraph (A)(i) during an episode of care (as determined by guidelines) if the treating physician initiated such care (consistent with a previous paragraph) before the arrival of a physician described in such subparagraph.

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

"(A) preventing an issuer from authorizing coverage of maintenance care or post-stabilization care in advance or at any time; or

"(B) preventing a treating physician or other individual described in paragraph (1)(C) and an issuer from agreeing to modify any of the time periods specified in paragraphs (5) as it relates to cases involving such persons.

"(c) LIMITS ON COST-SHARING FOR SERVICES FURNISHED IN EMERGENCY DEPARTMENTS.—If health insurance coverage provides any benefits with respect to emergency services, the health insurance issuer offering such

coverage may impose cost sharing with respect to such services only if the following conditions are met:

"(1) LIMITATIONS ON COST-SHARING DIFFERENTIAL FOR NONPARTICIPATING PROVIDERS.—

"(A) NO DIFFERENTIAL FOR CERTAIN SERVICES.—In the case of services furnished under the circumstances described in clause (i), (ii), or (iii) of subsection (a)(3)(B) (relating to circumstances beyond the control of the enrollee, the likelihood of an adverse health consequence based on layperson's judgment, and physician referral), the cost-sharing for such services provided by a nonparticipating provider or physician does not exceed the cost-sharing for such services provided by a participating provider or physician.

"(B) ONLY REASONABLE DIFFERENTIAL FOR OTHER SERVICES.—In the case of other emergency services, any differential by which the cost-sharing for such services provided by a nonparticipating provider or physician exceeds the cost-sharing for such services provided by a participating provider or physician is reasonable (as determined under guidelines).

''(2) ONLY REASONABLE DIFFERENTIAL BETWEEN EMERGENCY SERVICES AND OTHER SERVICES.—Any differential by which the cost-sharing for services furnished in an emergency department exceeds the cost-sharing for such services furnished in another setting is reasonable (as determined under guidelines).

''(3) CONSTRUCTION.—Nothing in paragraph (1)(B) or (2) shall be construed as authorizing guidelines other than guidelines that establish maximum cost-sharing differentials.

''(d) INFORMATION ON ACCESS TO EMERGENCY SERVICES.—A health insurance issuer, to the extent a health insurance issuer offers health insurance coverage, shall provide education to enrollees on—

''(1) coverage of emergency services (as defined in subsection (a)(2)(B)) by the issuer in accordance with the provisions of this section,

''(2) the appropriate use of emergency services, including use of the 911 telephone system or its local equivalent,

''(3) any cost sharing applicable to emergency services,

''(4) the process and procedures of the plan for obtaining emergency services, and

''(5) the locations of—

''(A) emergency departments, and

''(B) other settings,

in which participating physicians and hospitals provide emergency services and post-stabilization care.

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

''(1) COST SHARING.—The term 'cost sharing' means any deductible, coinsurance amount, copayment or other out-of-pocket payment (other than premiums or enrollment fees) that a health insurance issuer offering health insurance issuer imposes on enrollees with respect to the coverage of benefits.

''(2) GOOD FAITH EFFORT.—The term 'good faith effort' has the meaning given such term in guidelines and requires such appropriate documentation as is specified under such guidelines.

''(3) GUIDELINES.—The term 'guidelines' means guidelines established by the Secretary after consultation with an advisory panel that includes individuals representing emergency physicians, health insurance issuers, including at least one health maintenance organization, hospitals, employers, the States, and consumers.

''(4) PRIOR AUTHORIZATION DETERMINATION.—The term 'prior authorization determination' means, with respect to items and services for which coverage may be provided under health insurance coverage, a determination (before the provision of the items and services and as a condition of coverage of the items and services under the coverage) of whether or not such items and services will be covered under the coverage.

''(5) STABILIZE.—The term 'to stabilize' means, with respect to an emergency medical condition, to provide (in complying with section 1867 of the Social Security Act) 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 the facility.

''(6) STABILIZED.—The term 'stabilized' means, with respect to an emergency medical condition, that no material deterioration of the condition

is likely, within reasonable medical probability, to result from or occur before an individual can be transferred from the facility, in compliance with the requirements of section 1867 of the Social Security Act.

''(7) TREATING PHYSICIAN.—The term 'treating physician' includes a treating health care professional who is licensed under State law to provide emergency services other than under the supervision of a physician.

"SEC. 2772. ACCESS TO SPECIALTY CARE.

''(a) 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 gynecological 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.

''(b) SPECIALTY CARE.—

''(1) REFERRAL TO SPECIALTY CARE FOR ENROLLEES REQUIRING TREATMENT BY SPECIALISTS.—

''(A) 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.

''(B) 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.

''(C) CARE UNDER REFERRAL.—Care provided pursuant to such referral under subparagraph (A) shall be—

''(i) 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

"(ii) 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.

"(D) REFERRALS TO PARTICIPATING PROVIDERS.—An issuer is not required under subparagraph (A) 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.

"(E) 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.

''(2) SPECIALISTS AS PRIMARY CARE PROVIDERS.—

''(A) IN GENERAL.—A health insurance issuer, in connection with the provision of health insurance coverage, shall have a procedure by which a new enrollee upon enrollment, or an enrollee upon diagnosis, with an ongoing special condition (as defined in subparagraph (C)) may receive a referral to a specialist for such condition who shall be responsible for and capable of providing and coordinating the enrollee's primary and specialty care. If such an enrollee's care would most appropriately be coordinated by such a specialist, the issuer shall refer the enrollee to such specialist.

''(B) TREATMENT AS PRIMARY CARE PROVIDER.—Such specialist shall be permitted to treat the enrollee without a referral from the enrollee's primary care provider and may authorize such referrals, procedures, tests, and other medical services as the enrollee's primary care provider would otherwise be permitted to provide or authorize, subject to the terms of the

treatment plan (referred to in paragraph (1)(C)(i)).

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

''(i) is life-threatening, degenerative, or disabling, and

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

''(D) TERMS OF REFERRAL.—The provisions of subparagraphs (C) through (E) of paragraph (1) shall apply with respect to referrals under subparagraph (A) of this paragraph in the same manner as they apply to referrals under paragraph (1)(A).

''(3) STANDING REFERRALS.—

''(A) IN GENERAL.—A health insurance issuer, in connection with the provision of health insurance coverage, shall have a procedure by which an enrollee who has a condition that requires ongoing care from a specialist may receive a standing referral to such specialist for treatment of such condition. If the issuer, or the primary care provider in consultation with

the medical director of the issuer and the specialist (if any), determines that such a standing referral is appropriate, the issuer shall make such a referral to such a specialist.

''(C) TERMS OF REFERRAL.—The provisions of subparagraphs (C) through (E) of paragraph (1) shall apply with respect to referrals under subparagraph (A) of this paragraph in the same manner as they apply to referrals under paragraph (1)(A).

''SEC. 2773. CONTINUITY OF CARE.

''(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 undergoing a course of treatment from the provider at the time of such termination, the issuer shall—

''(1) notify the enrollee of such termination, and

''(2) subject to subsection (c), permit the enrollee to continue the course of treatment with the provider during a transitional period (provided under subsection (b)).

''(b) TRANSITIONAL PERIOD.—

''(1) IN GENERAL.—Except as provided in paragraphs (2) through (4), the transitional period under this subsection shall extend for at least—

''(A) 60 days from the date of the notice to the enrollee of the provider's termination in the case of a primary care provider, or

''(B) 120 days from such date in the case of another provider.

''(2) INSTITUTIONAL CARE.—The transitional period under this subsection 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.

''(3) PREGNANCY.—If—

''(A) an enrollee has entered the second trimester of pregnancy at the time of a provider's termination of participation, and

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

the transitional period under this subsection with respect to provider's treatment of the pregnancy shall

extend through the provision of post-partum care directly related to the delivery.

"(4) TERMINAL ILLNESS.—

"(A) IN GENERAL.—If—

"(i) an enrollee was determined to be terminally ill (as defined in subparagraph (B)) 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 subsection shall extend for the remainder of the enrollee's life for care directly related to the treatment of the terminal illness.

"(B) DEFINITION.—In subparagraph (A), 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 subsection (a)(2) upon the provider agreeing to the following terms and conditions:

''(1) 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.

''(2) 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.

''(3) 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.

''SEC. 2774. CHOICE OF PROVIDER.

''(a) PRIMARY CARE.—A health insurance issuer that offers health insurance coverage shall permit each enrollee to receive primary care from any participating primary care provider who is available to accept such enrollee.

''(b) SPECIALISTS.—

''(1) IN GENERAL.—Subject to paragraph (2), a health insurance issuer that offers health insurance

coverage shall permit each enrollee to receive medically necessary specialty care, pursuant to appropriate referral procedures, from any qualified participating health care provider who is available to accept such enrollee for such care.

''(2) LIMITATION.—Paragraph (1) shall not apply to speciality care if the issuer clearly informs enrollees of the limitations on choice of participating providers with respect to such care.

''(c) LIST OF PARTICIPATING PROVIDERS.—For disclosure of information about participating primary care and specialty care providers, see section 2782(b)(3).

''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. 2776. ACCESS TO NEEDED PRESCRIPTION DRUGS.

''If a health insurance issuer offers health insurance coverage 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.

''SUBPART 2—QUALITY ASSURANCE

''SEC. 2777. INTERNAL QUALITY ASSURANCE PROGRAM.

''(a) REQUIREMENT.—A health insurance issuer that offers health insurance coverage shall establish and maintain an ongoing, internal quality assurance and continuous quality improvement program that meets the requirements of subsection (b).

''(b) PROGRAM REQUIREMENTS.—The requirements of this subsection for a quality improvement program of an issuer are as follows:

''(1) ADMINISTRATION.—The issuer has a separate identifiable unit with responsibility for administration of the program.

''(2) WRITTEN PLAN.—The issuer has a written plan for the program that is updated annually and that specifies at least the following:

''(A) The activities to be conducted.

''(B) The organizational structure.

''(C) The duties of the medical director.

''(D) Criteria and procedures for the assessment of quality.

''(E) Systems for ongoing and focussed evaluation activities.

''(3) SYSTEMATIC REVIEW.—The program provides for systematic review of the type of health services provided, consistency of services provided with good medical practice, and patient outcomes.

''(4) QUALITY CRITERIA.—The program—

''(A) uses criteria that are based on performance and clinical outcomes where feasible and appropriate, and

''(B) includes criteria that are directed specifically at meeting the needs of at-risk populations and enrollees with chronic or severe illnesses.

''(5) SYSTEM FOR REPORTING.—The program has procedures for reporting of possible quality concerns by providers and enrollees and for remedial actions to correct quality problems, including written procedures for responding to concerns and taking appropriate corrective action.

''(6) DATA COLLECTION.—The program provides for the collection of systematic, scientifically based data to be used in the measure of quality.

''(c) DEEMING.—For purposes of subsection (a), the requirements of subsection (b) are deemed to be met with respect to a health insurance issuer if the issuer—

''(1) is a qualified health maintenance organization (as defined in section 1310(d)), or

''(2) is accredited by a national accreditation organization that is certified by the Secretary.

''SEC. 2778. COLLECTION OF STANDARDIZED DATA.

''(a) IN GENERAL.—A health insurance issuer that offers health insurance coverage shall collect uniform quality data that include—

''(1) a minimum uniform data set described in subsection (b), and

''(2) additional data that are consistent with the requirements of a nationally recognized body identified by the Secretary.

''(b) MINIMUM UNIFORM DATA SET.—The Secretary shall specify the data required to be included in the minimum uniform data set under subsection (a)(1) and the standard format for such data. Such data shall include at least—

''(1) aggregate utilization data;

''(2) data on the demographic characteristics of enrollees;

''(3) data on disease-specific and age-specific mortality rates of enrollees;

''(4) data on enrollee satisfaction, including data on enrollee disenrollment and grievances; and

''(5) data on quality indicators.

''(c) AVAILABILITY.—A summary of the data collected under subsection (a) shall be disclosed under section 2782(b)(4).

''SEC. 2779. PROCESS FOR SELECTION OF PROVIDERS.

''(a) IN GENERAL.—A health insurance issuer that offers health insurance coverage shall have a written process for the selection of participating health care professionals, including minimum professional requirements.

''(b) VERIFICATION OF BACKGROUND.—Such process shall include verification of a health care provider's license, a history of suspension or revocation, and liability claim history.

''(c) RESTRICTION.—Such process shall not use a high-risk patient base or location of a provider in an area with residents with poorer health status as a basis for excluding providers from participation.

"SEC. 2780. 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.

"SEC. 2781. STANDARDS FOR UTILIZATION REVIEW ACTIVITIES.

"(a) COMPLIANCE WITH REQUIREMENTS.—

"(1) IN GENERAL.—A health insurance issuer shall conduct utilization review activities in connection with the provision of health insurance coverage only in accordance with a utilization review program that meets the requirements of this section.

"(2) USE OF OUTSIDE AGENTS.—Nothing in this section shall be construed as preventing a health insurance issuer from arranging through a contract or otherwise for persons or entities to conduct utilization review activities on behalf of the issuer, so

long as such activities are conducted in accordance with a utilization review program that meets the requirements of this section.

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

''(b) WRITTEN POLICIES AND CRITERIA.—

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

''(2) USE OF WRITTEN CRITERIA.—

''(A) IN GENERAL.—Such a program shall utilize written clinical review criteria developed pursuant to the program with the input of appropriate physicians.

''(B) CONTINUING USE OF STANDARDS IN RETROSPECTIVE REVIEW.—If a health care service has been specifically pre-authorized or

approved for an enrollee under such a program, the program shall not, pursuant to retrospective review, revise or modify the specific standards, criteria, or procedures used for the utilization review for procedures, treatment, and services delivered to the enrollee during the same course of treatment.

''(C) NO ADVERSE DETERMINATION BASED ON REFUSAL TO OBSERVE SERVICE.—Such a program shall not base an adverse determination on—

''(i) a refusal to consent to observing any health care service, or

''(ii) lack of reasonable access to a health care provider's medical or treatment records, unless the program has provided reasonable notice to the enrollee.

''(c) CONDUCT OF PROGRAM ACTIVITIES.—

''(1) ADMINISTRATION BY HEALTH CARE PROFESSIONALS.—A utilization review program shall be administered by qualified health care professionals who shall oversee review decisions. In this subsection, the term 'health care professional' means a physician or other health care practitioner licensed,

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

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

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

''(B) PEER REVIEW OF ADVERSE CLINICAL DETERMINATIONS.—Such a program shall provide that clinical peers shall evaluate the clinical appropriateness of adverse clinical determinations. In this subsection, the term 'clinical peer' means, with respect to a review, a physician or other health care professional who holds a nonrestricted license in a State and in the same or similar specialty as typically manages the medical condition, procedure, or treatment under review.

''(C) PROHIBITION OF CONTINGENT COMPENSATION ARRANGEMENTS.—Such a program

shall not, with respect to utilization review activities, permit or provide compensation or anything of value to its employees, agents, or contractors in a manner that—

"(i) provides incentives, direct or indirect, for such persons to make inappropriate review decisions, or

"(ii) is based, directly or indirectly, on the quantity or type of adverse determinations rendered.

"(D) PROHIBITION OF CONFLICTS.—Such a program shall not permit a health care professional who provides health care services to an enrollee to perform utilization review activities in connection with the health care services being provided to the enrollee.

"(3) TOLL-FREE TELEPHONE NUMBER.—Such a program shall provide that—

"(A) appropriate personnel performing utilization review activities under the program are reasonably accessible by toll-free telephone not less than 40 hours per week during normal business hours to discuss patient care and allow response to telephone requests, and

''(B) the program has a telephone system capable of accepting, recording, or providing instruction to incoming telephone calls during other than normal business hours and to ensure response to accepted or recorded messages not less than one business day after the date on which the call was received.

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

''(5) LIMITATION ON INFORMATION REQUESTS.—Under such a program, information shall be required to be provided by health care providers only to the extent it is necessary to perform the utilization review activity involved.

''(d) DEADLINE FOR DETERMINATIONS.—

''(1) PRIOR AUTHORIZATION SERVICES.—Except as provided in paragraph (2), in the case of a utilization review activity involving the prior authorization of health care items and services, the utilization review program shall make a determination concerning such authorization, and provide notice of the

determination to the enrollee or the enrollee's designee and the enrollee's health care provider by telephone and in writing, as soon as possible in accordance with the medical exigencies of the cases, and in no event later than 3 business days after the date of receipt of the necessary information respecting such determination.

''(2) CONTINUED CARE.—In the case of a utilization review activity involving authorization for continued or extended health care services, or additional services for an enrollee undergoing a course of continued treatment prescribed by a health care provider, the utilization review program shall make a determination concerning such authorization, and provide notice of the determination to the enrollee or the enrollee's designee and the enrollee's health care provider by telephone and in writing, within 1 business day of the date of receipt of the necessary information respecting such determination. Such notice shall include, with respect to continued or extended health care services, the number of extended services approved, the new total of approved services, the date of onset of services, and the next review date.

''(3) PREVIOUSLY PROVIDED SERVICES.—In the case of a utilization review activity involving retrospective review of health care services previously provided, the utilization review program shall make a determination concerning such services, and provide notice of the determination to the enrollee or the enrollee's designee and the enrollee's health care provider by telephone and in writing, within 30 days of the date of receipt of the necessary information respecting such determination.

''(4) REFERENCE TO SPECIAL RULES FOR EMERGENCY SERVICES, MAINTENANCE CARE, AND POST-STABILIZATION CARE.—For waiver of prior authorization requirements in certain cases involving emergency services and maintenance care and post-stabilization care, see sections 2771(a)(1)(A) and 2771(a)(2)(A), respectively.

''(e) NOTICE OF ADVERSE DETERMINATIONS.—

''(1) IN GENERAL.—Notice of an adverse determination under a utilization review program (including as a result of a reconsideration under subsection (f)) shall be in writing and shall include—

''(A) the reasons for the determination (including the clinical rationale);

''(B) instructions on how to initiate an appeal under section 2785; and

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

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

''(f) RECONSIDERATION.—

''(1) AT REQUEST OF PROVIDER.—In the event that a utilization review program provides for an adverse determination without attempting to discuss such matter with the enrollee's health care provider who specifically recommended the health care service, procedure, or treatment under review, such health care provider shall have the opportunity to request a reconsideration of the adverse determination under this subsection.

''(2) TIMING AND CONDUCT.—Except in cases of retrospective reviews, such reconsideration shall occur as soon as possible in accordance with the

medical exigencies of the cases, and in no event later than 1 business day after the date of receipt of the request and shall be conducted by the enrollee's health care provider and the health care professional making the initial determination or a designated qualified health care professional if the original professional cannot be available.

''(3) NOTICE.—In the event that the adverse determination is upheld after reconsideration, the utilization review program shall provide notice as required under subsection (e).

''(4) CONSTRUCTION.—Nothing in this subsection shall preclude the enrollee from initiating an appeal from an adverse determination under section 2785.

''SUBPART 3—PATIENT INFORMATION

''SEC. 2782. PATIENT INFORMATION.

''(a) DISCLOSURE REQUIREMENT.—A health insurance issuer in connection with the provision of health insurance coverage shall submit to the applicable State authority, provide to enrollees (and prospective enrollees), and make available to the public, in writing the information described in subsection (b).

''(b) INFORMATION.—The information described in this subsection includes the following:

''(1) DESCRIPTION OF COVERAGE.—A description of coverage provisions, including health care benefits, benefit limits, coverage exclusions, coverage of emergency care, and the definition of medical necessity used in determining whether benefits will be covered.

''(2) ENROLLEE FINANCIAL RESPONSIBILITY.—An explanation of an enrollee's financial responsibility for payment of premiums, coinsurance, copayments, deductibles, and any other charges, including limits on such responsibility and responsibility for health care services that are provided by nonparticipating providers or are furnished without meeting applicable utilization review requirements.

''(3) INFORMATION ON PROVIDERS.—A description—

''(A) of procedures for enrollees to select, access, and change participating primary and specialty providers,

''(B) of the rights and procedures for obtaining referrals (including standing referrals) to participating and nonparticipating providers, and

"(C) in the case of each participating provider, of the name, address, and telephone number of the provider, the credentials of the provider, and the provider's availability to accept new patients.

"(4) UTILIZATION REVIEW ACTIVITIES.—A description of procedures used and requirements (including circumstances, time frames, and rights to reconsideration and appeal) under any utilization review program under section 2781 or any drug utilization program under section 2780, as well as a summary of the minimum uniform data collected under section 2778(a)(1).

"(5) GRIEVANCE PROCEDURES.—Information on the grievance procedures under sections 2784 and 2785, including information describing—

"(A) the grievance procedures used by the issuer to process and resolve disputes between the issuer and an enrollee (including method for filing grievances and the time frames and circumstances for acting on grievances);

"(B) written complaints and appeals, by type of complaint or appeal, received by the issuer relating to its coverage; and

''(C) the disposition of such complaints and appeals.

''(6) PAYMENT METHODOLOGY.—A description of the types of methodologies the issuer uses to reimburse different classes of providers and, as specified by the Secretary, the financial arrangements or contractual provisions with providers.

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

''(8) ASSURING COMMUNICATIONS WITH ENROLLEES.—A description of how the issuer addresses the needs of non-English-speaking enrollees and others with special communications needs, including the provision of information described in this subsection to such enrollees.

''(c) FORM OF DISCLOSURE.—

''(1) UNIFORMITY.—Information required to be disclosed under this section shall be provided in accordance with uniform, national reporting standards specified by the Secretary, after consultation with applicable State authorities, so that prospective enrollees may compare the attributes of different issuers and coverage offered within an area.

''(2) INFORMATION INTO HANDBOOK.—Nothing in this section shall be construed as preventing an issuer from making the information under subsection (b) available to enrollees through an enrollee handbook or similar publication.

''(3) UPDATING.—The information on participating providers described in subsection (a)(3)(C) shall be updated not less frequently than monthly. Nothing in this section shall prevent an issuer from changing or updating other information made available under this section.

''(4) CONSTRUCTION.—Nothing in subsection (a)(6) shall be construed as requiring disclosure of individual contracts or financial arrangements between an issuer and any provider. Nothing in this subsection shall be construed as preventing the information described in subsection (a)(3)(C) from being provided in a separate document.

''SEC. 2783. PROTECTION OF PATIENT CONFIDENTIALITY.

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

''SUBPART 4—GRIEVANCE PROCEDURES

''SEC. 2784. ESTABLISHMENT OF COMPLAINT AND APPEALS PROCESS.

''(a) ESTABLISHMENT OF SYSTEM.—A health insurance issuer in connection with the provision of health insurance coverage shall establish and maintain a system to provide for the presentation and resolution of complaints and appeals brought by enrollees, designees of enrollees, or by health care providers acting on behalf of an enrollee and with the enrollee's consent, regarding any aspect of the issuer's health care services, including complaints regarding quality of care, choice and accessibility of providers, network adequacy, and compliance with the requirements of this part.

''(b) COMPONENTS OF SYSTEM.—Such system shall include the following components (which shall be consistent with applicable requirements of section 2785):

''(1) Written notification to all enrollees and providers of the telephone numbers and business addresses of the issuer employees responsible for resolution of complaints and appeals.

''(2) A system to record and document, over a period of at least 3 years, all complaints and appeals made and their status.

''(3) The availability of an enrollee services representative to assist enrollees, as requested, with complaint and appeal procedures.

''(4) Establishment of a specified deadline (not to exceed 30 days after the date of receipt of a complaint or appeal) for the issuer to respond to complaints or appeals.

''(5) A process describing how complaints and appeals are processed and resolved.

''(6) Procedures for follow-up action, including the methods to inform the complainant or appellant of the resolution of a complaint or appeal.

''(7) Notification to the continuous quality improvement program under section 2777(a) of all complaints and appeals relating to quality of care.

''(c) NO REPRISAL FOR EXERCISE OF RIGHTS.—A health insurance issuer shall not take any action with respect to an enrollee or a health care provider that is intended to penalize the enrollee, a designee of the enrollee, or the health care provider for discussing or exercising any rights provided under this part (including the filing of a complaint or appeal pursuant to this section).

"SEC. 2785. PROVISIONS RELATING TO APPEALS OF UTILIZATION REVIEW DETERMINATIONS AND SIMILAR DETERMINATIONS.

''(a) 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 this section and (to the extent applicable) section 2784. 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 and as provided in section 2782(a)(5)

''(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 section 2781.

''(B) Denial of access to specialty and other care under section 2772.

''(C) Denial of continuation of care under section 2773.

''(D) Denial of a choice of provider under section 2774.

"(E) Denial of coverage of routine patient costs in connection with an approval clinical trial under section 2775.

"(F) Denial of access to needed drugs under section 2776(3).

"(G) The imposition of a limitation that is prohibited under section 2789.

"(H) Denial of payment for a benefit,

"(b) 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 (c).

''(c) 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 (as defined in section 2781(c)(2)(B)) 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.

''(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.

''(d) 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 (b) or (c), 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.

''(e) 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 except 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.

"(f) 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 decision that does not involve a decision described in subsection (e)(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 described in paragraph (2), by health insurance coverage.

''(g) 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.

''SEC. 2786. 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).

''SUBPART 5—PROTECTION OF PROVIDERS AGAINST INTERFERENCE WITH MEDICAL COMMUNICATIONS AND IMPROPER INCENTIVE ARRANGEMENTS

''SEC. 2787. 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 a health insurance issuer in relation to health insurance coverage (including any partnership, association, or other organization that enters into or administers such a contract or agreement) and a health care provider (or group of health care providers) shall not prohibit or restrict the provider from engaging in medical communications with the provider's patient.

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

''(3) PROHIBITION ON PROVISIONS.—A contract or agreement described in paragraph (1) shall not include a provision that violates paragraph (1).

''(b) RULES OF CONSTRUCTION.—Nothing in this section 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 insurance issuer to assure, 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 health insurance coverage or to otherwise require a health insurance issuer to reimburse providers for benefits not covered under the coverage.

''(c) MEDICAL COMMUNICATION DEFINED.—

''(1) IN GENERAL.—In this section, 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—

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

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

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

"(2) 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.

"SEC. 2788. PROHIBITION AGAINST TRANSFER OF INDEMNIFICATION OR IMPROPER INCENTIVE ARRANGEMENTS.

"(a) PROHIBITION OF TRANSFER OF INDEMNIFICATION.—No contract or agreement between a health insurance issuer (or any agent acting on behalf of such an issuer) and a health care provider shall contain any clause

purporting to transfer to the health care provider by indemnification or otherwise any liability relating to activities, actions, or omissions of the issuer or agent (as opposed to the provider).

"(b) PROHIBITION OF IMPROPER PHYSICIAN INCENTIVE PLANS.—

"(1) IN GENERAL.—A health insurance issuer offering health insurance coverage may not operate any physician incentive plan unless the following requirements are met:

"(A) No specific payment is made directly or indirectly by the issuer to a physician or physician group as an inducement to reduce or limit medically necessary services provided with respect to a specific individual enrolled with the issuer.

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

"(i) provides stop-loss protection for the physician or group that is adequate

and appropriate, based on standards developed by the Secretary that take into account the number of physicians placed at such substantial financial risk in the group or under the plan and the number of individuals enrolled with the issuer who receive services from the physician or the physician 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 applicable State authority (or the Secretary if such authority is implementing this section) with descriptive information regarding the plan, sufficient to permit the authority (or the Secretary in such case) to determine whether the plan is in compliance with the requirements of this paragraph.

''(2) PHYSICIAN INCENTIVE PLAN DEFINED.—In this section, the term 'physician incentive plan'

means any compensation arrangement between a health insurance issuer and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services provided with respect to individuals enrolled with the issuer.

''(3) APPLICATION OF MEDICARE RULES.—The Secretary shall provide for the application of rules under this subsection that are substantially the same as the rules established to carry out section 1876(i)(8) of the Social Security Act.

''SUBPART 6—PROMOTING GOOD MEDICAL PRACTICE AND PROTECTING THE DOCTOR-PATIENT RELATIONSHIP

''SEC. 2789. PROMOTING GOOD MEDICAL PRACTICE.

''(a) PROHIBITING ARBITRARY LIMITATIONS OR CONDITIONS FOR THE PROVISION OF SERVICES.—A health insurance issuer, in connection with the provision of health insurance coverage, may not impose limits on the manner in which particular services are delivered if the services are medically necessary and appropriate for the treatment or diagnosis of an illness or injury to the extent that such treatment or diagnosis is otherwise a covered benefit.

''(b) MEDICAL NECESSITY AND APPROPRIATENESS DEFINED.—In subsection (a), the term 'medically necessary and appropriate' means, with respect to a service

or benefit, a service or benefit determined by the treating physician participating in the health insurance coverage after consultation with the enrollee, to be required, accordingly to generally accepted principles of good medical practice, for the diagnosis or direct care and treatment of an illness or injury of the enrollee.

''(c) CONSTRUCTION.—Subsection (a) shall not be construed as requiring coverage of particular services the coverage of which is otherwise not covered under the terms of the coverage.''.

(b) APPLICATION TO 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. PATIENT PROTECTION STANDARDS.

''(a) IN GENERAL.—Each health insurance issuer shall comply with patient 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''.

(c) 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. PATIENT PROTECTION STANDARDS.

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

(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 PATIENT PROTECTION REQUIREMENTS.—Subject to subsection (a)(2), the provisions of section 2706 and part C (other than section 2771), and part D insofar as it applies to section 2706 or part C, shall not prevent a State from establishing requirements relating to the subject matter of such provisions (other than section 2771) so long as such requirements are at least as stringent on health insurance issuers as the requirements imposed under such provisions. Subsection (a) shall apply to the provisions of section 2771 (and section 2706 insofar as it relates to such section).''.

(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 MANAGED CARE REQUIREMENTS.—Subject to subsection (b), the provisions of section 2752 and part C (other than section 2771), and part D insofar as it applies to section 2752 or part C, shall not prevent a State from establishing requirements relating to the subject matter of such provisions so long as such requirements are at least as stringent on health insurance issuers as the requirements imposed under such section. Subsection (a) shall apply to the provisions of section 2771 (and section 2752 insofar as it relates to such section).''.

(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 subsections (a), (b),

(d)(1), and (e) 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 subsections (a), (b), (d)(1), and (e) 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 subsection (a) or (b) shall not be

treated as a termination of such collective bargaining agreement.

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

SEC. 3. AMENDMENTS TO 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. PATIENT PROTECTION STANDARDS.

"(a) IN GENERAL.—Subject to subsection (b), a group health plan (and a health insurance issuer offering group health insurance coverage in connection with such a plan) shall comply with the requirements of part C (other than section 2786) of title XXVII of the Public Health Service Act.

"(b) APPLICATION.—In applying subsection (a) under this part, any reference in such subpart 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) GROUP HEALTH PLAN OMBUDSMAN.—With respect to group health plans that provide benefits other than through health insurance coverage, the Secretary shall provide for the establishment and maintenance of such a Federal Group Health Plan Ombudsman that will carry out with respect to such plans the functions described in section 2786(a) of the Public Health Service Act with respect to health insurance issuers that offer group health insurance coverage.

''(d) 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 PATIENT PROTECTION REQUIREMENTS.—Subject to subsection (a)(2), the provisions of section 713 and part C of title XXVII of the Public Health Service Act (other than section 2771 of such Act), and subpart C insofar as it applies to section

713 or such part, shall not prevent a State from establishing requirements relating to the subject matter of such provisions (other than section 2771 of such Act) so long as such requirements are at least as stringent on health insurance issuers as the requirements imposed under such provisions. Subsection (a) shall apply to the provisions of section 2771 of such Act (and section 713 of this Act insofar as it relates to such section).''.

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