I

105TH CONGRESS
1ST SESSION

H. R. 1222

To amend the Employee Retirement Income Security Act of 1974 and the Public Health Service Act to require managed care group health plans and managed care health insurance coverage to meet certain consumer protection requirements.

IN THE HOUSE OF REPRESENTATIVES

MARCH 21, 1997

Mrs. ROUKEMA introduced the following bill; which was referred to the Committee on Education and the Workforce, and in addition to the Committee on Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To amend the Employee Retirement Income Security Act of 1974 and the Public Health Service Act to require managed care group health plans and managed care health insurance coverage to meet certain consumer protection requirements.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Quality Health Care and Consumer Protection Act''.

SEC. 2. PURPOSE.

The purpose of this Act is to ensure that enrollees in managed care group health plans and managed care health insurance coverage receive adequate health care services by ensuring that—

(1) enrollees have full and timely access to clinically appropriate health care personnel and facilities;

(2) enrollees have adequate choice among health care professionals who are accessible and qualified;

(3) there is open communication between physicians and enrollees;

(4) enrollees have access to comprehensive pharmaceutical services;

(5) enrollees have access to information regarding limits on coverage of experimental treatments;

(6) there is high quality care provided within the plan or coverage;

(7) medical decisions are made by the appropriate medical personnel;

(8) participating health care professionals are practitioners in good standing;

(9) data on the plan or coverage are available as appropriate;

(10) there is full public access to information regarding health care service delivery within the plan or coverage;

(11) there is a fair vehicle for resolving enrollee complaints under the plan or coverage; and

(12) there is timely resolution of enrollee grievances and appeals.

SEC. 3. QUALITY HEALTH CARE AND CONSUMER PROTECTION ACT UNDER GROUP HEALTH PLANS AND GROUP HEALTH INSURANCE COVERAGE.

(a) ERISA AMENDMENTS.—(1) Subpart B of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974, as amended by section 702(a) of Public Law 104–204, is amended by adding at the end the following new section:

"SEC. 713. QUALITY HEALTH CARE AND CONSUMER PROTECTION ACT.

''(a) ACCESS TO PERSONNEL AND FACILITIES.—

''(1) IN GENERAL.—A managed care group health plan (and a health insurance issuer offering managed care group health insurance) shall—

''(A) include a sufficient number and type of primary care practitioners and specialists, throughout the service area, to meet the needs of enrollees and to provide meaningful choice; and

''(B) demonstrate that it offers the following:

''(i) An adequate number of accessible acute care hospital services, within a reasonable distance and travel time for enrollees.

''(ii) An adequate number of accessible primary care practitioners, within a reasonable distance and travel time for enrollees.

''(iii) An adequate number of accessible specialists and subspecialists, within a reasonable distance and travel time for enrollees.

''(iv) The availability of specialty medical services, including physical therapy, occupational therapy, and rehabilitation services.

''(v) The availability of specialists who are not participating providers or professionals, when a patient's unique medical circumstances warrant it.

Clause (iii) shall be construed as requiring access to nonparticipating health care professionals who are specialists for treatment of a specific condition if and when there are not suf-

ficient number of such specialists who are participating health care professionals.

''(2) CONTINUITY OF CARE.—A managed care group health plan (and a health insurance issuer offering managed care group health insurance) shall—

''(A) provide for continuity of care with established primary care practitioners, when the health care professional's contract is terminated, and

''(B) allow enrollees, at no additional out-of-pocket cost, to continue receiving services from a primary care practitioner whose contract with the plan or issuer is terminated without cause for a period of at least 60 days if the enrollee requests such continuation.

''(3) TELEPHONE ACCESS.—A managed care group health plan (and a health insurance issuer offering managed care group health insurance) shall provide telephone access to the plan or issuer for sufficient time during business and evening hours to ensure enrollee access for routine care, and 24 hour telephone access to either the plan, issuer, or a participating provider or professional, for emergency care or authorization for such care.

''(4) STANDARDS FOR WAITING TIMES.—A managed care group health plan (and a health insurance issuer offering managed care group health insurance) shall establish reasonable standards for waiting times for enrollees to obtain appointments, subject to special rules for emergency services under paragraph (5). Such standards shall include appointment scheduling guidelines based on the type of health care service, including prenatal care appointments, well-child visits and immunizations, routine physicals, follow-up appointments for chronic conditions, and urgent care.

''(5) COVERAGE OF EMERGENCY SERVICES.—

''(A) IN GENERAL.—A managed care group health plan (and a health insurance issuer offering managed care group health insurance) shall cover and reimburse expenses for treatment of an emergency medical condition if the treatment is obtained, without prior authorization.

''(B) EMERGENCY MEDICAL CONDITION DEFINED.—The term 'emergency medical condition' means a medical condition, the onset of which is sudden and unexpected, that manifests itself by symptoms of sufficient severity, that a

prudent layperson, who possesses an average knowledge of health and medicine, could reasonably assume that the condition requires immediate medical treatment, and could expect the absence of medical attention to result in serious impairment to bodily functions or place the person's health in serious jeopardy.

''(C) PRUDENT LAYPERSON DEFINED.—In this paragraph, the term 'prudent layperson' means a person without specific medical training for the illness or condition in question who acts as a reasonable person would under similar circumstances.

''(b) ASSURING ADEQUATE CHOICE OF HEALTH CARE PROFESSIONALS.—

''(1) IN GENERAL.—A managed care group health plan (and a health insurance issuer offering managed care group health insurance) shall provide that each enrollee shall have adequate choice among participating health care professionals who are accessible and qualified.

''(2) CHOICE.—A managed care group health plan (and a health insurance issuer offering managed care group health insurance) shall permit enrollees to choose their own primary care practitioner

from a list of health care professionals within the plan or coverage. Such list shall be updated as health care professionals are added or removed and shall include—

"(A) a sufficient number of primary care practitioners who are accepting new enrollees; and

"(B) a sufficient mix of primary care practitioners that reflects a diversity that is adequate to meet the needs of the enrollees' varied characteristics, including age, gender, race, and health status.

"(3) MEDICAL SPECIALISTS.—A managed care group health plan (and a health insurance issuer offering managed care group health insurance) shall develop a system to permit enrollees to use a medical specialist primary care practitioner, when the enrollee's medical conditions (including suffering from a chronic disease or medical condition) warrant it.

"(4) CONTINUITY OF CARE.—A managed care group health plan (and a health insurance issuer offering managed care group health insurance) shall provide—

"(A) continuity of care and appropriate referral to specialists within the plan or coverage, when specialty care is warranted,

"(B) enrollees with access to medical specialists on a timely basis, and

"(C) enrollees with a choice of specialists when a referral is made.

"(5) REQUIREMENT FOR POINT OF SERVICE OPTION.—A managed care group health plan (and a health insurance issuer offering managed care group health insurance) shall offer each enrollee with an enrollment option under which the enrollee may receive benefits for services provided by nonparticipating health care professional or provider. The plan or issuer may require that the enrollee pay a reasonable premium to reflect the cost of such option.

"(6) CONSULTATION FOR SECOND OPINIONS.—A managed care group health plan (and a health insurance issuer offering managed care group health insurance) shall provide enrollees with access to a consultation for a second option.

"(c) PROHIBITION OF GAG RULES.—A managed care group health plan (and a health insurance issuer offering managed care group health insurance)—

''(1) shall not have any contract provision with a health care professional that limits the health care professional's disclosure to an enrollee or on behalf of an enrollee of any information relating to the enrollee's medical condition or treatment options; and

''(2) shall not penalize (through contract termination or otherwise) a health care professional—

''(A) because the professional offers referrals, or discusses any or all medically necessary or appropriate care or treatment options (including disclosing any information, determined by the health care professional to be in the best interest of the enrollee) with, or on behalf of, an enrollee; or

''(B) for discussing financial incentives and financial arrangements between the health care professional and the plan or issuer.

''(d) COVERAGE OF DRUGS AND DEVICES.—

''(1) IN GENERAL.—A managed care group health plan (and a health insurance issuer offering managed care group health insurance) that provides benefits with respect to drugs and medical devices shall provide coverage for all drugs and medical devices approved by the Food and Drug Administration, whether or not that drug or device has been

approved for the specific treatment or condition, so long as the primary care practitioner or other medical specialist treating the enrollee determines the drug or device is medically necessary and appropriate for the enrollee's condition.

"(2) OPERATION OF DRUG UTILIZATION REVIEW PROGRAM.—A managed care group health plan (and a health insurance issuer offering managed care group health insurance) that provides benefits with respect to prescription drugs shall establish and operate a drug utilization review program that includes the following:

"(A) Retrospective review of prescription drugs furnished to enrollees.

"(B) Education of physicians, enrollees, and pharmacists regarding the appropriate use of prescription drugs.

"(C) An ongoing periodic examination of data on outpatient prescription drugs to ensure quality therapeutic outcomes for enrollees.

"(D) A primary emphasis on enhancing quality of care for enrollees by assuring appropriate drug therapy.

"(E) Clinically relevant criteria and standards for drug therapy.

"(F) Application of nonproprietary criteria and standards, developed and revised through an open, professional consensus process.

"(G) Interventions which focus on improving therapeutic outcomes.

"(H) An educational outreach program that—

"(i) is directed to enrollees, pharmacists, and other health care professionals, and

"(ii) emphasizes the appropriate use of prescription drugs.

"(I) Denial of services under prospective review of drug therapy only in cases of enrollee ineligibility, coverage limitations, or fraud.

"(J) Determination of the appropriate drug therapy for the enrollee by the prescribing health care professional and prohibitions of substitutions without the direct approval of such professional.

"(e) COVERAGE OF EXPERIMENTAL TREATMENTS.—

"(1) IN GENERAL.—A managed care group health plan (and a health insurance issuer offering managed care group health insurance) that limits coverage for services shall define the limitation and

disclose the limits in any agreement or certificate of coverage. Such disclosure shall include—

"(A) who is authorized to make such a determination, and

"(B) the criteria the plan or issuer uses to determine whether a service is experimental.

"(2) DENIALS.—A managed care group health plan (and a health insurance issuer offering managed care group health insurance) that denies coverage for an experimental treatment, procedure, drug, or device, for an enrollee who has a terminal condition or illness shall provide the enrollee with a denial letter within 20 working days of the submitted request. The letter shall include—

"(A) the name and title of the individual making the decision;

"(B) a statement setting forth the specific medical and scientific reasons for denying coverage;

"(C) a description of alternative treatment, services, or supplies covered by the plan or under the coverage, if any; and

"(D) a copy of the plan's or issuer's grievance and appeal procedure.

''(3) EXPERIMENTAL TREATMENT DEFINED.—In this subsection, the term 'experimental treatment' means treatment that, while not commonly used for a particular condition or illness, nevertheless is recognized for treatment of the particular condition or illness, and there is no clearly superior, nonexperimental treatment alternative available to the enrollee.

''(f) QUALITY ASSURANCE PROGRAM.—

''(1) IN GENERAL.—A managed care group health plan (and a health insurance issuer offering managed care group health insurance) shall develop comprehensive quality assurance standards, adequate to identify, evaluate, and remedy problems relating to access, continuity, and quality of care. The standards shall include—

''(A) an ongoing, written, internal quality assurance program;

''(B) specific written guidelines for quality of care studies and monitoring, including attention to vulnerable populations;

''(C) performance and clinical outcomes-based criteria;

''(D) a procedure for remedial action to correct quality problems, including written procedures for taking appropriate corrective action;

''(E) a plan for data gathering and assessment under subsection (g); and

''(F) a peer review process.

''(2) PROCESS FOR SELECTION OF PROFESSIONALS.—A managed care group health plan (and a health insurance issuer offering managed care group health insurance) shall have a process for selection of health care professionals who will be participating professionals, with written policies and procedures for standards used by the plan or issuer. Such process shall meet the following requirements:

''(A) The plan or issuer shall establish minimum professional requirements.

''(B) The plan or issuer shall demonstrate that it has consulted with appropriately qualified health care professionals to establish the requirements.

''(C) The process shall include verification of the individual practitioner's license, history of suspension or revocation, and liability claims history.

"(D) The plan or issuer shall establish a formal, written, ongoing, process for the re-evaluation of all participating health care professionals within a specified number of years after the initial acceptance. Such reevaluations shall include updates of the previous review criteria and an assessment of the performance pattern based on criteria including enrollee clinical outcomes, number of complaints, and malpractice actions.

"(3) LIMITATION ON USE OF PROFESSIONALS.—A managed care group health plan (and a health insurance issuer offering managed care group health insurance) shall not use a health care professional beyond, or outside of, the professional's legally authorized scope of practice.

"(g) DATA SYSTEMS AND CONFIDENTIALITY.—

"(1) IN GENERAL.—A managed care group health plan (and a health insurance issuer offering managed care group health insurance) shall provide information on the plan's or issuer's structure, decision making process, health care benefits and exclusions, cost and cost-sharing requirements, list of participating providers and health care professionals as well as grievance and appeal procedures, to all

potential enrollees, all enrollees covered by the plan or coverage, and, to the Secretary of Labor and to the Secretary of Health and Human Services (or, with respect to a health insurance issuer, to the State oversight agency).

''(2) REPORTING OF DATA.—A managed care group health plan (and a health insurance issuer offering managed care group health insurance) shall collect and report annually to the Secretary of Labor and to the Secretary of Health and Human Services (or, in the case of a health insurance issuer, State oversight agency) specified data including—

''(A) gross outpatient and hospital utilization data;

''(B) enrollee clinical outcome data;

''(C) the number and types of enrollee grievances or complaints during the year, the status of decisions, and the average time required to reach a decision; and

''(D) the number, amount, and disposition of malpractice claims resolved during the year by the plan or issuer and any of its participating health care providers and professionals.

''(3) REPORTING.—All data specified in paragraphs (1) and (2) shall be reported to the Secretary

of Labor and to the Secretary of Health and Human Services (or, in the case of a health insurance issuer, the State oversight agency) and shall be available to the public on a timely basis.

''(4) MEDICAL RECORDS AND CONFIDENTIALITY.—A managed care group health plan (and a health insurance issuer offering managed care group health insurance) shall—

''(A) establish written policies and procedures for the handling of medical records and enrollee communications to ensure enrollee confidentiality;

''(B) ensure the confidentiality of specified enrollee information, including, prior medical history, medical record information and claims information, except where disclosure of this information is required by law; and

''(C) not release any individual patient record information, unless such a release is authorized in writing by the enrollee or otherwise required be law.

''(h) CLINICAL DECISION MAKING.—

''(1) APPOINTMENT OF MEDICAL DIRECTOR.—A managed care group health plan (and a health insurance issuer offering managed care group health in-

surance) shall appoint a medical director who is a licensed physician in the State in which the plan or issuer operates, who shall be responsible for treatment policies protocols, quality assurance activities, and utilization management decisions of the plan or issuer.

''(2) DISCLOSURE ABOUT FINANCIAL ARRANGEMENTS.—A managed care group health plan (and a health insurance issuer offering managed care group health insurance) shall inform enrollees of the financial arrangements between the plan or issuer and participating providers and professionals (including pharmacists), if those arrangements include incentives or bonuses for restriction of services.

''(3) QUALITY ASSURANCE DEFINED.—In this subsection, the term 'quality assurance' means the ongoing evaluation of the quality of health care provided to enrollees.

''(4) OVERSIGHT.—The Secretary of Labor and the Secretary of Health and Human Services are responsible for performance of annual audits of managed care group health plans and, in the case of a health insurance issuer, the State oversight agency is responsible for performance of annual audits of managed care health insurance coverage offered by

such issuers, in order to review enrollee clinical outcome data, enrollee service data, and operational and other financial data.

''(i) GRIEVANCE PROCEDURES, REVIEWS, AND APPEALS.—

''(1) IN GENERAL.—A managed care group health plan (and a health insurance issuer offering managed care group health insurance) shall provide written notification to enrollees, in a language enrollees understand, regarding the right to file a grievance concerning denials or limitations of coverage under the plan or coverage. At a minimum, such notification shall be given—

''(A) prior to enrollment in the plan or under the coverage; and

''(B) at the time care is denied or limited under the plan or coverage.

''(2) NOTICE OF RIGHT TO FILE GRIEVANCE.—At the time of such a denial, such a plan or issuer shall notify the enrollee of the right to file a grievance. Such notice shall be in writing and shall include the reason for denial, the name of the individual responsible for the decision, the criteria for determination, and the enrollee's right to file a grievance.

''(3) GRIEVANCE PROCEDURES.—The grievance procedures under the plan or coverage shall include—

''(A) identification of the reviewing body and an explanation of the process of review;

''(B) an initial investigation and review;

''(C) notification within a reasonable amount of time of the outcome of the grievance; and

''(D) an appeal procedure.

''(4) TIME LIMITS.—

''(A) IN GENERAL.—Such a plan or issuer shall set reasonable time limits for each part of the review process, but in no case shall the review extend beyond 30 days.

''(B) EXPEDITED REVIEW.—Such a plan or issuer shall provide for expedited review for cases involving an imminent, emergent, or serious threat to the health of an enrollee. In such case the plan or issuer shall—

''(i) immediately inform the enrollee of this right, and

''(ii) provide the enrollee with a written statement of the disposition or pending

status of the grievance within 72 hours of the commencement of the review process.

''(5) REPORTING.—Such a plan or issuer shall report to the Secretary of Labor and to the Secretary of Health and Human Services (or, in the case of a health insurance issuer, the State oversight agency), the number of grievances and appeals received by the plan or issuer within a specified time period, including if applicable, the outcomes or current status of the grievance and appeals as well as the average time taken to resolve both grievances and appeals.

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

''(A) APPEAL.—The term 'appeal' means a formal process whereby an enrollee whose care has been reduced, denied, or terminated, or whereby the enrollee deems the care inappropriate, can contest an adverse grievance decision by the plan or issuer.

''(B) The term 'expedited review' means a review process which takes no more than 72 hours after the review is commenced.

''(C) The term 'grievance' means a written complaint submitted by or on behalf of the enrollee.

''(j) NOTICE UNDER GROUP HEALTH PLAN.—The imposition of the requirements of this section shall be treated as a material modification in the terms of the plan described in section 102(a)(1), for purposes of assuring notice of such requirements under the plan; except that the summary description required to be provided under the last sentence of section 104(b)(1) with respect to such modification shall be provided by not later than 60 days after the first day of the first plan year in which such requirements apply.

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

''(1) The term 'enrollee' means an individual who is entitled to benefits under a managed care group health plan or under managed care health insurance coverage offered in connection with such a plan.

''(2) The term 'health care provider' means a clinic, hospital physician organization, preferred provider organization, independent practice association, or other appropriately licensed provider of health care services or supplies.

''(3) The term 'health care professional' means a physician or other health care practitioner providing health care services.

''(4) The term 'managed care' means, with respect to a group health plan or health insurance coverage, a plan or coverage that provides financial incentives for enrollees to obtain benefits through participating health care providers or professionals.

''(5) The term 'participating' means, with respect to a health care provider or professional and a group health plan or health insurance coverage offered by a health insurance issuer, such a provider or professional that has entered into an agreement with the plan or issuer with respect to the provision of health care services to enrollees under the plan or coverage.

''(6) The term 'primary care practitioner' means, with respect to a group health plan or health insurance coverage offered by a health insurance issuer, a health care professional (who may be a family practice physician, general practice physician, internist, obstetrician/gynecologist, or pediatrician) designated by the plan or issuer to coordinate, supervise, or provide ongoing care to enrollees.

''(7) The term 'State oversight agency' means, with respect to a health insurance issuer, the State agency responsible for the regulation of the issuer.''.

(B) Section 731(c) of such Act (29 U.S.C. 1191(c)), as amended by section 603(b)(1) of Public Law 104–204, is amended by striking ''section 711'' and inserting ''sections 711 and 713''.

(C) Section 732(a) of such Act (29 U.S.C. 1191a(a)), as amended by section 603(b)(2) of Public Law 104–204, is amended by striking ''section 711'' and inserting ''sections 711 and 713''.

(D) 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. Managed care consumer protections.''.

(b) PHSA AMENDMENTS.—(1) Subpart 2 of part A of title XXVII of the Public Health Service Act, as amended by section 703(a) of Public Law 104–204, is amended by adding at the end the following new section:

''SEC. 2706. QUALITY HEALTH CARE AND CONSUMER PROTECTION ACT.

''(a) ACCESS TO PERSONNEL AND FACILITIES.—

''(1) IN GENERAL.—A managed care group health plan (and a health insurance issuer offering managed care group health insurance) shall—

''(A) include a sufficient number and type of primary care practitioners and specialists, throughout the service area, to meet the needs

of enrollees and to provide meaningful choice; and

''(B) demonstrate that it offers the following:

''(i) An adequate number of accessible acute care hospital services, within a reasonable distance and travel time for enrollees.

''(ii) An adequate number of accessible primary care practitioners, within a reasonable distance and travel time for enrollees.

''(iii) An adequate number of accessible specialists and subspecialists, within a reasonable distance and travel time for enrollees.

''(iv) The availability of specialty medical services, including physical therapy, occupational therapy, and rehabilitation services.

''(v) The availability of specialists who are not participating providers or professionals, when a patient's unique medical circumstances warrant it.

Clause (iii) shall be construed as requiring access to nonparticipating health care professionals who are specialists for treatment of a specific condition if and when there are not sufficient number of such specialists who are participating health care professionals.

''(2) CONTINUITY OF CARE.—A managed care group health plan (and a health insurance issuer offering managed care group health insurance) shall—

''(A) provide for continuity of care with established primary care practitioners, when the health care professional's contract is terminated, and

''(B) allow enrollees, at no additional out-of-pocket cost, to continue receiving services from a primary care practitioner whose contract with the plan or issuer is terminated without cause for a period of at least 60 days if the enrollee requests such continuation.

''(3) TELEPHONE ACCESS.—A managed care group health plan (and a health insurance issuer offering managed care group health insurance) shall provide telephone access to the plan or issuer for sufficient time during business and evening hours to ensure enrollee access for routine care, and 24 hour

telephone access to either the plan, issuer, or a participating provider or professional, for emergency care or authorization for such care.

''(4) STANDARDS FOR WAITING TIMES.—A managed care group health plan (and a health insurance issuer offering managed care group health insurance) shall establish reasonable standards for waiting times for enrollees to obtain appointments, subject to special rules for emergency services under paragraph (5). Such standards shall include appointment scheduling guidelines based on the type of health care service, including prenatal care appointments, well-child visits and immunizations, routine physicals, follow-up appointments for chronic conditions, and urgent care.

''(5) COVERAGE OF EMERGENCY SERVICES.—

''(A) IN GENERAL.—A managed care group health plan (and a health insurance issuer offering managed care group health insurance) shall cover and reimburse expenses for treatment of an emergency medical condition if the treatment is obtained, without prior authorization.

''(B) EMERGENCY MEDICAL CONDITION DEFINED.—The term 'emergency medical con-

dition' means a medical condition, the onset of which is sudden and unexpected, that manifests itself by symptoms of sufficient severity, that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably assume that the condition requires immediate medical treatment, and could expect the absence of medical attention to result in serious impairment to bodily functions or place the person's health in serious jeopardy.

''(C) PRUDENT LAYPERSON DEFINED.—In this paragraph, the term 'prudent layperson' means a person without specific medical training for the illness or condition in question who acts as a reasonable person would under similar circumstances.

''(b) ASSURING ADEQUATE CHOICE OF HEALTH CARE PROFESSIONALS.—

''(1) IN GENERAL.—A managed care group health plan (and a health insurance issuer offering managed care group health insurance) shall provide that each enrollee shall have adequate choice among participating health care professionals who are accessible and qualified.

''(2) CHOICE.—A managed care group health plan (and a health insurance issuer offering managed care group health insurance) shall permit enrollees to choose their own primary care practitioner from a list of health care professionals within the plan or coverage. Such list shall be updated as health care professionals are added or removed and shall include—

''(A) a sufficient number of primary care practitioners who are accepting new enrollees; and

''(B) a sufficient mix of primary care practitioners that reflects a diversity that is adequate to meet the needs of the enrollees' varied characteristics, including age, gender, race, and health status.

''(3) MEDICAL SPECIALISTS.—A managed care group health plan (and a health insurance issuer offering managed care group health insurance) shall develop a system to permit enrollees to use a medical specialist primary care practitioner, when the enrollee's medical conditions (including suffering from a chronic disease or medical condition) warrant it.

''(4) CONTINUITY OF CARE.—A managed care group health plan (and a health insurance issuer of-

fering managed care group health insurance) shall provide—

"(A) continuity of care and appropriate referral to specialists within the plan or coverage, when specialty care is warranted,

"(B) enrollees with access to medical specialists on a timely basis, and

"(C) enrollees with a choice of specialists when a referral is made.

"(5) REQUIREMENT FOR POINT OF SERVICE OPTION.—A managed care group health plan (and a health insurance issuer offering managed care group health insurance) shall offer each enrollee with an enrollment option under which the enrollee may receive benefits for services provided by nonparticipating health care professional or provider. The plan or issuer may require that the enrollee pay a reasonable premium to reflect the cost of such option.

"(6) CONSULTATION FOR SECOND OPINIONS.—A managed care group health plan (and a health insurance issuer offering managed care group health insurance) shall provide enrollees with access to a consultation for a second option.

''(c) PROHIBITION OF GAG RULES.—A managed care group health plan (and a health insurance issuer offering managed care group health insurance)—

''(1) shall not have any contract provision with a health care professional that limits the health care professional's disclosure to an enrollee or on behalf of an enrollee of any information relating to the enrollee's medical condition or treatment options; and

''(2) shall not penalize (through contract termination or otherwise) a health care professional—

''(A) because the professional offers referrals, or discusses any or all medically necessary or appropriate care or treatment options (including disclosing any information, determined by the health care professional to be in the best interest of the enrollee) with, or on behalf of, an enrollee; or

''(B) for discussing financial incentives and financial arrangements between the health care professional and the plan or issuer.

''(d) COVERAGE OF DRUGS AND DEVICES.—

''(1) IN GENERAL.—A managed care group health plan (and a health insurance issuer offering managed care group health insurance) that provides benefits with respect to drugs and medical devices

shall provide coverage for all drugs and medical devices approved by the Food and Drug Administration, whether or not that drug or device has been approved for the specific treatment or condition, so long as the primary care practitioner or other medical specialist treating the enrollee determines the drug or device is medically necessary and appropriate for the enrollee's condition.

''(2) OPERATION OF DRUG UTILIZATION REVIEW PROGRAM.—A managed care group health plan (and a health insurance issuer offering managed care group health insurance) that provides benefits with respect to prescription drugs shall establish and operate a drug utilization review program that includes the following:

''(A) Retrospective review of prescription drugs furnished to enrollees.

''(B) Education of physicians, enrollees, and pharmacists regarding the appropriate use of prescription drugs.

''(C) An ongoing periodic examination of data on outpatient prescription drugs to ensure quality therapeutic outcomes for enrollees.

"(D) A primary emphasis on enhancing quality of care for enrollees by assuring appropriate drug therapy.

"(E) Clinically relevant criteria and standards for drug therapy.

"(F) Application of nonproprietary criteria and standards, developed and revised through an open, professional consensus process.

"(G) Interventions which focus on improving therapeutic outcomes.

"(H) An educational outreach program that—

"(i) is directed to enrollees, pharmacists, and other health care professionals, and

"(ii) emphasizes the appropriate use of prescription drugs.

"(I) Denial of services under prospective review of drug therapy only in cases of enrollee ineligibility, coverage limitations, or fraud.

"(J) Determination of the appropriate drug therapy for the enrollee by the prescribing health care professional and prohibitions of substitutions without the direct approval of such professional.

''(e) COVERAGE OF EXPERIMENTAL TREATMENTS.—

''(1) IN GENERAL.—A managed care group health plan (and a health insurance issuer offering managed care group health insurance) that limits coverage for services shall define the limitation and disclose the limits in any agreement or certificate of coverage. Such disclosure shall include—

''(A) who is authorized to make such a determination, and

''(B) the criteria the plan or issuer uses to determine whether a service is experimental.

''(2) DENIALS.—A managed care group health plan (and a health insurance issuer offering managed care group health insurance) that denies coverage for an experimental treatment, procedure, drug, or device, for an enrollee who has a terminal condition or illness shall provide the enrollee with a denial letter within 20 working days of the submitted request. The letter shall include—

''(A) the name and title of the individual making the decision;

''(B) a statement setting forth the specific medical and scientific reasons for denying coverage;

''(C) a description of alternative treatment, services, or supplies covered by the plan or under the coverage, if any; and

''(D) a copy of the plan's or issuer's grievance and appeal procedure.

''(3) EXPERIMENTAL TREATMENT DEFINED.—In this subsection, the term 'experimental treatment' means treatment that, while not commonly used for a particular condition or illness, nevertheless is recognized for treatment of the particular condition or illness, and there is no clearly superior, nonexperimental treatment alternative available to the enrollee.

''(f) QUALITY ASSURANCE PROGRAM.—

''(1) IN GENERAL.—A managed care group health plan (and a health insurance issuer offering managed care group health insurance) shall develop comprehensive quality assurance standards, adequate to identify, evaluate, and remedy problems relating to access, continuity, and quality of care. The standards shall include—

''(A) an ongoing, written, internal quality assurance program;

"(B) specific written guidelines for quality of care studies and monitoring, including attention to vulnerable populations;

"(C) performance and clinical outcomes-based criteria;

"(D) a procedure for remedial action to correct quality problems, including written procedures for taking appropriate corrective action;

"(E) a plan for data gathering and assessment under subsection (g); and

"(F) a peer review process.

"(2) PROCESS FOR SELECTION OF PROFESSIONALS.—A managed care group health plan (and a health insurance issuer offering managed care group health insurance) shall have a process for selection of health care professionals who will be participating professionals, with written policies and procedures for standards used by the plan or issuer. Such process shall meet the following requirements:

"(A) The plan or issuer shall establish minimum professional requirements.

"(B) The plan or issuer shall demonstrate that it has consulted with appropriately qualified health care professionals to establish the requirements.

"(C) The process shall include verification of the individual practitioner's license, history of suspension or revocation, and liability claims history.

"(D) The plan or issuer shall establish a formal, written, ongoing, process for the re-evaluation of all participating health care professionals within a specified number of years after the initial acceptance. Such reevaluations shall include updates of the previous review criteria and an assessment of the performance pattern based on criteria including enrollee clinical outcomes, number of complaints, and malpractice actions.

"(3) LIMITATION ON USE OF PROFESSIONALS.—A managed care group health plan (and a health insurance issuer offering managed care group health insurance) shall not use a health care professional beyond, or outside of, the professional's legally authorized scope of practice.

"(g) DATA SYSTEMS AND CONFIDENTIALITY.—

"(1) IN GENERAL.—A managed care group health plan (and a health insurance issuer offering managed care group health insurance) shall provide information on the plan's or issuer's structure, deci-

sion making process, health care benefits and exclusions, cost and cost-sharing requirements, list of participating providers and health care professionals as well as grievance and appeal procedures, to all potential enrollees, all enrollees covered by the plan or coverage, and, to the Secretary (or, with respect to a health insurance issuer, to the State oversight agency).

''(2) REPORTING OF DATA.—A managed care group health plan (and a health insurance issuer offering managed care group health insurance) shall collect and report annually to the Secretary (or, in the case of a health insurance issuer, State oversight agency) specified data including—

''(A) gross outpatient and hospital utilization data;

''(B) enrollee clinical outcome data;

''(C) the number and types of enrollee grievances or complaints during the year, the status of decisions, and the average time required to reach a decision; and

''(D) the number, amount, and disposition of malpractice claims resolved during the year by the plan or issuer and any of its participating health care providers and professionals.

''(3) REPORTING.—All data specified in paragraphs (1) and (2) shall be reported to the Secretary or, in the case of a health insurance issuer, the State oversight agency and shall be available to the public on a timely basis.

''(4) MEDICAL RECORDS AND CONFIDENTIALITY.—A managed care group health plan (and a health insurance issuer offering managed care group health insurance) shall—

''(A) establish written policies and procedures for the handling of medical records and enrollee communications to ensure enrollee confidentiality;

''(B) ensure the confidentiality of specified enrollee information, including, prior medical history, medical record information and claims information, except where disclosure of this information is required by law; and

''(C) not release any individual patient record information, unless such a release is authorized in writing by the enrollee or otherwise required be law.

''(h) CLINICAL DECISION MAKING.—

''(1) APPOINTMENT OF MEDICAL DIRECTOR.—A managed care group health plan (and a health insur-

ance issuer offering managed care group health insurance) shall appoint a medical director who is a licensed physician in the State in which the plan or issuer operates, who shall be responsible for treatment policies protocols, quality assurance activities, and utilization management decisions of the plan or issuer.

''(2) DISCLOSURE ABOUT FINANCIAL ARRANGEMENTS.—A managed care group health plan (and a health insurance issuer offering managed care group health insurance) shall inform enrollees of the financial arrangements between the plan or issuer and participating providers and professionals (including pharmacists), if those arrangements include incentives or bonuses for restriction of services.

''(3) QUALITY ASSURANCE DEFINED.—In this subsection, the term 'quality assurance' means the ongoing evaluation of the quality of health care provided to enrollees.

''(4) OVERSIGHT.—The Secretary is responsible for performance of annual audits of managed care group health plans and, in the case of a health insurance issuer, the State oversight agency is responsible for performance of annual audits of managed care health insurance coverage offered by such issu-

ers, in order to review enrollee clinical outcome data, enrollee service data, and operational and other financial data.

"(i) GRIEVANCE PROCEDURES, REVIEWS, AND APPEALS.—

"(1) IN GENERAL.—A managed care group health plan (and a health insurance issuer offering managed care group health insurance) shall provide written notification to enrollees, in a language enrollees understand, regarding the right to file a grievance concerning denials or limitations of coverage under the plan or coverage. At a minimum, such notification shall be given—

"(A) prior to enrollment in the plan or under the coverage; and

"(B) at the time care is denied or limited under the plan or coverage.

"(2) NOTICE OF RIGHT TO FILE GRIEVANCE.—At the time of such a denial, such a plan or issuer shall notify the enrollee of the right to file a grievance. Such notice shall be in writing and shall include the reason for denial, the name of the individual responsible for the decision, the criteria for determination, and the enrollee's right to file a grievance.

''(3) GRIEVANCE PROCEDURES.—The grievance procedures under the plan or coverage shall include—

''(A) identification of the reviewing body and an explanation of the process of review;

''(B) an initial investigation and review;

''(C) notification within a reasonable amount of time of the outcome of the grievance; and

''(D) an appeal procedure.

''(4) TIME LIMITS.—

''(A) IN GENERAL.—Such a plan or issuer shall set reasonable time limits for each part of the review process, but in no case shall the review extend beyond 30 days.

''(B) EXPEDITED REVIEW.—Such a plan or issuer shall provide for expedited review for cases involving an imminent, emergent, or serious threat to the health of an enrollee. In such case the plan or issuer shall—

''(i) immediately inform the enrollee of this right, and

''(ii) provide the enrollee with a written statement of the disposition or pending

status of the grievance within 72 hours of the commencement of the review process.

''(5) REPORTING.—Such a plan or issuer shall report to the Secretary or, in the case of a health insurance issuer, the State oversight agency, the number of grievances and appeals received by the plan or issuer within a specified time period, including if applicable, the outcomes or current status of the grievance and appeals as well as the average time taken to resolve both grievances and appeals.

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

''(A) APPEAL.—The term 'appeal' means a formal process whereby an enrollee whose care has been reduced, denied, or terminated, or whereby the enrollee deems the care inappropriate, can contest an adverse grievance decision by the plan or issuer.

''(B) The term 'expedited review' means a review process which takes no more than 72 hours after the review is commenced.

''(C) The term 'grievance' means a written complaint submitted by or on behalf of the enrollee.

''(j) NOTICE.—A group health plan under this part shall comply with the notice requirement under section

713(j) of the Employee Retirement Income Security Act of 1974 with respect to the requirements of this section as if such section applied to such plan.

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

''(1) The term 'enrollee' means an individual who is entitled to benefits under a managed care group health plan or under managed care health insurance coverage offered in connection with such a plan.

''(2) The term 'health care provider' means a clinic, hospital physician organization, preferred provider organization, independent practice association, or other appropriately licensed provider of health care services or supplies.

''(3) The term 'health care professional' means a physician or other health care practitioner providing health care services.

''(4) The term 'managed care' means, with respect to a group health plan or health insurance coverage, a plan or coverage that provides financial incentives for enrollees to obtain benefits through participating health care providers or professionals.

''(5) The term 'participating' means, with respect to a health care provider or professional and

a group health plan or health insurance coverage offered by a health insurance issuer, such a provider or professional that has entered into an agreement with the plan or issuer with respect to the provision of health care services to enrollees under the plan or coverage.

''(6) The term 'primary care practitioner' means, with respect to a group health plan or health insurance coverage offered by a health insurance issuer, a health care professional (who may be a family practice physician, general practice physician, internist, obstetrician/gynecologist, or pediatrician) designated by the plan or issuer to coordinate, supervise, or provide ongoing care to enrollees.

''(7) The term 'State oversight agency' means, with respect to a health insurance issuer, the State agency responsible for the regulation of the issuer.''.

(2) Section 2723(c) of such Act (42 U.S.C. 300gg–23(c)), as amended by section 604(b)(2) of Public Law 104–204, is amended by striking ''section 2704'' and inserting ''sections 2704 and 2706''.

SEC. 4. MANAGED CARE CONSUMER PROTECTIONS UNDER INDIVIDUAL HEALTH INSURANCE COVERAGE.

(a) IN GENERAL.—Part B of title XXVII of the Public Health Service Act, as amended by section 605(a) of

Public Law 104–204, is amended by inserting after section 2751 the following new section:

"SEC. 2752. MANAGED CARE CONSUMER PROTECTIONS.

"(a) IN GENERAL.—The provisions of section 2706 (other than subsection (j)) shall apply to health insurance coverage offered by a health insurance issuer in the individual market in the same manner as it applies to health insurance coverage offered by a health insurance issuer in connection with a group health plan.

"(b) NOTICE.—A health insurance issuer under this part shall comply with the notice requirement under section 713(j) of the Employee Retirement Income Security Act of 1974 with respect to the requirements referred to in subsection (a) as if such section applied to such issuer and such issuer were a group health plan.".

(b) CONFORMING AMENDMENT.—Section 2762(b)(2) of such Act (42 U.S.C. 300gg–62(b)(2)), as added by section 605(b)(3)(B) of Public Law 104–204, is amended by striking "section 2751" and inserting "sections 2751 and 2752".

SEC. 5. EFFECTIVE DATES.

(a) GROUP HEALTH PLANS AND GROUP HEALTH INSURANCE COVERAGE.—(1) Subject to paragraph (2), the amendments made by section 3 shall apply with respect

to group health plans for plan years beginning on or after January 1, 1998.

(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 section 3 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) January 1, 1998.

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 section 3 shall not be treated as a termination of such collective bargaining agreement.

(b) INDIVIDUAL HEALTH INSURANCE COVERAGE.—The amendments made by section 4 shall apply with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market on or after January 1, 1998.

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