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

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.

- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,
- 3 SECTION 1. SHORT TITLE.
- 4 This Act may be cited as the "Quality Health Care
- 5 and Consumer Protection Act".

1 SEC. 2. PURPOSE.

2	The purpose of this Act is to ensure that enrollees
3	in managed care group health plans and managed care
4	health insurance coverage receive adequate health care
5	services by ensuring that—
6	(1) enrollees have full and timely access to clini-
7	cally appropriate health care personnel and facilities;
8	(2) enrollees have adequate choice among health
9	care professionals who are accessible and qualified;
10	(3) there is open communication between physi-
11	cians and enrollees;
12	(4) enrollees have access to comprehensive
13	pharmaceutical services;
14	(5) enrollees have access to information regard-
15	ing limits on coverage of experimental treatments;
16	(6) there is high quality care provided within
17	the plan or coverage;
18	(7) medical decisions are made by the appro-
19	priate medical personnel;
20	(8) participating health care professionals are
21	practitioners in good standing;
22	(9) data on the plan or coverage are available
23	as appropriate;
24	(10) there is full public access to information
25	regarding health care service delivery within the plan
26	or coverage;

1	(11) there is a fair vehicle for resolving enrollee
2	complaints under the plan or coverage; and
3	(12) there is timely resolution of enrollee griev-
4	ances and appeals.
5	SEC. 3. QUALITY HEALTH CARE AND CONSUMER PROTEC-
6	TION ACT UNDER GROUP HEALTH PLANS
7	AND GROUP HEALTH INSURANCE COVERAGE.
8	(a) ERISA AMENDMENTS.—(1) Subpart B of part
9	7 of subtitle B of title I of the Employee Retirement In-
10	come Security Act of 1974, as amended by section 702(a)
11	of Public Law 104–204, is amended by adding at the end
12	the following new section:
13	"SEC. 713. QUALITY HEALTH CARE AND CONSUMER PRO-
14	TECTION ACT.
15	"(a) Access to Personnel and Facilities.—
16	"(1) In general.—A managed care group
17	health plan (and a health insurance issuer offering
18	managed care group health insurance) shall—
19	"(A) include a sufficient number and type
20	of primary care practitioners and specialists,
21	throughout the service area, to meet the needs
22	of enrollees and to provide meaningful choice;
23	and
24	"(B) demonstrate that it offers the follow-
25	ing:

1	"(i) An adequate number of accessible
2	acute care hospital services, within a rea-
3	sonable distance and travel time for enroll-
4	ees.
5	"(ii) An adequate number of acces-
6	sible primary care practitioners, within a
7	reasonable distance and travel time for en-
8	rollees.
9	"(iii) An adequate number of acces-
10	sible specialists and subspecialists, within a
11	reasonable distance and travel time for en-
12	rollees.
13	"(iv) The availability of specialty med-
14	ical services, including physical therapy,
15	occupational therapy, and rehabilitation
16	services.
17	"(v) The availability of specialists who
18	are not participating providers or profes-
19	sionals, when a patient's unique medical
20	circumstances warrant it.
21	Clause (iii) shall be construed as requiring ac-
22	cess to nonparticipating health care profes-
23	sionals who are specialists for treatment of a
24	specific condition if and when there are not suf-

1	ficient number of such specialists who are par-
2	ticipating 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 outof-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.
- 14 "(b) Assuring Adequate Choice of Health 15 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

1	from a list of health care professionals within the
2	plan or coverage. Such list shall be updated as
3	health care professionals are added or removed and
4	shall include—
5	"(A) a sufficient number of primary care

- "(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—

1	"(A) continuity of care and appropriate re-
2	ferral to specialists within the plan or coverage,
3	when specialty care is warranted,
4	"(B) enrollees with access to medical spe-
5	cialists on a timely basis, and
6	"(C) enrollees with a choice of specialists
7	when a referral is made.
8	"(5) Requirement for point of service op-
9	TION.—A managed care group health plan (and a
10	health insurance issuer offering managed care group
11	health insurance) shall offer each enrollee with an
12	enrollment option under which the enrollee may re-
13	ceive benefits for services provided by nonparticipat-
14	ing health care professional or provider. The plan or
15	issuer may require that the enrollee pay a reasonable
16	premium to reflect the cost of such option.
17	"(6) Consultation for second opinions.—
18	A managed care group health plan (and a health in-
19	surance issuer offering managed care group health
20	insurance) shall provide enrollees with access to a
21	consultation for a second option.
22	"(c) Prohibition of Gag Rules.—A managed care
23	group health plan (and a health insurance issuer offering
24	managed care group health insurance)—

1	"(1) shall not have any contract provision with
2	a health care professional that limits the health care
3	professional's disclosure to an enrollee or on behalf
4	of an enrollee of any information relating to the en-
5	rollee's medical condition or treatment options; and
6	"(2) shall not penalize (through contract termi-
7	nation or otherwise) a health care professional—
8	"(A) because the professional offers refer-
9	rals, or discusses any or all medically necessary
10	or appropriate care or treatment options (in-
11	cluding disclosing any information, determined
12	by the health care professional to be in the best
13	interest of the enrollee) with, or on behalf of,
14	an enrollee; or
15	"(B) for discussing financial incentives and
16	financial arrangements between the health care
17	professional and the plan or issuer.
18	"(d) Coverage of Drugs and Devices.—
19	"(1) In general.—A managed care group
20	health plan (and a health insurance issuer offering
21	managed care group health insurance) that provides
22	benefits with respect to drugs and medical devices
23	shall provide coverage for all drugs and medical de-
24	vices approved by the Food and Drug Administra-

tion, whether or not that drug or device has been

1	approved for the specific treatment or condition, so
2	long as the primary care practitioner or other medi-
3	cal specialist treating the enrollee determines the
4	drug or device is medically necessary and appro-
5	priate for the enrollee's condition.
6	"(2) Operation of drug utilization re-
7	VIEW PROGRAM.—A managed care group health plan
8	(and a health insurance issuer offering managed
9	care group health insurance) that provides benefits
10	with respect to prescription drugs shall establish and
11	operate a drug utilization review program that in-
12	cludes the following:
13	"(A) Retrospective review of prescription
14	drugs furnished to enrollees.
15	"(B) Education of physicians, enrollees
16	and pharmacists regarding the appropriate use
17	of prescription drugs.
18	"(C) An ongoing periodic examination of
19	data on outpatient prescription drugs to ensure
20	quality therapeutic outcomes for enrollees.
21	"(D) A primary emphasis on enhancing
22	quality of care for enrollees by assuring appro-
23	priate drug therapy.

"(E) Clinically relevant criteria and stand-

ards for drug therapy.

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1	"(F) Application of nonproprietary criteria
2	and standards, developed and revised through
3	an open, professional consensus process.
4	"(G) Interventions which focus on improv-
5	ing therapeutic outcomes.
6	"(H) An educational outreach program
7	that—
8	"(i) is directed to enrollees, phar-
9	macists, and other health care profes-
10	sionals, and
11	"(ii) emphasizes the appropriate use
12	of prescription drugs.
13	"(I) Denial of services under prospective
14	review of drug therapy only in cases of enrollee
15	ineligibility, coverage limitations, or fraud.
16	"(J) Determination of the appropriate
17	drug therapy for the enrollee by the prescribing
18	health care professional and prohibitions of sub-
19	stitutions without the direct approval of such
20	professional.
21	"(e) Coverage of Experimental Treatments.—
22	"(1) In general.—A managed care group
23	health plan (and a health insurance issuer offering
24	managed care group health insurance) that limits
25	coverage for services shall define the limitation and

1	disclose the limits in any agreement or certificate of
2	coverage. Such disclosure shall include—
3	"(A) who is authorized to make such a de-
4	termination, and
5	"(B) the criteria the plan or issuer uses to
6	determine whether a service is experimental.
7	"(2) Denials.—A managed care group health
8	plan (and a health insurance issuer offering man-
9	aged care group health insurance) that denies cov-
10	erage for an experimental treatment, procedure,
11	drug, or device, for an enrollee who has a terminal
12	condition or illness shall provide the enrollee with a
13	denial letter within 20 working days of the submit-
14	ted request. The letter shall include—
15	"(A) the name and title of the individual
16	making the decision;
17	"(B) a statement setting forth the specific
18	medical and scientific reasons for denying cov-
19	erage;
20	"(C) a description of alternative treatment,
21	services, or supplies covered by the plan or
22	under the coverage, if any; and
23	"(D) a copy of the plan's or issuer's griev-
24	ance and appeal procedure.

1	"(3) Experimental treatment defined.—
2	In this subsection, the term 'experimental treatment
3	means treatment that, while not commonly used for
4	a particular condition or illness, nevertheless is rec-
5	ognized for treatment of the particular condition or
6	illness, and there is no clearly superior, nonexperi-
7	mental treatment alternative available to the en-
8	rollee.
9	"(f) Quality Assurance Program.—
10	"(1) In general.—A managed care group
11	health plan (and a health insurance issuer offering
12	managed care group health insurance) shall develop
13	comprehensive quality assurance standards, ade-
14	quate to identify, evaluate, and remedy problems re-
15	lating to access, continuity, and quality of care. The
16	standards shall include—
17	"(A) an ongoing, written, internal quality
18	assurance program;
19	"(B) specific written guidelines for quality
20	of care studies and monitoring, including atten-
21	tion to vulnerable populations;
22	"(C) performance and clinical outcomes-
23	based criteria;

1	"(D) a procedure for remedial action to
2	correct quality problems, including written pro-
3	cedures for taking appropriate corrective action;
4	"(E) a plan for data gathering and assess-
5	ment under subsection (g); and
6	"(F) a peer review process.
7	"(2) Process for selection of profes-
8	SIONALS.—A managed care group health plan (and
9	a health insurance issuer offering managed care
10	group health insurance) shall have a process for se-
11	lection of health care professionals who will be par-
12	ticipating professionals, with written policies and
13	procedures for standards used by the plan or issuer.
14	Such process shall meet the following requirements:
15	"(A) The plan or issuer shall establish
16	minimum professional requirements.
17	"(B) The plan or issuer shall demonstrate
18	that it has consulted with appropriately quali-
19	fied health care professionals to establish the
20	requirements.
21	"(C) The process shall include verification
22	of the individual practitioner's license, history
23	of suspension or revocation, and liability claims
24	history.

"(D) The plan or issuer shall establish a formal, written, ongoing, process for the reevaluation 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

1	potential enrollees, all enrollees covered by the plan
2	or coverage, and, to the Secretary of Labor and to
3	the Secretary of Health and Human Services (or,
4	with respect to a health insurance issuer, to the
5	State oversight agency).
6	"(2) Reporting of Data.—A managed care
7	group health plan (and a health insurance issuer of-
8	fering managed care group health insurance) shall
9	collect and report annually to the Secretary of Labor
10	and to the Secretary of Health and Human Services
11	(or, in the case of a health insurance issuer, State
12	oversight agency) specified data including—
13	"(A) gross outpatient and hospital utiliza-
14	tion data;
15	"(B) enrollee clinical outcome data;
16	"(C) the number and types of enrollee
17	grievances or complaints during the year, the
18	status of decisions, and the average time re-
19	quired to reach a decision; and
20	"(D) the number, amount, and disposition
21	of malpractice claims resolved during the year
22	by the plan or issuer and any of its participat-
23	ing health care providers and professionals.
24	"(3) Reporting.—All data specified in para-
25	graphs (1) and (2) shall be reported to the Secretary

1	of Labor and to the Secretary of Health and Human
2	Services (or, in the case of a health insurance issuer,
3	the State oversight agency) and shall be available to
4	the public on a timely basis.
5	"(4) Medical records and confidential-
6	ITY.—A managed care group health plan (and a
7	health insurance issuer offering managed care group
8	health insurance) shall—
9	"(A) establish written policies and proce-
10	dures for the handling of medical records and
11	enrollee communications to ensure enrollee con-
12	fidentiality;
13	"(B) ensure the confidentiality of specified
14	enrollee information, including, prior medical
15	history, medical record information and claims
16	information, except where disclosure of this in-
17	formation is required by law; and
18	"(C) not release any individual patient
19	record information, unless such a release is au-
20	thorized in writing by the enrollee or otherwise
21	required be law.
22	"(h) CLINICAL DECISION MAKING.—
23	"(1) Appointment of medical director.—A
24	managed care group health plan (and a health insur-
25	ance issuer offering managed care group health in-

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- 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 ARRANGE-MENTS.—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

1	such issuers, in order to review enrollee clinical out-
2	come data, enrollee service data, and operational and
3	other financial data.
4	"(i) Grievance Procedures, Reviews, and Ap-
5	PEALS.—
6	"(1) In General.—A managed care group
7	health plan (and a health insurance issuer offering
8	managed care group health insurance) shall provide
9	written notification to enrollees, in a language en-
10	rollees understand, regarding the right to file a
11	grievance concerning denials or limitations of cov-
12	erage under the plan or coverage. At a minimum,
13	such notification shall be given—
14	"(A) prior to enrollment in the plan or
15	under the coverage; and
16	"(B) at the time care is denied or limited
17	under the plan or coverage.
18	"(2) Notice of right to file grievance.—
19	At the time of such a denial, such a plan or issuer
20	shall notify the enrollee of the right to file a griev-
21	ance. Such notice shall be in writing and shall in-
22	clude the reason for denial, the name of the individ-
23	ual responsible for the decision, the criteria for de-
24	termination, and the enrollee's right to file a griev-

ance.

1	"(3) Grievance procedures.—The grievance
2	procedures under the plan or coverage shall in-
3	clude—
4	"(A) identification of the reviewing body
5	and an explanation of the process of review;
6	"(B) an initial investigation and review;
7	"(C) notification within a reasonable
8	amount of time of the outcome of the grievance;
9	and
10	"(D) an appeal procedure.
11	"(4) Time limits.—
12	"(A) In general.—Such a plan or issuer
13	shall set reasonable time limits for each part of
14	the review process, but in no case shall the re-
15	view extend beyond 30 days.
16	"(B) Expedited review.—Such a plan
17	or issuer shall provide for expedited review for
18	cases involving an imminent, emergent, or seri-
19	ous threat to the health of an enrollee. In such
20	case the plan or issuer shall—
21	"(i) immediately inform the enrollee
22	of this right, and
23	"(ii) provide the enrollee with a writ-
24	ten 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
- 4 described in section 102(a)(1), for purposes of assuring
- 5 notice of such requirements under the plan; except that
- 6 the summary description required to be provided under the
- 7 last sentence of section 104(b)(1) with respect to such
- 8 modification shall be provided by not later than 60 days
- 9 after the first day of the first plan year in which such
- 10 requirements apply.
- 11 "(k) General Definitions.—For purposes of this 12 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.
- 23 "(3) The term 'health care professional' means 24 a physician or other health care practitioner provid-25 ing health care services.

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- "(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.".

1	(B) Section 731(c) of such Act (29 U.S.C.
2	1191(e)), as amended by section 603(b)(1) of Public
3	Law 104–204, is amended by striking "section 711"
4	and inserting "sections 711 and 713".
5	(C) Section 732(a) of such Act (29 U.S.C.
6	1191a(a)), as amended by section 603(b)(2) of Pub-
7	lic Law 104–204, is amended by striking "section
8	711" and inserting "sections 711 and 713".
9	(D) The table of contents in section 1 of such
10	Act is amended by inserting after the item relating
11	to section 712 the following new item:
	"Sec. 713. Managed care consumer protections.".
12	(b) PHSA AMENDMENTS.—(1) Subpart 2 of part A
13	of title XXVII of the Public Health Service Act, as amend-
14	ed by section 703(a) of Public Law 104–204, is amended
15	by adding at the end the following new section:
16	"SEC. 2706. QUALITY HEALTH CARE AND CONSUMER PRO-
17	TECTION ACT.
18	"(a) Access to Personnel and Facilities.—
19	"(1) In general.—A managed care group
20	health plan (and a health insurance issuer offering
21	managed care group health insurance) shall—
22	"(A) include a sufficient number and type
23	of primary care practitioners and specialists,

1	of enrollees and to provide meaningful choice
2	and
3	"(B) demonstrate that it offers the follow-
4	ing:
5	"(i) An adequate number of accessible
6	acute care hospital services, within a rea-
7	sonable distance and travel time for enroll-
8	ees.
9	"(ii) An adequate number of acces-
10	sible primary care practitioners, within a
11	reasonable distance and travel time for en-
12	rollees.
13	"(iii) An adequate number of acces-
14	sible specialists and subspecialists, within a
15	reasonable distance and travel time for en-
16	rollees.
17	"(iv) The availability of specialty med-
18	ical services, including physical therapy
19	occupational therapy, and rehabilitation
20	services.
21	"(v) The availability of specialists who
22	are not participating providers or profes-
23	sionals, when a patient's unique medical
24	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 outof-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-

1 dition' means a medical condition, the onset of 2 which is sudden and unexpected, that manifests 3 itself by symptoms of sufficient severity, that a 4 prudent layperson, who possesses an average 5 knowledge of health and medicine, could reason-6 ably assume that the condition requires imme-7 diate medical treatment, and could expect the 8 absence of medical attention to result in serious 9 impairment to bodily functions or place the per-10 son'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.
- 17 "(b) Assuring Adequate Choice of Health 18 Care Professionals.—
- 19 "(1) IN GENERAL.—A managed care group 20 health plan (and a health insurance issuer offering 21 managed care group health insurance) shall provide 22 that each enrollee shall have adequate choice among 23 participating health care professionals who are ac-24 cessible and qualified.

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- 1 "(2) Choice.—A managed care group health
 2 plan (and a health insurance issuer offering man3 aged care group health insurance) shall permit en4 rollees to choose their own primary care practitioner
 5 from a list of health care professionals within the
 6 plan or coverage. Such list shall be updated as
 7 health care professionals are added or removed and
 8 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-

1	fering managed care group health insurance) shall
2	provide—
3	"(A) continuity of care and appropriate re-
4	ferral to specialists within the plan or coverage,
5	when specialty care is warranted,
6	"(B) enrollees with access to medical spe-
7	cialists on a timely basis, and
8	"(C) enrollees with a choice of specialists
9	when a referral is made.
10	"(5) Requirement for point of service op-
11	TION.—A managed care group health plan (and a
12	health insurance issuer offering managed care group
13	health insurance) shall offer each enrollee with an
14	enrollment option under which the enrollee may re-
15	ceive benefits for services provided by nonparticipat-
16	ing health care professional or provider. The plan or
17	issuer may require that the enrollee pay a reasonable
18	premium to reflect the cost of such option.
19	"(6) Consultation for second opinions.—
20	A managed care group health plan (and a health in-
21	surance issuer offering managed care group health
22	insurance) shall provide enrollees with access to a
23	consultation for a second option.

1	"(c) Prohibition of Gag Rules.—A managed care
2	group health plan (and a health insurance issuer offering
3	managed care group health insurance)—
4	"(1) shall not have any contract provision with
5	a health care professional that limits the health care
6	professional's disclosure to an enrollee or on behalf
7	of an enrollee of any information relating to the en-
8	rollee's medical condition or treatment options; and
9	"(2) shall not penalize (through contract termi-
10	nation or otherwise) a health care professional—
11	"(A) because the professional offers refer-
12	rals, or discusses any or all medically necessary
13	or appropriate care or treatment options (in-
14	cluding disclosing any information, determined
15	by the health care professional to be in the best
16	interest of the enrollee) with, or on behalf of,
17	an enrollee; or
18	"(B) for discussing financial incentives and
19	financial arrangements between the health care
20	professional and the plan or issuer.
21	"(d) Coverage of Drugs and Devices.—
22	"(1) In general.—A managed care group
23	health plan (and a health insurance issuer offering
24	managed care group health insurance) that provides
25	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 RE-VIEW 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.

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1	"(D) A primary emphasis on enhancing
2	quality of care for enrollees by assuring appro-
3	priate drug therapy.
4	"(E) Clinically relevant criteria and stand-
5	ards for drug therapy.
6	"(F) Application of nonproprietary criteria
7	and standards, developed and revised through
8	an open, professional consensus process.
9	"(G) Interventions which focus on improv-
10	ing therapeutic outcomes.
11	"(H) An educational outreach program
12	that—
13	"(i) is directed to enrollees, phar-
14	macists, and other health care profes-
15	sionals, and
16	"(ii) emphasizes the appropriate use
17	of prescription drugs.
18	"(I) Denial of services under prospective
19	review of drug therapy only in cases of enrollee
20	ineligibility, coverage limitations, or fraud.
21	"(J) Determination of the appropriate
22	drug therapy for the enrollee by the prescribing
23	health care professional and prohibitions of sub-
24	stitutions without the direct approval of such
25	professional.

1	"(e) Coverage of Experimental Treatments.—
2	"(1) In general.—A managed care group
3	health plan (and a health insurance issuer offering
4	managed care group health insurance) that limits
5	coverage for services shall define the limitation and
6	disclose the limits in any agreement or certificate of
7	coverage. Such disclosure shall include—
8	"(A) who is authorized to make such a de-
9	termination, and
10	"(B) the criteria the plan or issuer uses to
11	determine whether a service is experimental.
12	"(2) Denials.—A managed care group health
13	plan (and a health insurance issuer offering man-
14	aged care group health insurance) that denies cov-
15	erage for an experimental treatment, procedure,
16	drug, or device, for an enrollee who has a terminal
17	condition or illness shall provide the enrollee with a
18	denial letter within 20 working days of the submit-
19	ted request. The letter shall include—
20	"(A) the name and title of the individual
21	making the decision;
22	"(B) a statement setting forth the specific
23	medical and scientific reasons for denying cov-
24	erage;

1	"(C) a description of alternative treatment,
2	services, or supplies covered by the plan or
3	under the coverage, if any; and
4	"(D) a copy of the plan's or issuer's griev-
5	ance and appeal procedure.
6	"(3) Experimental treatment defined.—
7	In this subsection, the term 'experimental treatment'
8	means treatment that, while not commonly used for
9	a particular condition or illness, nevertheless is rec-
10	ognized for treatment of the particular condition or
11	illness, and there is no clearly superior, nonexperi-
12	mental treatment alternative available to the en-
13	rollee.
14	"(f) QUALITY ASSURANCE PROGRAM.—
15	"(1) In general.—A managed care group
16	health plan (and a health insurance issuer offering
17	managed care group health insurance) shall develop
18	comprehensive quality assurance standards, ade-
19	quate to identify, evaluate, and remedy problems re-
20	lating to access, continuity, and quality of care. The
21	standards shall include—
22	"(A) an ongoing, written, internal quality
23	assurance program;

1	"(B) specific written guidelines for quality
2	of care studies and monitoring, including atten-
3	tion to vulnerable populations;
4	"(C) performance and clinical outcomes-
5	based criteria;
6	"(D) a procedure for remedial action to
7	correct quality problems, including written pro-
8	cedures for taking appropriate corrective action;
9	"(E) a plan for data gathering and assess-
10	ment under subsection (g); and
11	"(F) a peer review process.
12	"(2) Process for selection of profes-
13	SIONALS.—A managed care group health plan (and
14	a health insurance issuer offering managed care
15	group health insurance) shall have a process for se-
16	lection of health care professionals who will be par-
17	ticipating professionals, with written policies and
18	procedures for standards used by the plan or issuer.
19	Such process shall meet the following requirements:
20	"(A) The plan or issuer shall establish
21	minimum professional requirements.
22	"(B) The plan or issuer shall demonstrate
23	that it has consulted with appropriately quali-
24	fied health care professionals to establish the
25	requirements.

- 1 "(C) The process shall include verification 2 of the individual practitioner's license, history 3 of suspension or revocation, and liability claims 4 history.
 - "(D) The plan or issuer shall establish a formal, written, ongoing, process for the reevaluation 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.

21 "(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.

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1	"(3) Reporting.—All data specified in para-
2	graphs (1) and (2) shall be reported to the Secretary
3	or, in the case of a health insurance issuer, the
4	State oversight agency and shall be available to the
5	public on a timely basis.
6	"(4) Medical records and confidential-
7	ITY.—A managed care group health plan (and a
8	health insurance issuer offering managed care group
9	health insurance) shall—
10	"(A) establish written policies and proce-
11	dures for the handling of medical records and
12	enrollee communications to ensure enrollee con-
13	fidentiality;
14	"(B) ensure the confidentiality of specified
15	enrollee information, including, prior medical
16	history, medical record information and claims
17	information, except where disclosure of this in-
18	formation is required by law; and
19	"(C) not release any individual patient
20	record information, unless such a release is au-
21	thorized in writing by the enrollee or otherwise
22	required be law.
23	"(h) CLINICAL DECISION MAKING.—
24	"(1) Appointment of medical director.—A
25	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 ARRANGE-MENTS.—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-

1	ers, in order to review enrollee clinical outcome data,
2	enrollee service data, and operational and other fi-
3	nancial data.
4	"(i) Grievance Procedures, Reviews, and Ap-
5	PEALS.—
6	"(1) In general.—A managed care group
7	health plan (and a health insurance issuer offering
8	managed care group health insurance) shall provide
9	written notification to enrollees, in a language en-
10	rollees understand, regarding the right to file a
11	grievance concerning denials or limitations of cov-
12	erage under the plan or coverage. At a minimum,
13	such notification shall be given—
14	"(A) prior to enrollment in the plan or
15	under the coverage; and
16	"(B) at the time care is denied or limited
17	under the plan or coverage.
18	"(2) Notice of right to file grievance.—
19	At the time of such a denial, such a plan or issuer
20	shall notify the enrollee of the right to file a griev-
21	ance. Such notice shall be in writing and shall in-
22	clude the reason for denial, the name of the individ-
23	ual responsible for the decision, the criteria for de-
24	termination, and the enrollee's right to file a griev-

ance.

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1	"(3) Grievance procedures.—The grievance
2	procedures under the plan or coverage shall in-
3	clude—
4	"(A) identification of the reviewing body
5	and an explanation of the process of review;
6	"(B) an initial investigation and review;
7	"(C) notification within a reasonable
8	amount of time of the outcome of the grievance;
9	and
10	"(D) an appeal procedure.
11	"(4) Time limits.—
12	"(A) In general.—Such a plan or issuer
13	shall set reasonable time limits for each part of
14	the review process, but in no case shall the re-
15	view extend beyond 30 days.
16	"(B) Expedited review.—Such a plan
17	or issuer shall provide for expedited review for
18	cases involving an imminent, emergent, or seri-
19	ous threat to the health of an enrollee. In such
20	case the plan or issuer shall—
21	"(i) immediately inform the enrollee
22	of this right, and
23	"(ii) provide the enrollee with a writ-
24	ten statement of the disposition or pending

1	status of the grievance within 72 hours of
2	the commencement of the review process.
3	"(5) Reporting.—Such a plan or issuer shall
4	report to the Secretary or, in the case of a health
5	insurance issuer, the State oversight agency, the
6	number of grievances and appeals received by the
7	plan or issuer within a specified time period, includ-
8	ing if applicable, the outcomes or current status of
9	the grievance and appeals as well as the average
10	time taken to resolve both grievances and appeals.
11	"(6) Definitions.—In this subsection:
12	"(A) Appeal.—The term 'appeal' means a
13	formal process whereby an enrollee whose care
14	has been reduced, denied, or terminated, or
15	whereby the enrollee deems the care inappropri-
16	ate, can contest an adverse grievance decision
17	by the plan or issuer.
18	"(B) The term 'expedited review' means a
19	review process which takes no more than 72
20	hours after the review is commenced.
21	"(C) The term 'grievance' means a written
22	complaint submitted by or on behalf of the en-
23	rollee.
24	"(j) Notice.—A group health plan under this part
25	shall comply with the notice requirement under section

- 1 713(j) of the Employee Retirement Income Security Act
- 2 of 1974 with respect to the requirements of this section
- 3 as if such section applied to such plan.
- 4 "(k) GENERAL DEFINITIONS.—For purposes of this
- 5 section:
- 6 "(1) The term 'enrollee' means an individual
- 7 who is entitled to benefits under a managed care
- 8 group health plan or under managed care health in-
- 9 surance coverage offered in connection with such a
- plan.
- 11 "(2) The term 'health care provider' means a
- 12 clinic, hospital physician organization, preferred pro-
- vider organization, independent practice association,
- or other appropriately licensed provider of health
- 15 care services or supplies.
- 16 "(3) The term 'health care professional' means
- a physician or other health care practitioner provid-
- ing health care services.
- 19 "(4) The term 'managed care' means, with re-
- spect to a group health plan or health insurance cov-
- erage, a plan or coverage that provides financial in-
- centives for enrollees to obtain benefits through par-
- 23 ticipating health care providers or professionals.
- 24 "(5) The term 'participating' means, with re-
- spect 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.
- 7 The term 'primary care practitioner' 8 means, with respect to a group health plan or health 9 insurance coverage offered by a health insurance is-10 suer, a health care professional (who may be a fam-11 ily practice physician, general practice physician, in-12 ternist, obstetrician/gynecologist, or pediatrician) 13 designated by the plan or issuer to coordinate, su-14 pervise, or provide ongoing care to enrollees.
- 15 "(7) The term 'State oversight agency' means, 16 with respect to a health insurance issuer, the State 17 agency responsible for the regulation of the issuer.".
- 18 (2) Section 2723(c) of such Act (42 U.S.C. 300gg-
- 19 23(c)), as amended by section 604(b)(2) of Public Law
- 20 104–204, is amended by striking "section 2704" and in-
- 21 serting "sections 2704 and 2706".
- 22 SEC. 4. MANAGED CARE CONSUMER PROTECTIONS UNDER
- 23 INDIVIDUAL HEALTH INSURANCE COVERAGE.
- 24 (a) IN GENERAL.—Part B of title XXVII of the Pub-
- 25 lie Health Service Act, as amended by section 605(a) of

- 1 Public Law 104–204, is amended by inserting after sec-
- 2 tion 2751 the following new section:
- 3 "SEC. 2752. MANAGED CARE CONSUMER PROTECTIONS.
- 4 "(a) In General.—The provisions of section 2706
- 5 (other than subsection (j)) shall apply to health insurance
- 6 coverage offered by a health insurance issuer in the indi-
- 7 vidual market in the same manner as it applies to health
- 8 insurance coverage offered by a health insurance issuer
- 9 in connection with a group health plan.
- 10 "(b) Notice.—A health insurance issuer under this
- 11 part shall comply with the notice requirement under sec-
- 12 tion 713(j) of the Employee Retirement Income Security
- 13 Act of 1974 with respect to the requirements referred to
- 14 in subsection (a) as if such section applied to such issuer
- 15 and such issuer were a group health plan.".
- 16 (b) Conforming Amendment.—Section 2762(b)(2)
- 17 of such Act (42 U.S.C. 300gg-62(b)(2)), as added by sec-
- 18 tion 605(b)(3)(B) of Public Law 104–204, is amended by
- 19 striking "section 2751" and inserting "sections 2751 and
- 20 2752".
- 21 SEC. 5. EFFECTIVE DATES.
- 22 (a) Group Health Plans and Group Health In-
- 23 SURANCE COVERAGE.—(1) Subject to paragraph (2), the
- 24 amendments made by section 3 shall apply with respect

- 1 to group health plans for plan years beginning on or after
- 2 January 1, 1998.
- 3 (2) In the case of a group health plan maintained
- 4 pursuant to 1 or more collective bargaining agreements
- 5 between employee representatives and 1 or more employ-
- 6 ers ratified before the date of enactment of this Act, the
- 7 amendments made by section 3 shall not apply to plan
- 8 years beginning before the later of—
- 9 (A) the date on which the last collective bar-
- gaining agreements relating to the plan terminates
- 11 (determined without regard to any extension thereof
- agreed to after the date of enactment of this Act),
- 13 or
- 14 (B) January 1, 1998.
- 15 For purposes of subparagraph (A), any plan amendment
- 16 made pursuant to a collective bargaining agreement relat-
- 17 ing to the plan which amends the plan solely to conform
- 18 to any requirement added by section 3 shall not be treated
- 19 as a termination of such collective bargaining agreement.
- 20 (b) Individual Health Insurance Coverage.—
- 21 The amendments made by section 4 shall apply with re-
- 22 spect to health insurance coverage offered, sold, issued,
- 23 renewed, in effect, or operated in the individual market
- 24 on or after January 1, 1998.