

106TH CONGRESS
1ST SESSION

H. R. 719

To amend the Public Health Service Act and the Employee Retirement Income Security Act of 1974 to protect consumers in managed care plans and other health coverage.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 11, 1999

Mr. GANSKE (for himself, Mrs. ROUKEMA, Mr. LEACH, Mr. WAMP, Mr. FORBES, Mr. PETRI, Mr. SHAYS, Mr. HORN, Mr. FRELINGHUYSEN, Mr. FOLEY, and Mr. COOKSEY) introduced the following bill; which was referred to the Committee on Commerce, and in addition to the Committee on Education and the Workforce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend the Public Health Service Act and the Employee Retirement Income Security Act of 1974 to protect consumers in managed care plans and other health coverage.

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; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Managed Care Reform Act of 1999”.

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

Sec. 1. Short title; table of contents.

TITLE I—MANAGED CARE CONSUMER PROTECTIONS

Subtitle A—Access to Care

- Sec. 101. Access to emergency care.
- Sec. 102. Offering of choice of coverage options under group health plans.
- Sec. 103. Choice of providers.
- Sec. 104. Access to specialty care.
- Sec. 105. Continuity of care.
- Sec. 106. Coverage for individuals participating in approved clinical trials.
- Sec. 107. Access to needed prescription drugs.
- Sec. 108. Adequacy of provider network.

Subtitle B—Quality Assurance

- Sec. 111. Standards for utilization review activities.

Subtitle C—Patient Information

- Sec. 121. Patient information.
- Sec. 122. Protection of patient confidentiality.
- Sec. 123. Health insurance ombudsmen.

Subtitle D—Grievance and Appeals Procedures

- Sec. 131. Establishment of grievance process.
- Sec. 132. Internal appeals of adverse determinations.
- Sec. 133. External appeals of adverse determinations.

Subtitle E—Protecting the Doctor-Patient Relationship

- Sec. 141. Prohibition of interference with certain medical communications.
- Sec. 142. Prohibition against transfer of indemnification or improper incentive arrangements.
- Sec. 143. Additional rules regarding participation of health care professionals.
- Sec. 144. Protection for patient advocacy.

Subtitle F—Promoting Good Medical Practice

- Sec. 151. Promoting good medical practice.
- Sec. 152. Standards relating to benefits for certain breast cancer treatment.

Subtitle G—Definitions

- Sec. 191. Definitions.
- Sec. 192. Preemption; State flexibility; construction.
- Sec. 193. Regulations.

TITLE II—APPLICATION OF PATIENT PROTECTION STANDARDS TO GROUP HEALTH PLANS AND HEALTH INSURANCE COVERAGE UNDER PUBLIC HEALTH SERVICE ACT

- Sec. 201. Application to group health plans and group health insurance coverage.
- Sec. 202. Application to individual health insurance coverage.

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

Sec. 301. Application of patient protection standards to group health plans and group health insurance coverage under the Employee Retirement Income Security Act of 1974.

Sec. 302. ERISA preemption not to apply to certain actions involving health insurance policyholders.

TITLE IV—EFFECTIVE DATES; COORDINATION IN
IMPLEMENTATION

Sec. 401. Effective dates.

Sec. 402. Coordination in implementation.

1 **TITLE I—MANAGED CARE**
2 **CONSUMER PROTECTIONS**
3 **Subtitle A—Access to Care**

4 **SEC. 101. ACCESS TO EMERGENCY CARE.**

5 (a) COVERAGE OF EMERGENCY SERVICES.—

6 (1) IN GENERAL.—If a group health plan, or
7 health insurance coverage offered by a health insur-
8 ance issuer, provides any benefits with respect to
9 emergency services (as defined in paragraph (2)(B)),
10 the plan or issuer shall cover emergency services fur-
11 nished under the plan or coverage—

12 (A) without the need for any prior author-
13 ization determination;

14 (B) whether or not the health care pro-
15 vider furnishing such services is a participating
16 provider with respect to such services;

17 (C) in a manner so that, if such services
18 are provided to a participant, beneficiary, or en-
19 rollee by a nonparticipating health care provider

1 the participant, beneficiary, or enrollee is not
2 liable for amounts that exceed the amounts of
3 liability that would be incurred if the services
4 were provided by a participating health care
5 provider; and

6 (D) without regard to any other term or
7 condition of such coverage (other than exclusion
8 or coordination of benefits, or an affiliation or
9 waiting period, permitted under section 2701 of
10 the Public Health Service Act, section 701 of
11 the Employee Retirement Income Security Act
12 of 1974, or section 9801 of the Internal Reve-
13 nue Code of 1986, and other than applicable
14 cost-sharing).

15 (2) DEFINITIONS.—In this section:

16 (A) EMERGENCY MEDICAL CONDITION
17 BASED ON PRUDENT LAYPERSON STANDARD.—
18 The term “emergency medical condition” means
19 a medical condition manifesting itself by acute
20 symptoms of sufficient severity (including se-
21 vere pain) such that a prudent layperson, who
22 possesses an average knowledge of health and
23 medicine, could reasonably expect the absence
24 of immediate medical attention to result in a
25 condition described in clause (i), (ii), or (iii) of

1 section 1867(e)(1)(A) of the Social Security
2 Act.

3 (B) EMERGENCY SERVICES.—The term
4 “emergency services” means—

5 (i) a medical screening examination
6 (as required under section 1867 of the So-
7 cial Security Act) that is within the capa-
8 bility of the emergency department of a
9 hospital, including ancillary services rou-
10 tinely available to the emergency depart-
11 ment to evaluate an emergency medical
12 condition (as defined in subparagraph
13 (A)), and

14 (ii) within the capabilities of the staff
15 and facilities available at the hospital, such
16 further medical examination and treatment
17 as are required under section 1867 of such
18 Act to stabilize the patient.

19 (b) REIMBURSEMENT FOR MAINTENANCE CARE AND
20 POST-STABILIZATION CARE.—In the case of services
21 (other than emergency services) for which benefits are
22 available under a group health plan, or under health insur-
23 ance coverage offered by a health insurance issuer, the
24 plan or issuer shall provide for reimbursement with re-
25 spect to such services provided to a participant, bene-

1 ficiary, or enrollee other than through a participating
2 health care provider in a manner consistent with sub-
3 section (a)(1)(C) (and shall otherwise comply with the
4 guidelines established under section 1852(d)(2) of the So-
5 cial Security Act (relating to promoting efficient and time-
6 ly coordination of appropriate maintenance and post-sta-
7 bilization care of an enrollee after an enrollee has been
8 determined to be stable), or, in the absence of guidelines
9 under such section, such guidelines as the Secretary shall
10 establish to carry out this subsection), if the services are
11 maintenance care or post-stabilization care covered under
12 such guidelines.

13 **SEC. 102. OFFERING OF CHOICE OF COVERAGE OPTIONS**
14 **UNDER GROUP HEALTH PLANS.**

15 (a) REQUIREMENT.—

16 (1) OFFERING OF POINT-OF-SERVICE COV-
17 ERAGE OPTION.—Except as provided in paragraph
18 (2), if a group health plan (or health insurance cov-
19 erage offered by a health insurance issuer in connec-
20 tion with a group health plan) provides benefits only
21 through participating health care providers, the plan
22 or issuer shall offer the participant the option to
23 purchase point-of-service coverage (as defined in
24 subsection (b)) for all such benefits for which cov-
25 erage is otherwise so limited. Such option shall be

1 made available to the participant at the time of en-
2 rollment under the plan or coverage and at such
3 other times as the plan or issuer offers the partici-
4 pant a choice of coverage options.

5 (2) EXCEPTION.—Paragraph (1) shall not
6 apply with respect to a participant in a group health
7 plan if the plan offers the participant—

8 (A) a choice of health insurance coverage;
9 and

10 (B) one or more coverage options which do
11 not provide benefits only through participating
12 health care providers and which provide for
13 payment for nonparticipating providers in an
14 amount that is not less than the amount paid
15 to a participating provider for the same serv-
16 ices.

17 (b) POINT-OF-SERVICE COVERAGE DEFINED.—In
18 this section, the term “point-of-service coverage” means,
19 with respect to benefits covered under a group health plan
20 or health insurance issuer, coverage of such benefits when
21 provided by a nonparticipating health care provider
22 through payment of an amount that is not less than the
23 amount paid to a participating health care provider for
24 the same services. Such coverage need not include cov-

1 erage of providers that the plan or issuer excludes because
2 of fraud, quality, or similar reasons.

3 (c) CONSTRUCTION.—Nothing in this section shall be
4 construed—

5 (1) as requiring coverage for benefits for a par-
6 ticular type of health care provider;

7 (2) as requiring an employer to pay any costs
8 as a result of this section or to make equal contribu-
9 tions with respect to different health coverage op-
10 tions; or

11 (3) as preventing a group health plan or health
12 insurance issuer from imposing higher premiums or
13 cost-sharing on a participant for the exercise of a
14 point-of-service coverage option.

15 (d) NO REQUIREMENT FOR GUARANTEED AVAIL-
16 ABILITY.—If a health insurance issuer offers health insur-
17 ance coverage that includes point-of-service coverage with
18 respect to an employer solely in order to meet the require-
19 ment of subsection (a), nothing in section 2711(a)(1)(A)
20 of the Public Health Service Act shall be construed as re-
21 quiring the offering of such coverage with respect to an-
22 other employer.

23 **SEC. 103. CHOICE OF PROVIDERS.**

24 (a) PRIMARY CARE.—A group health plan, and a
25 health insurance issuer that offers health insurance cov-

1 erage, shall permit each participant, beneficiary, and en-
2 rollee to receive primary care from any participating pri-
3 mary care provider who is available to accept such individ-
4 ual.

5 (b) SPECIALISTS.—

6 (1) IN GENERAL.—Subject to paragraph (2), a
7 group health plan and a health insurance issuer that
8 offers health insurance coverage shall permit each
9 participant, beneficiary, or enrollee to receive medi-
10 cally necessary or appropriate specialty care, pursu-
11 ant to appropriate referral procedures, from any
12 qualified participating health care provider who is
13 available to accept such individual for such care.

14 (2) LIMITATION.—Paragraph (1) shall not
15 apply to specialty care if the plan or issuer clearly
16 informs participants, beneficiaries, and enrollees of
17 the limitations on choice of participating providers
18 with respect to such care.

19 **SEC. 104. ACCESS TO SPECIALTY CARE.**

20 (a) OBSTETRICAL AND GYNECOLOGICAL CARE.—

21 (1) IN GENERAL.—If a group health plan, or a
22 health insurance issuer in connection with the provi-
23 sion of health insurance coverage, requires or pro-
24 vides for a participant, beneficiary, or enrollee to

1 designate a participating primary care provider, the
2 plan or issuer—

3 (A) may not require authorization or a re-
4 ferral by the individual's primary care provider
5 or otherwise for coverage of routine gynecolo-
6 gical care (such as preventive women's health
7 examinations) and pregnancy-related services
8 provided by a participating health care profes-
9 sional who specializes in obstetrics and gynecol-
10 ogy to the extent such care is otherwise cov-
11 ered, and

12 (B) may treat the ordering of other gynecol-
13 ological care by such a participating physician
14 as the authorization of the primary care pro-
15 vider with respect to such care under the plan
16 or coverage.

17 (2) CONSTRUCTION.—Nothing in paragraph
18 (1)(B) shall waive any requirements of coverage re-
19 lating to medical necessity or appropriateness with
20 respect to coverage of gynecological care so ordered.

21 (b) PEDIATRIC CARE.—If a group health plan, or a
22 health insurance issuer in connection with the provision
23 of health insurance coverage, requires or providers for an
24 enrollee to designate a participating primary care provider
25 for a child of such enrollee, the plan or issuer shall permit

1 the enrollee to designate a physician who specializes in pe-
2 diatrics as the child’s primary care provider.

3 (c) SPECIALTY CARE.—

4 (1) SPECIALTY CARE FOR COVERED SERV-
5 ICES.—

6 (A) IN GENERAL.—If—

7 (i) an individual is a participant or
8 beneficiary under a group health plan or
9 an enrollee who is covered under health in-
10 surance coverage offered by a health insur-
11 ance issuer,

12 (ii) the individual has a condition or
13 disease of sufficient seriousness and com-
14 plexity to require treatment by a specialist,
15 and

16 (iii) benefits for such treatment are
17 provided under the plan or coverage,

18 the plan or issuer shall make or provide for a
19 referral to a specialist who is available and ac-
20 cessible to provide the treatment for such condi-
21 tion or disease.

22 (B) SPECIALIST DEFINED.—For purposes
23 of this subsection, the term “specialist” means,
24 with respect to a condition, a health care practi-
25 tioner, facility, or center (such as a center of

1 excellence) that has adequate expertise through
2 appropriate training and experience (including,
3 in the case of a child, appropriate pediatric ex-
4 pertise) to provide high quality care in treating
5 the condition.

6 (C) CARE UNDER REFERRAL.—A group
7 health plan or health insurance issuer may re-
8 quire that the care provided to an individual
9 pursuant to such referral under subparagraph
10 (A) be—

11 (i) pursuant to a treatment plan, only
12 if the treatment plan is developed by the
13 specialist and approved by the plan or
14 issuer, in consultation with the designated
15 primary care provider or specialist and the
16 individual (or the individual's designee),
17 and

18 (ii) in accordance with applicable
19 quality assurance and utilization review
20 standards of the plan or issuer.

21 Nothing in this subsection shall be construed as
22 preventing such a treatment plan for an individ-
23 ual from requiring a specialist to provide the
24 primary care provider with regular updates on

1 the specialty care provided, as well as all nec-
2 essary medical information.

3 (D) REFERRALS TO PARTICIPATING PRO-
4 VIDERS.—A group health plan or health insur-
5 ance issuer is not required under subparagraph
6 (A) to provide for a referral to a specialist that
7 is not a participating provider, unless the plan
8 or issuer does not have an appropriate specialist
9 that is available and accessible to treat the indi-
10 vidual's condition and that is a participating
11 provider with respect to such treatment.

12 (E) TREATMENT OF NONPARTICIPATING
13 PROVIDERS.—If a plan or issuer refers an indi-
14 vidual to a nonparticipating specialist pursuant
15 to subparagraph (A), services provided pursu-
16 ant to the approved treatment plan (if any)
17 shall be provided at no additional cost to the in-
18 dividual beyond what the individual would oth-
19 erwise pay for services received by such a spe-
20 cialist that is a participating provider.

21 (2) SPECIALISTS AS GATEKEEPER FOR TREAT-
22 MENT OF ONGOING SPECIAL CONDITIONS.—

23 (A) IN GENERAL.—A group health plan, or
24 a health insurance issuer, in connection with
25 the provision of health insurance coverage, shall

1 have a procedure by which an individual who is
2 a participant, beneficiary, or enrollee and who
3 has an ongoing special condition (as defined in
4 subparagraph (C)) may receive a referral to a
5 specialist for such condition who shall be re-
6 sponsible for and capable of providing and co-
7 ordinating the individual's care with respect to
8 the condition. If such an individual's care would
9 most appropriately be coordinated by such a
10 specialist, such plan or issuer shall refer the in-
11 dividual to such specialist.

12 (B) TREATMENT AS PRIMARY CARE PRO-
13 VIDER FOR RELATED REFERRALS.—Such spe-
14 cialist shall be permitted to treat the individual
15 without a referral from the individual's primary
16 care provider and may authorize such referrals,
17 procedures, tests, and other medical services as
18 the individual's primary care provider would
19 otherwise be permitted to provide or authorize,
20 subject to the terms of the treatment plan (re-
21 ferred to in paragraph (1)(C)(i)) with respect to
22 the ongoing special condition.

23 (C) ONGOING SPECIAL CONDITION DE-
24 FINED.—In this paragraph, the term “ongoing

1 special condition” means a condition or disease
2 that—

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

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

7 (D) TERMS OF REFERRAL.—The provi-
8 sions of subparagraphs (C) through (E) of
9 paragraph (1) apply with respect to referrals
10 under subparagraph (A) of this paragraph in
11 the same manner as they apply to referrals
12 under paragraph (1)(A).

13 (3) STANDING REFERRALS.—

14 (A) IN GENERAL.—A group health plan,
15 and a health insurance issuer in connection
16 with the provision of health insurance coverage,
17 shall have a procedure by which an individual
18 who is a participant, beneficiary, or enrollee
19 and who has a condition that requires ongoing
20 care from a specialist may receive a standing
21 referral to such specialist for treatment of such
22 condition. If the plan or issuer, or if the pri-
23 mary care provider in consultation with the
24 medical director of the plan or issuer and the
25 specialist (if any), determines that such a

1 standing referral is appropriate, the plan or
2 issuer shall make such a referral to such a spe-
3 cialist.

4 (B) TERMS OF REFERRAL.—The provi-
5 sions of subparagraphs (C) through (E) of
6 paragraph (1) apply with respect to referrals
7 under subparagraph (A) of this paragraph in
8 the same manner as they apply to referrals
9 under paragraph (1)(A).

10 **SEC. 105. CONTINUITY OF CARE.**

11 (a) IN GENERAL.—

12 (1) TERMINATION OF PROVIDER.—If a contract
13 between a group health plan, or a health insurance
14 issuer in connection with the provision of health in-
15 surance coverage, and a health care provider is ter-
16 minated (as defined in paragraph (3)), or benefits or
17 coverage provided by a health care provider are ter-
18 minated because of a change in the terms of pro-
19 vider participation in a group health plan, and an in-
20 dividual who is a participant, beneficiary, or enrollee
21 in the plan or coverage is undergoing a course of
22 treatment from the provider at the time of such ter-
23 mination, the plan or issuer shall—

24 (A) notify the individual on a timely basis
25 of such termination, and

1 (B) subject to subsection (c), permit the
2 individual to continue or be covered with re-
3 spect to the course of treatment with the pro-
4 vider during a transitional period (provided
5 under subsection (b)).

6 (2) TREATMENT OF TERMINATION OF CON-
7 TRACT WITH HEALTH INSURANCE ISSUER.—If a
8 contract for the provision of health insurance cov-
9 erage between a group health plan and a health in-
10 surance issuer is terminated and, as a result of such
11 termination, coverage of services of a health care
12 provider is terminated with respect to an individual,
13 the provisions of paragraph (1) (and the succeeding
14 provisions of this section) shall apply under the plan
15 in the same manner as if there had been a contract
16 between the plan and the provider that had been ter-
17 minated, but only with respect to benefits that are
18 covered under the plan after the contract termi-
19 nation.

20 (3) TERMINATION.—In this section, the term
21 “terminated” includes, with respect to a contract,
22 the expiration or nonrenewal of the contract, but
23 does not include a termination of the contract by the
24 plan or issuer for failure to meet applicable quality
25 standards or for fraud.

1 (b) TRANSITIONAL PERIOD.—

2 (1) IN GENERAL.—Except as provided in para-
3 graphs (2) through (4), the transitional period under
4 this subsection shall extend for at least 90 days from
5 the date of the notice described in subsection
6 (a)(1)(A) of the provider’s termination.

7 (2) INSTITUTIONAL CARE.—The transitional pe-
8 riod under this subsection for institutional or inpa-
9 tient care from a provider shall extend until the dis-
10 charge or termination of the period of institutional-
11 ization and also shall include institutional care pro-
12 vided within a reasonable time of the date of termi-
13 nation of the provider status if the care was sched-
14 uled before the date of the announcement of the ter-
15 mination of the provider status under subsection
16 (a)(1)(A) or if the individual on such date was on
17 an established waiting list or otherwise scheduled to
18 have such care.

19 (3) PREGNANCY.—If—

20 (A) a participant, beneficiary, or enrollee
21 has entered the second trimester of pregnancy
22 at the time of a provider’s termination of par-
23 ticipation, and

24 (B) the provider was treating the preg-
25 nancy before date of the termination,

1 the transitional period under this subsection with re-
2 spect to provider's treatment of the pregnancy shall
3 extend through the provision of post-partum care di-
4 rectly related to the delivery.

5 (4) TERMINAL ILLNESS.—If—

6 (A) a participant, beneficiary, or enrollee
7 was determined to be terminally ill (as deter-
8 mined under section 1861(dd)(3)(A) of the So-
9 cial Security Act) at the time of a provider's
10 termination of participation, and

11 (B) the provider was treating the terminal
12 illness before the date of termination,

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

17 (c) PERMISSIBLE TERMS AND CONDITIONS.—A
18 group health plan or health insurance issuer may condi-
19 tion coverage of continued treatment by a provider under
20 subsection (a)(1)(B) upon the provider agreeing to the fol-
21 lowing terms and conditions:

22 (1) The provider agrees to accept reimburse-
23 ment from the plan or issuer and individual involved
24 (with respect to cost-sharing) at the rates applicable
25 prior to the start of the transitional period as pay-

1 ment in full (or, in the case described in subsection
2 (a)(2), at the rates applicable under the replacement
3 plan or issuer after the date of the termination of
4 the contract with the health insurance issuer) and
5 not to impose cost-sharing with respect to the indi-
6 vidual in an amount that would exceed the cost-shar-
7 ing that could have been imposed if the contract re-
8 ferred to in subsection (a)(1) had not been termi-
9 nated.

10 (2) The provider agrees to adhere to the quality
11 assurance standards of the plan or issuer responsible
12 for payment under paragraph (1) and to provide to
13 such plan or issuer necessary medical information
14 related to the care provided.

15 (3) The provider agrees otherwise to adhere to
16 such plan's or issuer's policies and procedures, in-
17 cluding procedures regarding referrals and obtaining
18 prior authorization and providing services pursuant
19 to a treatment plan (if any) approved by the plan or
20 issuer.

21 (d) CONSTRUCTION.—Nothing in this section shall be
22 construed to require the coverage of benefits which would
23 not have been covered if the provider involved remained
24 a participating provider.

1 **SEC. 106. COVERAGE FOR INDIVIDUALS PARTICIPATING IN**
2 **APPROVED CLINICAL TRIALS.**

3 (a) **COVERAGE.**—

4 (1) **IN GENERAL.**—If a group health plan, or
5 health insurance issuer that is providing health in-
6 surance coverage, provides coverage to a qualified in-
7 dividual (as defined in subsection (b)), the plan or
8 issuer—

9 (A) may not deny the individual participa-
10 tion in the clinical trial referred to in subsection
11 (b)(2);

12 (B) subject to subsection (c), may not deny
13 (or limit or impose additional conditions on) the
14 coverage of routine patient costs for items and
15 services furnished in connection with participa-
16 tion in the trial; and

17 (C) may not discriminate against the indi-
18 vidual on the basis of the enrollee's participa-
19 tion in such trial.

20 (2) **EXCLUSION OF CERTAIN COSTS.**—For pur-
21 poses of paragraph (1)(B), routine patient costs do
22 not include the cost of the tests or measurements
23 conducted primarily for the purpose of the clinical
24 trial involved.

25 (3) **USE OF IN-NETWORK PROVIDERS.**—If one
26 or more participating providers is participating in a

1 clinical trial, nothing in paragraph (1) shall be con-
2 strued as preventing a plan or issuer from requiring
3 that a qualified individual participate in the trial
4 through such a participating provider if the provider
5 will accept the individual as a participant in the
6 trial.

7 (b) QUALIFIED INDIVIDUAL DEFINED.—For pur-
8 poses of subsection (a), the term “qualified individual”
9 means an individual who is a participant or beneficiary
10 in a group health plan, or who is an enrollee under health
11 insurance coverage, and who meets the following condi-
12 tions:

13 (1)(A) The individual has a life-threatening or
14 serious illness for which no standard treatment is ef-
15 fective.

16 (B) The individual is eligible to participate in
17 an approved clinical trial according to the trial pro-
18 tocol with respect to treatment of such illness.

19 (C) The individual’s participation in the trial
20 offers meaningful potential for significant clinical
21 benefit for the individual.

22 (2) Either—

23 (A) the referring physician is a participat-
24 ing health care professional and has concluded
25 that the individual’s participation in such trial

1 would be appropriate based upon the individual
2 meeting the conditions described in paragraph
3 (1); or

4 (B) the participant, beneficiary, or enrollee
5 provides medical and scientific information es-
6 tablishing that the individual's participation in
7 such trial would be appropriate based upon the
8 individual meeting the conditions described in
9 paragraph (1).

10 (c) PAYMENT.—

11 (1) IN GENERAL.—Under this section a group
12 health plan or health insurance issuer shall provide
13 for payment for routine patient costs described in
14 subsection (a)(2) but is not required to pay for costs
15 of items and services that are reasonably expected
16 (as determined by the Secretary) to be paid for by
17 the sponsors of an approved clinical trial.

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

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

22 (B) a nonparticipating provider, the pay-
23 ment rate shall be at the rate the plan or issuer
24 would normally pay for comparable services
25 under subparagraph (A).

1 (d) APPROVED CLINICAL TRIAL DEFINED.—

2 (1) IN GENERAL.—In this section, the term
3 “approved clinical trial” means a clinical research
4 study or clinical investigation approved and funded
5 (which may include funding through in-kind con-
6 tributions) by one or more of the following:

7 (A) The National Institutes of Health.

8 (B) A cooperative group or center of the
9 National Institutes of Health.

10 (C) Either of the following if the condi-
11 tions described in paragraph (2) are met:

12 (i) The Department of Veterans Af-
13 fairs.

14 (ii) The Department of Defense.

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

21 (A) to be comparable to the system of peer
22 review of studies and investigations used by the
23 National Institutes of Health, and

1 (B) assures unbiased review of the highest
2 scientific standards by qualified individuals who
3 have no interest in the outcome of the review.

4 (e) CONSTRUCTION.—Nothing in this section shall be
5 construed to limit a plan’s or issuer’s coverage with re-
6 spect to clinical trials.

7 **SEC. 107. ACCESS TO NEEDED PRESCRIPTION DRUGS.**

8 (a) IN GENERAL.—If a group health plan, or health
9 insurance issuer that offers health insurance coverage,
10 provides benefits with respect to prescription drugs but
11 the coverage limits such benefits to drugs included in a
12 formulary, the plan or issuer shall—

13 (1) ensure participation of participating physi-
14 cians and pharmacists in the development of the for-
15 mulary;

16 (2) disclose to providers and, disclose upon re-
17 quest under section 121(c)(6) to participants, bene-
18 ficiaries, and enrollees, the nature of the formulary
19 restrictions; and

20 (3) consistent with the standards for a utiliza-
21 tion review program under section 111, provide for
22 exceptions from the formulary limitation when a
23 non-formulary alternative is medically indicated.

24 (b) COVERAGE OF APPROVED DRUGS AND MEDICAL
25 DEVICES.—

1 (1) IN GENERAL.—A group health plan (or
2 health insurance coverage offered in connection with
3 such a plan) that provides any coverage of prescrip-
4 tion drugs or medical devices shall not deny coverage
5 of such a drug or device on the basis that the use
6 is investigational, if the use—

7 (A) in the case of a prescription drug—

8 (i) is included in the labeling author-
9 ized by the application in effect for the
10 drug pursuant to subsection (b) or (j) of
11 section 505 of the Federal Food, Drug,
12 and Cosmetic Act, without regard to any
13 postmarketing requirements that may
14 apply under such Act; or

15 (ii) is included in the labeling author-
16 ized by the application in effect for the
17 drug under section 351 of the Public
18 Health Service Act, without regard to any
19 postmarketing requirements that may
20 apply pursuant to such section; or

21 (B) in the case of a medical device, is in-
22 cluded in the labeling authorized by a regula-
23 tion under subsection (d) or (3) of section 513
24 of the Federal Food, Drug, and Cosmetic Act,
25 an order under subsection (f) of such section, or

1 an application approved under section 515 of
2 such Act, without regard to any postmarketing
3 requirements that may apply under such Act.

4 (2) CONSTRUCTION.—Nothing in this sub-
5 section shall be construed as requiring a group
6 health plan (or health insurance coverage offered in
7 connection with such a plan) to provide any coverage
8 of prescription drugs or medical devices.

9 **SEC. 108. ADEQUACY OF PROVIDER NETWORK.**

10 (a) IN GENERAL.—Each group health plan, and each
11 health insurance issuer offering health insurance coverage,
12 that provides benefits, in whole or in part, through partici-
13 pating health care providers shall have (in relation to the
14 coverage) a sufficient number, distribution, and variety of
15 qualified participating health care providers to ensure that
16 all covered health care services, including specialty serv-
17 ices, will be available and accessible in a timely manner
18 to all participants, beneficiaries, and enrollees under the
19 plan or coverage. This subsection shall only apply to a
20 plan’s or issuer’s application of restrictions on the partici-
21 pation of health care providers in a network and shall not
22 be construed as requiring a plan or issuer to create or
23 establish new health care providers in an area.

24 (b) TREATMENT OF CERTAIN PROVIDERS.—The
25 qualified health care providers under subsection (a) may

1 include Federally qualified health centers, rural health
2 clinics, migrant health centers, and other essential com-
3 munity providers located in the service area of the plan
4 or issuer and shall include such providers if necessary to
5 meet the standards established to carry out such sub-
6 section.

7 **Subtitle B—Quality Assurance**

8 **SEC. 111. STANDARDS FOR UTILIZATION REVIEW ACTIVI-** 9 **TIES.**

10 (a) COMPLIANCE WITH REQUIREMENTS.—

11 (1) IN GENERAL.—A group health plan, and a
12 health insurance issuer that provides health insur-
13 ance coverage, shall conduct utilization review activi-
14 ties in connection with the provision of benefits
15 under such plan or coverage only in accordance with
16 a utilization review program that meets the require-
17 ments of this section.

18 (2) USE OF OUTSIDE AGENTS.—Nothing in this
19 section shall be construed as preventing a group
20 health plan or health insurance issuer from arrang-
21 ing through a contract or otherwise for persons or
22 entities to conduct utilization review activities on be-
23 half of the plan or issuer, so long as such activities
24 are conducted in accordance with a utilization review
25 program that meets the requirements of this section.

1 (3) UTILIZATION REVIEW DEFINED.—For pur-
2 poses of this section, the terms “utilization review”
3 and “utilization review activities” mean procedures
4 used to monitor or evaluate the clinical necessity,
5 appropriateness, efficacy, or efficiency of health care
6 services, procedures or settings, and includes pro-
7 spective review, concurrent review, second opinions,
8 case management, discharge planning, or retrospec-
9 tive review.

10 (b) WRITTEN POLICIES AND CRITERIA.—

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

15 (2) USE OF WRITTEN CRITERIA.—

16 (A) IN GENERAL.—Such a program shall
17 utilize written clinical review criteria developed
18 pursuant to the program with the input of ap-
19 propriate physicians.

20 (B) CONTINUING USE OF STANDARDS IN
21 RETROSPECTIVE REVIEW.—If a health care
22 service has been specifically pre-authorized or
23 approved for an enrollee under such a program,
24 the program shall not, pursuant to retrospective
25 review, revise or modify the specific standards,

1 criteria, or procedures used for the utilization
2 review for procedures, treatment, and services
3 delivered to the enrollee during the same course
4 of treatment.

5 (c) CONDUCT OF PROGRAM ACTIVITIES.—

6 (1) ADMINISTRATION BY HEALTH CARE PRO-
7 FESSIONALS.—A utilization review program shall be
8 administered by qualified health care professionals
9 who shall oversee review decisions. In this sub-
10 section, the term “health care professional” means a
11 physician or other health care practitioner licensed,
12 accredited, or certified to perform specified health
13 services consistent with State law.

14 (2) USE OF QUALIFIED, INDEPENDENT PER-
15 SONNEL.—

16 (A) IN GENERAL.—A utilization review
17 program shall provide for the conduct of utiliza-
18 tion review activities only through personnel
19 who are qualified and, to the extent required,
20 who have received appropriate training in the
21 conduct of such activities under the program.

22 (B) PEER REVIEW OF SAMPLE OF AD-
23 VERSE CLINICAL DETERMINATIONS.—Such a
24 program shall provide that clinical peers (as de-
25 fined in section 191(c)(2)) shall evaluate the

1 clinical appropriateness of at least a sample of
2 adverse clinical determinations.

3 (C) PROHIBITION OF CONTINGENT COM-
4 PENSATION ARRANGEMENTS.—Such a program
5 shall not, with respect to utilization review ac-
6 tivities, permit or provide compensation or any-
7 thing of value to its employees, agents, or con-
8 tractors in a manner that—

9 (i) provides incentives, direct or indi-
10 rect, for such persons to make inappropri-
11 ate review decisions, or

12 (ii) is based, directly or indirectly, on
13 the quantity or type of adverse determina-
14 tions rendered.

15 (D) PROHIBITION OF CONFLICTS.—Such a
16 program shall not permit a health care profes-
17 sional who provides health care services to an
18 individual to perform utilization review activi-
19 ties in connection with the health care services
20 being provided to the individual.

21 (3) ACCESSIBILITY OF REVIEW.—Such a pro-
22 gram shall provide that appropriate personnel per-
23 forming utilization review activities under the pro-
24 gram are reasonably accessible by toll-free telephone
25 during normal business hours to discuss patient care

1 and allow response to telephone requests, and that
2 appropriate provision is made to receive and respond
3 promptly to calls received during other hours.

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

10 (5) LIMITATION ON INFORMATION REQUESTS.—
11 Under such a program, information shall be required
12 to be provided by health care providers only to the
13 extent it is necessary to perform the utilization re-
14 view activity involved.

15 (d) DEADLINE FOR DETERMINATIONS.—

16 (1) PRIOR AUTHORIZATION SERVICES.—Except
17 as provided in paragraph (2), in the case of a utili-
18 zation review activity involving the prior authoriza-
19 tion of health care items and services for an individ-
20 ual, the utilization review program shall make a de-
21 termination concerning such authorization, and pro-
22 vide notice of the determination to the individual or
23 the individual's designee and the individual's health
24 care provider by telephone and in printed form, as
25 soon as possible in accordance with the medical ex-

1 agencies of the cases, and in no event later than 3
2 business days after the date of receipt of information
3 that is reasonably necessary to make such deter-
4 mination.

5 (2) CONTINUED CARE.—In the case of a utiliza-
6 tion review activity involving authorization for con-
7 tinued or extended health care services for an indi-
8 vidual, or additional services for an individual under-
9 going a course of continued treatment prescribed by
10 a health care provider, the utilization review pro-
11 gram shall make a determination concerning such
12 authorization, and provide notice of the determina-
13 tion to the individual or the individual’s designee
14 and the individual’s health care provider by tele-
15 phone and in printed form, as soon as possible in ac-
16 cordance with the medical exigencies of the cases,
17 and in no event later than 1 business day after the
18 date of receipt of information that is reasonably nec-
19 essary to make such determination. Such notice shall
20 include, with respect to continued or extended health
21 care services, the number of extended services ap-
22 proved, the new total of approved services, the date
23 of onset of services, and the next review date, if any.

24 (3) PREVIOUSLY PROVIDED SERVICES.—In the
25 case of a utilization review activity involving retro-

1 spective review of health care services previously pro-
2 vided for an individual, the utilization review pro-
3 gram shall make a determination concerning such
4 services, and provide notice of the determination to
5 the individual or the individual's designee and the
6 individual's health care provider by telephone and in
7 printed form, within 30 days of the date of receipt
8 of information that is reasonably necessary to make
9 such determination.

10 (4) REFERENCE TO SPECIAL RULES FOR EMER-
11 GENCY SERVICES, MAINTENANCE CARE, AND POST-
12 STABILIZATION CARE.—For waiver of prior author-
13 ization requirements in certain cases involving emer-
14 gency services and maintenance care and post-sta-
15 bilization care, see subsections (a)(1) and (b) of sec-
16 tion 101, respectively.

17 (e) NOTICE OF ADVERSE DETERMINATIONS.—

18 (1) IN GENERAL.—Notice of an adverse deter-
19 mination under a utilization review program shall be
20 provided in printed form and shall include—

21 (A) the reasons for the determination (in-
22 cluding the clinical rationale);

23 (B) instructions on how to initiate an ap-
24 peal under section 132; and

1 (C) notice of the availability, upon request
2 of the individual (or the individual's designee)
3 of the clinical review criteria relied upon to
4 make such determination.

5 (2) SPECIFICATION OF ANY ADDITIONAL INFOR-
6 MATION.—Such a notice shall also specify what (if
7 any) additional necessary information must be pro-
8 vided to, or obtained by, the person making the de-
9 termination in order to make a decision on such an
10 appeal.

11 **Subtitle C—Patient Information**

12 **SEC. 121. PATIENT INFORMATION.**

13 (a) DISCLOSURE REQUIREMENT.—

14 (1) GROUP HEALTH PLANS.—A group health
15 plan shall—

16 (A) provide to participants and bene-
17 ficiaries at the time of initial coverage under
18 the plan (or the effective date of this section, in
19 the case of individuals who are participants or
20 beneficiaries as of such date), and at least an-
21 nually thereafter, the information described in
22 subsection (b) in printed form;

23 (B) provide to participants and bene-
24 ficiaries, within a reasonable period (as speci-
25 fied by the appropriate Secretary) before or

1 after the date of significant changes in the in-
2 formation described in subsection (b), informa-
3 tion in printed form on such significant
4 changes; and

5 (C) upon request, make available to par-
6 ticipants and beneficiaries, the applicable au-
7 thority, and prospective participants and bene-
8 ficiaries, the information described in sub-
9 section (b) or (c) in printed form.

10 (2) HEALTH INSURANCE ISSUERS.—A health
11 insurance issuer in connection with the provision of
12 health insurance coverage shall—

13 (A) provide to individuals enrolled under
14 such coverage at the time of enrollment, and at
15 least annually thereafter, the information de-
16 scribed in subsection (b) in printed form;

17 (B) provide to enrollees, within a reason-
18 able period (as specified by the appropriate Sec-
19 retary) before or after the date of significant
20 changes in the information described in sub-
21 section (b), information in printed form on such
22 significant changes; and

23 (C) upon request, make available to the
24 applicable authority, to individuals who are pro-
25 spective enrollees, and to the public the infor-

1 mation described in subsection (b) or (c) in
2 printed form.

3 (b) INFORMATION PROVIDED.—The information de-
4 scribed in this subsection with respect to a group health
5 plan or health insurance coverage offered by a health in-
6 surance issuer includes the following:

7 (1) SERVICE AREA.—The service area of the
8 plan or issuer.

9 (2) BENEFITS.—Benefits offered under the
10 plan or coverage, including—

11 (A) covered benefits, including benefit lim-
12 its and coverage exclusions;

13 (B) cost sharing, such as deductibles, coin-
14 surance, and copayment amounts, including any
15 liability for balance billing, any maximum limi-
16 tations on out of pocket expenses, and the max-
17 imum out of pocket costs for services that are
18 provided by nonparticipating providers or that
19 are furnished without meeting the applicable
20 utilization review requirements;

21 (C) the extent to which benefits may be ob-
22 tained from nonparticipating providers;

23 (D) the extent to which a participant, ben-
24 eficiary, or enrollee may select from among par-

1 participating providers and the types of providers
2 participating in the plan or issuer network;

3 (E) process for determining experimental
4 coverage; and

5 (F) use of a prescription drug formulary.

6 (3) ACCESS.—A description of the following:

7 (A) The number, mix, and distribution of
8 providers under the plan or coverage.

9 (B) Out-of-network coverage (if any) pro-
10 vided by the plan or coverage.

11 (C) Any point-of-service option (including
12 any supplemental premium or cost-sharing for
13 such option).

14 (D) The procedures for participants, bene-
15 ficiaries, and enrollees to select, access, and
16 change participating primary and specialty pro-
17 viders.

18 (E) The rights and procedures for obtain-
19 ing referrals (including standing referrals) to
20 participating and nonparticipating providers.

21 (F) The name, address, and telephone
22 number of participating health care providers
23 and an indication of whether each such provider
24 is available to accept new patients.

1 (G) Any limitations imposed on the selec-
2 tion of qualifying participating health care pro-
3 viders, including any limitations imposed under
4 section 103(b)(2).

5 (H) How the plan or issuer addresses the
6 needs of participants, beneficiaries, and enroll-
7 ees and others who do not speak English or
8 who have other special communications needs in
9 accessing providers under the plan or coverage,
10 including the provision of information described
11 in this subsection and subsection (c) to such in-
12 dividuals and including the provision of infor-
13 mation in a language other than English if 5
14 percent of the number of participants, bene-
15 ficiaries, and enrollees communicate in that lan-
16 guage instead of English.

17 (4) OUT-OF-AREA COVERAGE.—Out-of-area cov-
18 erage provided by the plan or issuer.

19 (5) EMERGENCY COVERAGE.—Coverage of
20 emergency services, including—

21 (A) the appropriate use of emergency serv-
22 ices, including use of the 911 telephone system
23 or its local equivalent in emergency situations
24 and an explanation of what constitutes an
25 emergency situation;

1 (B) the process and procedures of the plan
2 or issuer for obtaining emergency services; and

3 (C) the locations of (i) emergency depart-
4 ments, and (ii) other settings, in which plan
5 physicians and hospitals provide emergency
6 services and post-stabilization care.

7 (6) PERCENTAGE OF PREMIUMS USED FOR
8 BENEFITS (LOSS-RATIOS).—In the case of health in-
9 surance coverage only (and not with respect to group
10 health plans that do not provide coverage through
11 health insurance coverage), a description of the over-
12 all loss-ratio for the coverage (as defined in accord-
13 ance with rules established or recognized by the Sec-
14 retary of Health and Human Services).

15 (7) PRIOR AUTHORIZATION RULES.—Rules re-
16 garding prior authorization or other review require-
17 ments that could result in noncoverage or non-
18 payment.

19 (8) GRIEVANCE AND APPEALS PROCEDURES.—
20 All appeal or grievance rights and procedures under
21 the plan or coverage, including the method for filing
22 grievances and the time frames and circumstances
23 for acting on grievances and appeals, who is the ap-
24 plicable authority with respect to the plan or issuer,
25 and the availability of assistance through an om-

1 budsman to individuals in relation to group health
2 plans and health insurance coverage.

3 (9) SUMMARY OF PROVIDER FINANCIAL INCEN-
4 TIVES.—A summary description of the information
5 on the types of financial payment incentives (de-
6 scribed in section 1852(j)(4) of the Social Security
7 Act) provided by the plan or issuer under the cov-
8 erage.

9 (10) INFORMATION ON ISSUER.—Notice of ap-
10 propriate mailing addresses and telephone numbers
11 to be used by participants, beneficiaries, and enroll-
12 ees in seeking information or authorization for treat-
13 ment.

14 (11) AVAILABILITY OF INFORMATION ON RE-
15 QUEST.—Notice that the information described in
16 subsection (c) is available upon request.

17 (c) INFORMATION MADE AVAILABLE UPON RE-
18 QUEST.—The information described in this subsection is
19 the following:

20 (1) UTILIZATION REVIEW ACTIVITIES.—A de-
21 scription of procedures used and requirements (in-
22 cluding circumstances, time frames, and appeal
23 rights) under any utilization review program under
24 section 111, including under any drug formulary
25 program under section 107.

1 (2) GRIEVANCE AND APPEALS INFORMATION.—
2 Information on the number of grievances and ap-
3 peals and on the disposition in the aggregate of such
4 matters.

5 (3) METHOD OF PHYSICIAN COMPENSATION.—
6 An overall summary description as to the method of
7 compensation of participating physicians, including
8 information on the types of financial payment incen-
9 tives (described in section 1852(j)(4) of the Social
10 Security Act) provided by the plan or issuer under
11 the coverage.

12 (4) SPECIFIC INFORMATION ON CREDENTIALS
13 OF PARTICIPATING PROVIDERS.—In the case of each
14 participating provider, a description of the creden-
15 tials of the provider as they relate to education,
16 training, specialty qualifications, and national ac-
17 creditation.

18 (5) CONFIDENTIALITY POLICIES AND PROCE-
19 DURES.—A description of the policies and proce-
20 dures established to carry out section 122.

21 (6) FORMULARY RESTRICTIONS.—A description
22 of the nature of any drug formula restrictions.

23 (7) PARTICIPATING PROVIDER LIST.—A list of
24 current participating health care providers.

25 (d) FORM OF DISCLOSURE.—

1 (1) UNIFORMITY.—Information required to be
2 disclosed under this section shall be provided in ac-
3 cordance with uniform, national reporting standards
4 specified by the Secretary, after consultation with
5 applicable State authorities, so that prospective en-
6 rollees may compare the attributes of different
7 issuers and coverage offered within an area.

8 (2) INFORMATION INTO HANDBOOK.—Nothing
9 in this section shall be construed as preventing a
10 group health plan or health insurance issuer from
11 making the information under subsections (b) and
12 (c) available to participants, beneficiaries, and en-
13 rollees through an enrollee handbook or similar pub-
14 lication.

15 (3) UPDATING PARTICIPATING PROVIDER IN-
16 FORMATION.—The information on participating
17 health care providers described in subsection
18 (b)(3)(C) shall be updated within such reasonable
19 period as determined appropriate by the Secretary.
20 Nothing in this section shall prevent an issuer from
21 changing or updating other information made avail-
22 able under this section.

23 (e) CONSTRUCTION.—Nothing in this section shall be
24 construed as requiring public disclosure of individual con-

1 tracts or financial arrangements between a group health
2 plan or health insurance issuer and any provider.

3 **SEC. 122. PROTECTION OF PATIENT CONFIDENTIALITY.**

4 Insofar as a group health plan, or a health insurance
5 issuer that offers health insurance coverage, maintains
6 medical records or other health information regarding par-
7 ticipants, beneficiaries, and enrollees, the plan or issuer
8 shall establish procedures—

9 (1) to safeguard the privacy of any individually
10 identifiable enrollee information;

11 (2) to maintain such records and information in
12 a manner that is accurate and timely, and

13 (3) to assure timely access of such individuals
14 to such records and information.

15 **SEC. 123. HEALTH INSURANCE OMBUDSMEN.**

16 (a) IN GENERAL.—Each State that obtains a grant
17 under subsection (c) shall provide for creation and oper-
18 ation of a Health Insurance Ombudsman through a con-
19 tract with a not-for-profit organization that operates inde-
20 pendent of group health plans and health insurance
21 issuers. Such Ombudsman shall be responsible for at least
22 the following:

23 (1) To assist consumers in the State in choos-
24 ing among health insurance coverage or among cov-
25 erage options offered within group health plans.

1 (2) To provide counseling and assistance to en-
2 rollees dissatisfied with their treatment by health in-
3 surance issuers and group health plans in regard to
4 such coverage or plans and with respect to griev-
5 ances and appeals regarding determinations under
6 such coverage or plans.

7 (b) FEDERAL ROLE.—In the case of any State that
8 does not provide for such an Ombudsman under sub-
9 section (a), the Secretary shall provide for the creation
10 and operation of a Health Insurance Ombudsman through
11 a contract with a not-for-profit organization that operates
12 independent of group health plans and health insurance
13 issuers and that is responsible for carrying out with re-
14 spect to that State the functions otherwise provided under
15 subsection (a) by a Health Insurance Ombudsman.

16 (c) AUTHORIZATION OF APPROPRIATIONS.—There
17 are authorized to be appropriated to the Secretary of
18 Health and Human Services such amounts as may be nec-
19 essary to provide for grants to States for contracts for
20 Health Insurance Ombudsmen under subsection (a) or
21 contracts for such Ombudsmen under subsection (b).

22 (d) CONSTRUCTION.—Nothing in this section shall be
23 construed to prevent the use of other forms of enrollee
24 assistance.

1 **Subtitle D—Grievance and Appeals**
2 **Procedures**

3 **SEC. 131. ESTABLISHMENT OF GRIEVANCE PROCESS.**

4 (a) ESTABLISHMENT OF GRIEVANCE SYSTEM.—

5 (1) IN GENERAL.—A group health plan, and a
6 health insurance issuer in connection with the provi-
7 sion of health insurance coverage, shall establish and
8 maintain a system to provide for the presentation
9 and resolution of oral and written grievances
10 brought by individuals who are participants, bene-
11 ficiaries, or enrollees, or health care providers or
12 other individuals acting on behalf of an individual
13 and with the individual’s consent, regarding any as-
14 pect of the plan’s or issuer’s services.

15 (2) SCOPE.—The system shall include griev-
16 ances regarding access to and availability of services,
17 quality of care, choice and accessibility of providers,
18 network adequacy, and compliance with the require-
19 ments of this title.

20 (b) GRIEVANCE SYSTEM.—Such system shall include
21 the following components with respect to individuals who
22 are participants, beneficiaries, or enrollees:

23 (1) Written notification to all such individuals
24 and providers of the telephone numbers and business

1 addresses of the plan or issuer personnel responsible
2 for resolution of grievances and appeals.

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

6 (3) A process providing for timely processing
7 and resolution of grievances.

8 (4) Procedures for follow-up action, including
9 the methods to inform the person making the griev-
10 ance of the resolution of the grievance.

11 **SEC. 132. INTERNAL APPEALS OF ADVERSE DETERMINA-**
12 **TIONS.**

13 (a) RIGHT OF APPEAL.—

14 (1) IN GENERAL.—A participant or beneficiary
15 in a group health plan, and an enrollee in health in-
16 surance coverage offered by a health insurance
17 issuer, and any provider or other person acting on
18 behalf of such an individual with the individual's
19 consent, may appeal any appealable decision (as de-
20 fined in paragraph (2)) under the procedures de-
21 scribed in this section and (to the extent applicable)
22 section 133. Such individuals and providers shall be
23 provided with a written explanation of the appeal
24 process and the determination upon the conclusion

1 of the appeals process and as provided in section
2 121(b)(8).

3 (2) APPEALABLE DECISION DEFINED.—In this
4 section, the term “appealable decision” means any of
5 the following:

6 (A) Denial, reduction, or termination of, or
7 failure to provide or make payment (in whole or
8 in part) for, a benefit, including a failure to
9 cover an item or service for which benefits are
10 otherwise provided because it is determined to
11 be experimental or investigational or not medi-
12 cally necessary or appropriate.

13 (B) Failure to provide coverage of emer-
14 gency services or reimbursement of mainte-
15 nance care or post-stabilization care under sec-
16 tion 101.

17 (C) Failure to provide a choice of provider
18 under section 103.

19 (D) Failure to provide qualified health care
20 providers under section 103.

21 (E) Failure to provide access to specialty
22 and other care under section 104.

23 (F) Failure to provide continuation of care
24 under section 105.

1 (G) Failure to provide coverage of routine
2 patient costs in connection with an approval
3 clinical trial under section 106.

4 (H) Failure to provide access to needed
5 drugs under section 107(a)(3) or 107(b).

6 (I) An adverse determination under a utili-
7 zation review program under section 111.

8 (J) The imposition of a limitation that is
9 prohibited under section 151.

10 (b) INTERNAL APPEAL PROCESS.—

11 (1) IN GENERAL.—Each group health plan and
12 health insurance issuer shall establish and maintain
13 an internal appeal process under which any partici-
14 pant, beneficiary, enrollee, or provider acting on be-
15 half of such an individual with the individual's con-
16 sent, who is dissatisfied with any appealable decision
17 has the opportunity to appeal the decision through
18 an internal appeal process. The appeal may be com-
19 municated orally.

20 (2) CONDUCT OF REVIEW.—

21 (A) IN GENERAL.—The process shall in-
22 clude a review of the decision by a physician or
23 other health care professional (or professionals)
24 who has been selected by the plan or issuer and

1 who has not been involved in the appealable de-
2 cision at issue in the appeal.

3 (B) AVAILABILITY AND PARTICIPATION OF
4 CLINICAL PEERS.—The individuals conducting
5 such review shall include one or more clinical
6 peers (as defined in section 191(c)(2)) who have
7 not been involved in the appealable decision at
8 issue in the appeal.

9 (3) DEADLINE.—

10 (A) IN GENERAL.—Subject to subsection
11 (c), the plan or issuer shall conclude each ap-
12 peal as soon as possible after the time of the re-
13 ceipt of the appeal in accordance with medical
14 exigencies of the case involved, but in no event
15 later than—

16 (i) 72 hours after the time of receipt
17 of an expedited appeal, and

18 (ii) except as provided in subpara-
19 graph (B), 30 days after such time (or, if
20 the participant, beneficiary, or enrollee
21 supplies additional information that was
22 not available to the plan or issuer at the
23 time of the receipt of the appeal, after the
24 date of supplying such additional informa-
25 tion) in the case of all other appeals.

1 (B) EXTENSION.—In the case of an appeal
2 that does not relate to a decision regarding an
3 expedited appeal and that does not involve med-
4 ical exigencies, if a group health plan or health
5 insurance issuer is unable to conclude the ap-
6 peal within the time period provided under sub-
7 paragraph (A)(ii) due to circumstances beyond
8 the control of the plan or issuer, the deadline
9 shall be extended for up to an additional 3 busi-
10 ness days if the plan or issuer provides, on or
11 before 10 days before the deadline otherwise ap-
12 plicable, written notice to the participant, bene-
13 ficiary, or enrollee and the provider involved of
14 the extension and the reasons for the extension.

15 (4) NOTICE.—If a plan or issuer denies an ap-
16 peal, the plan or issuer shall provide the participant,
17 beneficiary, or enrollee and provider involved with
18 notice in printed form of the denial and the reasons
19 therefore, together with a notice in printed form of
20 rights to any further appeal.

21 (c) EXPEDITED REVIEW PROCESS.—

22 (1) IN GENERAL.—A group health plan, and a
23 health insurance issuer, shall establish procedures in
24 writing for the expedited consideration of appeals
25 under subsection (b) in situations in which the appli-

1 cation of the normal timeframe for making a deter-
2 mination could seriously jeopardize the life or health
3 of the participant, beneficiary, or enrollee or such an
4 individual's ability to regain maximum function.

5 (2) PROCESS.—Under such procedures—

6 (A) the request for expedited appeal may
7 be submitted orally or in writing by an individ-
8 ual or provider who is otherwise entitled to re-
9 quest the appeal;

10 (B) all necessary information, including
11 the plan's or issuer's decision, shall be trans-
12 mitted between the plan or issuer and the re-
13 quester by telephone, facsimile, or other simi-
14 larly expeditious available method; and

15 (C) the plan or issuer shall expedite the
16 appeal if the request for an expedited appeal is
17 submitted under subparagraph (A) by a physi-
18 cian and the request indicates that the situation
19 described in paragraph (1) exists.

20 (d) DIRECT USE OF FURTHER APPEALS.—In the
21 event that the plan or issuer fails to comply with any of
22 the deadlines for completion of appeals under this section
23 or in the event that the plan or issuer for any reason ex-
24 pressly waives its rights to an internal review of an appeal
25 under subsection (b), the participant, beneficiary, or en-

1 rollee involved and the provider involved shall be relieved
2 of any obligation to complete the appeal involved and may,
3 at such an individual's or provider's option, proceed di-
4 rectly to seek further appeal through any applicable exter-
5 nal appeals process.

6 **SEC. 133. EXTERNAL APPEALS OF ADVERSE DETERMINA-**
7 **TIONS.**

8 (a) **RIGHT TO EXTERNAL APPEAL.—**

9 (1) **IN GENERAL.—**A group health plan, and a
10 health insurance issuer offering group health insur-
11 ance coverage, shall provide for an external appeals
12 process that meets the requirements of this section
13 in the case of an externally appealable decision de-
14 scribed in paragraph (2), for which a timely appeal
15 is made either by the plan or issuer or by the partic-
16 ipant, beneficiary, or enrollee, or a representative of
17 any of them. The appropriate Secretary shall estab-
18 lish standards to carry out such requirements.

19 (2) **EXTERNALLY APPEALABLE DECISION DE-**
20 **FINED.—**For purposes of this section, the term “ex-
21 ternally appealable decision” means an appealable
22 decision (as defined in section 132(a)(2)) if—

23 (A) the amount involved exceeds \$100; or

24 (B) the patient's life or health is jeopard-
25 ized as a consequence of the decision.

1 Such term does not include a denial of coverage for
2 services that are specifically listed in plan or cov-
3 erage documents as excluded from coverage.

4 (3) EXHAUSTION OF INTERNAL APPEALS PROC-
5 ESS.—A plan or issuer may condition the use of an
6 external appeal process in the case of an externally
7 appealable decision upon completion of the internal
8 review process provided under section 132, but only
9 if the decision is made in a timely basis consistent
10 with the deadlines provided under this subtitle.

11 (b) GENERAL ELEMENTS OF EXTERNAL APPEALS
12 PROCESS.—

13 (1) CONTRACT WITH QUALIFIED EXTERNAL AP-
14 PEAL ENTITY.—

15 (A) CONTRACT REQUIREMENT.—Subject to
16 subparagraph (B), the external appeal process
17 under this section of a plan or issuer shall be
18 conducted under a contract between the plan or
19 issuer and one or more qualified external appeal
20 entities (as defined in subsection (c)).

21 (B) RESTRICTIONS ON QUALIFIED EXTER-
22 NAL APPEAL ENTITY.—

23 (i) BY STATE FOR HEALTH INSUR-
24 ANCE ISSUERS.—With respect to health in-
25 surance issuers in a State, the State may

1 provide for external review activities to be
2 conducted by a qualified external appeal
3 entity that is designated by the State or
4 that is selected by the State in such a
5 manner as to assure an unbiased deter-
6 mination.

7 (ii) BY FEDERAL GOVERNMENT FOR
8 GROUP HEALTH PLANS.—With respect to
9 group health plans, the appropriate Sec-
10 retary may exercise the same authority as
11 a State may exercise with respect to health
12 insurance issuers under clause (i). Such
13 authority may include requiring the use of
14 the qualified external appeal entity des-
15 ignated or selected under such clause.

16 (iii) LIMITATION ON PLAN OR ISSUER
17 SELECTION.—If an applicable authority
18 permits more than one entity to qualify as
19 a qualified external appeal entity with re-
20 spect to a group health plan or health in-
21 surance issuer and the plan or issuer may
22 select among such qualified entities, the
23 applicable authority—

24 (I) shall assure that the selection
25 process will not create any incentives

1 for external appeal entities to make a
2 decision in a biased manner, and

3 (II) shall implement procedures
4 for auditing a sample of decisions by
5 such entities to assure that no such
6 decisions are made in a biased man-
7 ner.

8 (C) OTHER TERMS AND CONDITIONS.—

9 The terms and conditions of a contract under
10 this paragraph shall be consistent with the
11 standards the appropriate Secretary shall estab-
12 lish to assure there is no real or apparent con-
13 flict of interest in the conduct of external ap-
14 peal activities. Such contract shall provide that
15 the direct costs of the process (not including
16 costs of representation of a participant, bene-
17 ficiary, or enrollee) shall be paid by the plan or
18 issuer, and not by the participant, beneficiary,
19 or enrollee.

20 (2) ELEMENTS OF PROCESS.—An external ap-
21 peal process shall be conducted consistent with
22 standards established by the appropriate Secretary
23 that include at least the following:

24 (A) FAIR PROCESS; DE NOVO DETERMINA-
25 TION.—The process shall provide for a fair, de

1 novo determination. In carrying out this sub-
2 paragraph, the determination of medical neces-
3 sity shall be made under the process without re-
4 gard to the definition used by the plan or
5 issuer. However, nothing in this sentence shall
6 be construed as providing for coverage of items
7 and services for which benefits are specifically
8 excluded under the plan or coverage.

9 (B) DETERMINATION CONCERNING EXTER-
10 NALLY APPEALABLE DECISIONS.—A qualified
11 external appeal entity shall determine whether a
12 decision is an externally appealable decision and
13 related decisions, including—

14 (i) whether such a decision involves an
15 expedited appeal;

16 (ii) the appropriate deadlines for in-
17 ternal review process required due to medi-
18 cal exigencies in a case; and

19 (iii) whether such a process has been
20 completed.

21 (C) OPPORTUNITY TO SUBMIT EVIDENCE,
22 HAVE REPRESENTATION, AND MAKE ORAL
23 PRESENTATION.—Each party to an externally
24 appealable decision (directly or through an au-

1 thorized representative or representatives, any
2 of whom may be an attorney)—

3 (i) may submit and review evidence
4 related to the issues in dispute,

5 (ii) may use the assistance or rep-
6 resentation of one or more individuals (any
7 of whom may be an attorney), and

8 (iii) may make an oral presentation.

9 (D) PROVISION OF INFORMATION.—The
10 plan or issuer involved shall provide timely ac-
11 cess to all its records relating to the matter of
12 the externally appealable decision and to all
13 provisions of the plan or health insurance cov-
14 erage (including any coverage manual) relating
15 to the matter.

16 (E) TIMELY DECISIONS.—A determination
17 by the external appeal entity on the decision
18 shall—

19 (i) be made orally or in writing and,
20 if it is made orally, shall be supplied to the
21 parties in writing as soon as possible;

22 (ii) be binding on the plan or issuer;

23 (iii) be made in accordance with the
24 medical exigencies of the case involved, but
25 in no event later than 60 days (or 72

1 hours in the case of an expedited appeal
2 or, in the case of an appeal involving emer-
3 gency circumstances, as soon as possible in
4 accordance with the medical exigencies of
5 the case, and in no event later than 24
6 hours) from the date of completion of the
7 filing of notice requesting an external ap-
8 peal of the decision;

9 (iv) state, in layperson’s language, the
10 basis for the determination, including, if
11 relevant, any basis in the terms or condi-
12 tions of the plan or coverage; and

13 (v) inform the participant, beneficiary,
14 or enrollee of the individual’s rights (in-
15 cluding any limitation on such rights) to
16 seek further review by the courts (or other
17 process) of the external appeal determina-
18 tion.

19 (c) QUALIFICATIONS OF EXTERNAL APPEAL ENTI-
20 TIES.—

21 (1) IN GENERAL.—For purposes of this section,
22 the term “qualified external appeal entity” means,
23 in relation to a plan or issuer, an entity (which may
24 be a governmental entity) that is certified under

1 paragraph (2) as meeting the following require-
2 ments:

3 (A) There is no real or apparent conflict of
4 interest that would impede the entity conduct-
5 ing external appeal activities independent of the
6 plan or issuer.

7 (B) The entity conducts external appeal
8 activities through clinical peers.

9 (C) The entity has sufficient medical, legal,
10 and other expertise and sufficient staffing to
11 conduct external appeal activities for the plan
12 or issuer on a timely basis consistent with sub-
13 section (b)(3)(E).

14 (D) The entity meets such other require-
15 ments as the appropriate Secretary may im-
16 pose.

17 (2) CERTIFICATION OF EXTERNAL APPEAL EN-
18 TITIES.—

19 (A) IN GENERAL.—In order to be treated
20 as a qualified external appeal entity with re-
21 spect to—

22 (i) a group health plan, the entity
23 must be certified (and, in accordance with
24 subparagraph (B), periodically recertified)
25 as meeting the requirements of paragraph

1 (1) by the Secretary of Labor (or under a
2 process recognized or approved by the Sec-
3 retary of Labor); or

4 (ii) a health insurance issuer operat-
5 ing in a State, the entity must be certified
6 (and, in accordance with subparagraph
7 (B), periodically recertified) as meeting
8 such requirements by the applicable State
9 authority (or, if the State has not estab-
10 lished an adequate certification and recer-
11 tification process, by the Secretary of
12 Health and Human Services, or under a
13 process recognized or approved by such
14 Secretary).

15 (B) RECERTIFICATION PROCESS.—The ap-
16 propriate Secretary shall develop standards for
17 the recertification of external appeal entities.
18 Such standards shall include a specification
19 of—

20 (i) the information required to be sub-
21 mitted as a condition of recertification on
22 the entity's performance of external appeal
23 activities, which information shall include
24 the number of cases reviewed, a summary
25 of the disposition of those cases, the length

1 of time in making determinations on those
2 cases, and such information as may be nec-
3 essary to assure the independence of the
4 entity from the plans or issuers for which
5 external appeal activities are being con-
6 ducted; and

7 (ii) the periodicity which recertifi-
8 cation will be required.

9 (3) LIMITATION ON LIABILITY OF REVIEW-
10 ERS.—No qualified external appeal entity having a
11 contract with a plan or issuer under this part and
12 no person who is employed by, or who has a fidu-
13 ciary relationship with, any such entity or who fur-
14 nishes professional services to such entity, shall be
15 held by reason of the performance of any duty, func-
16 tion, or activity required or authorized pursuant to
17 this section, to have violated any criminal law, or to
18 be civilly liable under any law of the United States
19 or of any State (or political subdivision thereof) if
20 due care was exercised in the performance of such
21 duty, function, or activity and there was no actual
22 malice or gross misconduct in the performance of
23 such duty, function, or activity.

24 (d) EXTERNAL APPEAL DETERMINATION BINDING
25 ON PLAN.—

1 (1) IN GENERAL.—Subject to paragraph (2),
2 the determination by an external appeals entity
3 under this section is binding on the plan (and issuer,
4 if any) involved in the determination.

5 (2) VACATION OR MODIFICATION OF DECI-
6 SION.—The determination by an external appeals
7 entity under this section may be vacated or modified
8 by a court under the same circumstances as the de-
9 cision of an arbitrator may be vacated or modified
10 under sections 10 and 11 of title 9, United States
11 Code.

12 **Subtitle E—Protecting the Doctor-** 13 **Patient Relationship**

14 **SEC. 141. PROHIBITION OF INTERFERENCE WITH CERTAIN** 15 **MEDICAL COMMUNICATIONS.**

16 (a) PROHIBITION.—

17 (1) GENERAL RULE.—The provisions of any
18 contract or agreement, or the operation of any con-
19 tract or agreement, between a group health plan or
20 health insurance issuer in relation to health insur-
21 ance coverage (including any partnership, associa-
22 tion, or other organization that enters into or ad-
23 ministers such a contract or agreement) and a
24 health care provider (or group of health care provid-
25 ers) shall not prohibit or otherwise restrict a covered

1 health care professional (as defined in subsection
2 (b)) from advising such a participant, beneficiary, or
3 enrollee who is a patient of the professional about
4 the health status of the individual or medical care or
5 treatment for the individual's condition or disease,
6 regardless of whether benefits for such care or treat-
7 ment are provided under the plan or coverage, if the
8 professional is acting within the lawful scope of
9 practice.

10 (2) NULLIFICATION.—Any contract provision or
11 agreement that restricts or prohibits medical com-
12 munications in violation of paragraph (1) shall be
13 null and void.

14 (b) HEALTH CARE PROFESSIONAL DEFINED.—For
15 purposes of this section, the term “health care profes-
16 sional” means a physician (as defined in section 1861(r)
17 of the Social Security Act) or other health care profes-
18 sional if coverage for the professional's services of the pro-
19 fessional is provided under the group health plan or health
20 insurance coverage. Such term includes a podiatrist, op-
21 tometrist, chiropractor, psychologist, dentist, physician as-
22 sistant, physical or occupational therapist and therapy as-
23 sistant, speech-language pathologist, audiologist, reg-
24 istered or licensed practical nurse (including nurse practi-
25 tioner, clinical nurse specialist, certified registered nurse

1 anesthetist, and certified nurse-midwife), licensed clinical
2 social worker, registered respiratory therapist, and cer-
3 tified respiratory therapy technician.

4 **SEC. 142. PROHIBITION AGAINST TRANSFER OF INDEM-**
5 **NIFICATION OR IMPROPER INCENTIVE AR-**
6 **RANGEMENTS.**

7 (a) PROHIBITION OF TRANSFER OF INDEMNIFICA-
8 TION.—

9 (1) IN GENERAL.—No contract or agreement
10 between a group health plan or health insurance
11 issuer (or any agent acting on behalf of such a plan
12 or issuer) and a health care provider shall contain
13 any provision purporting to transfer to the health
14 care provider by indemnification or otherwise any li-
15 ability relating to activities, actions, or omissions of
16 the plan, issuer, or agent (as opposed to the pro-
17 vider).

18 (2) NULLIFICATION.—Any contract or agree-
19 ment provision described in paragraph (1) shall be
20 null and void.

21 (b) PROHIBITION OF IMPROPER PHYSICIAN INCEN-
22 TIVE PLANS.—

23 (1) IN GENERAL.—A group health plan and a
24 health insurance issuer offering health insurance
25 coverage may not operate any physician incentive

1 plan (as defined in subparagraph (B) of section
2 1876(i)(8) of the Social Security Act) unless the re-
3 quirements described in subparagraph (A) of such
4 section are met with respect to such a plan.

5 (2) APPLICATION.—For purposes of carrying
6 out paragraph (1), any reference in section
7 1876(i)(8) of the Social Security Act to the Sec-
8 retary, an eligible organization, or an individual en-
9 rolled with the organization shall be treated as a ref-
10 erence to the applicable authority, a group health
11 plan or health insurance issuer, respectively, and a
12 participant, beneficiary, or enrollee with the plan or
13 organization, respectively.

14 **SEC. 143. ADDITIONAL RULES REGARDING PARTICIPATION**
15 **OF HEALTH CARE PROFESSIONALS.**

16 (a) PROCEDURES.—Insofar as a group health plan,
17 or health insurance issuer that offers health insurance cov-
18 erage, provides benefits through participating health care
19 professionals, the plan or issuer shall establish reasonable
20 procedures relating to the participation (under an agree-
21 ment between a professional and the plan or issuer) of
22 such professionals under the plan or coverage. Such proce-
23 dures shall include—

24 (1) providing notice of the rules regarding par-
25 ticipation;

1 (2) providing written notice of participation de-
2 cisions that are adverse to professionals; and

3 (3) providing a process within the plan or issuer
4 for appealing such adverse decisions, including the
5 presentation of information and views of the profes-
6 sional regarding such decision.

7 (b) CONSULTATION IN MEDICAL POLICIES.—A group
8 health plan, and health insurance issuer that offers health
9 insurance coverage, shall consult with participating physi-
10 cians (if any) regarding the plan’s or issuer’s medical pol-
11 icy, quality, and medical management procedures.

12 **SEC. 144. PROTECTION FOR PATIENT ADVOCACY.**

13 (a) PROTECTION FOR USE OF UTILIZATION REVIEW
14 AND GRIEVANCE PROCESS.—A group health plan, and a
15 health insurance issuer with respect to the provision of
16 health insurance coverage, may not retaliate against a par-
17 ticipant, beneficiary, enrollee, or health care provider
18 based on the participant’s, beneficiary’s, enrollee’s or pro-
19 vider’s use of, or participation in, a utilization review proc-
20 ess or a grievance process of the plan or issuer (including
21 an internal or external review or appeal process) under
22 this title.

23 (b) PROTECTION FOR QUALITY ADVOCACY BY
24 HEALTH CARE PROFESSIONALS.—

1 (1) IN GENERAL.—A group health plan or
2 health insurance issuer may not retaliate or dis-
3 criminate against a protected health care profes-
4 sional because the professional in good faith—

5 (A) discloses information relating to the
6 care, services, or conditions affecting one or
7 more participants, beneficiaries, or enrollees of
8 the plan or issuer to an appropriate public reg-
9 ulatory agency, an appropriate private accredi-
10 tation body, or appropriate management per-
11 sonnel of the plan or issuer;

12 (B) initiates, cooperates, or otherwise par-
13 ticipates in an investigation or proceeding by
14 such an agency with respect to such care, serv-
15 ices, or conditions; or

16 (C) participates in an external appeals
17 process under section 133.

18 If an institutional health care provider is a partici-
19 pating provider with such a plan or issuer or other-
20 wise receives payments for benefits provided by such
21 a plan or issuer, the provisions of the previous sen-
22 tence shall apply to the provider in relation to care,
23 services, or conditions affecting one or more patients
24 within an institutional health care provider in the
25 same manner as they apply to the plan or issuer in

1 relation to care, services, or conditions provided to
2 one or more participants, beneficiaries, or enrollees;
3 and for purposes of applying this sentence, any ref-
4 erence to a plan or issuer is deemed a reference to
5 the institutional health care provider.

6 (2) GOOD FAITH ACTION.—For purposes of
7 paragraph (1), a protected health care professional
8 is considered to be acting in good faith with respect
9 to disclosure of information or participation if, with
10 respect to the information disclosed as part of the
11 action—

12 (A) the disclosure is made on the basis of
13 personal knowledge and is consistent with that
14 degree of learning and skill ordinarily possessed
15 by health care professionals with the same li-
16 censure or certification and the same experi-
17 ence;

18 (B) the professional reasonably believes the
19 information to be true;

20 (C) the information evidences either a vio-
21 lation of a law, rule, or regulation, of an appli-
22 cable accreditation standard, or of a generally
23 recognized professional or clinical standard or
24 that a patient is in imminent hazard of loss of
25 life or serious injury; and

1 (D) subject to subparagraphs (B) and (C)
2 of paragraph (3), the professional has followed
3 reasonable internal procedures of the plan,
4 issuer, or institutional health care provider es-
5 tablished or the purpose of addressing quality
6 concerns before making the disclosure.

7 (3) EXCEPTION AND SPECIAL RULE.—

8 (A) GENERAL EXCEPTION.—Paragraph (1)
9 does not protect disclosures that would violate
10 Federal or State law or diminish or impair the
11 rights of any person to the continued protection
12 of confidentiality of communications provided
13 by such law.

14 (B) NOTICE OF INTERNAL PROCEDURES.—
15 Subparagraph (D) of paragraph (2) shall not
16 apply unless the internal procedures involved
17 are reasonably expected to be known to the
18 health care professional involved. For purposes
19 of this subparagraph, a health care professional
20 is reasonably expected to know of internal pro-
21 cedures if those procedures have been made
22 available to the professional through distribu-
23 tion or posting.

1 (C) INTERNAL PROCEDURE EXCEPTION.—

2 Subparagraph (D) of paragraph (2) also shall
3 not apply if—

4 (i) the disclosure relates to an immi-
5 nent hazard of loss of life or serious injury
6 to a patient;

7 (ii) the disclosure is made to an ap-
8 propriate private accreditation body pursu-
9 ant to disclosure procedures established by
10 the body; or

11 (iii) the disclosure is in response to an
12 inquiry made in an investigation or pro-
13 ceeding of an appropriate public regulatory
14 agency and the information disclosed is
15 limited to the scope of the investigation or
16 proceeding.

17 (4) ADDITIONAL CONSIDERATIONS.—It shall
18 not be a violation of paragraph (1) to take an ad-
19 verse action against a protected health care profes-
20 sional if the plan, issuer, or provider taking the ad-
21 verse action involved demonstrates that it would
22 have taken the same adverse action even in the ab-
23 sence of the activities protected under such para-
24 graph.

1 (5) NOTICE.—A group health plan, health in-
2 surance issuer, and institutional health care provider
3 shall post a notice, to be provided or approved by
4 the Secretary of Labor, setting forth excerpts from,
5 or summaries of, the pertinent provisions of this
6 subsection and information pertaining to enforce-
7 ment of such provisions.

8 (6) CONSTRUCTIONS.—

9 (A) DETERMINATIONS OF COVERAGE.—

10 Nothing in this subsection shall be construed to
11 prohibit a plan or issuer from making a deter-
12 mination not to pay for a particular medical
13 treatment or service or the services of a type of
14 health care professional.

15 (B) ENFORCEMENT OF PEER REVIEW PRO-

16 TOCOLS AND INTERNAL PROCEDURES.—Noth-
17 ing in this subsection shall be construed to pro-
18 hibit a plan, issuer, or provider from establish-
19 ing and enforcing reasonable peer review or uti-
20 lization review protocols or determining whether
21 a protected health care professional has com-
22 plied with those protocols or from establishing
23 and enforcing internal procedures for the pur-
24 pose of addressing quality concerns.

1 (C) RELATION TO OTHER RIGHTS.—Noth-
2 ing in this subsection shall be construed to
3 abridge rights of participants, beneficiaries, en-
4 rollees, and protected health care professionals
5 under other applicable Federal or State laws.

6 (7) PROTECTED HEALTH CARE PROFESSIONAL
7 DEFINED.—For purposes of this subsection, the
8 term “protected health care professional” means an
9 individual who is a licensed or certified health care
10 professional and who—

11 (A) with respect to a group health plan or
12 health insurance issuer, is an employee of the
13 plan or issuer or has a contract with the plan
14 or issuer for provision of services for which ben-
15 efits are available under the plan or issuer; or

16 (B) with respect to an institutional health
17 care provider, is an employee of the provider or
18 has a contract or other arrangement with the
19 provider respecting the provision of health care
20 services.

21 **Subtitle F—Promoting Good** 22 **Medical Practice**

23 **SEC. 151. PROMOTING GOOD MEDICAL PRACTICE.**

24 (a) PROHIBITING ARBITRARY LIMITATIONS OR CON-
25 DITIONS FOR THE PROVISION OF SERVICES.—

1 (1) IN GENERAL.—A group health plan, and a
2 health insurance issuer in connection with the provi-
3 sion of health insurance coverage, may not arbitrar-
4 ily interfere with or alter the decision of the treating
5 physician regarding the manner or setting in which
6 particular services are delivered if the services are
7 medically necessary or appropriate for treatment or
8 diagnosis to the extent that such treatment or diag-
9 nosis is otherwise a covered benefit.

10 (2) CONSTRUCTION.—Paragraph (1) shall not
11 be construed as prohibiting a plan or issuer from
12 limiting the delivery of services to one or more
13 health care providers within a network of such pro-
14 viders.

15 (3) MANNER OR SETTING DEFINED.—In para-
16 graph (1), the term “manner or setting” means the
17 location of treatment, such as whether treatment is
18 provided on an inpatient or outpatient basis, and the
19 duration of treatment, such as the number of days
20 in a hospital. Such term does not include the cov-
21 erage of a particular service or treatment.

22 (b) NO CHANGE IN COVERAGE.—Subsection (a) shall
23 not be construed as requiring coverage of particular serv-
24 ices the coverage of which is otherwise not covered under

1 the terms of the plan or coverage or from conducting utili-
2 zation review activities consistent with this subsection.

3 (c) **MEDICAL NECESSITY OR APPROPRIATENESS DE-**
4 **FINED.**—In subsection (a), the term “medically necessary
5 or appropriate” means, with respect to a service or benefit,
6 a service or benefit which is consistent with generally ac-
7 cepted principles of professional medical practice.

8 **SEC. 152. STANDARDS RELATING TO BENEFITS FOR CER-**
9 **TAIN BREAST CANCER TREATMENT.**

10 (a) **INPATIENT CARE.**—

11 (1) **IN GENERAL.**—A group health plan, and a
12 health insurance issuer offering group health insur-
13 ance coverage, that provides medical and surgical
14 benefits shall ensure that inpatient coverage with re-
15 spect to the treatment of breast cancer is provided
16 for a period of time as is determined by the attend-
17 ing physician, in the physician’s professional judg-
18 ment consistent with generally accepted medical
19 standards, in consultation with the patient, to be
20 medically appropriate following—

21 (A) a mastectomy;

22 (B) a lumpectomy; or

23 (C) a lymph node dissection for the treat-
24 ment of breast cancer.

1 (2) EXCEPTION.—Nothing in this section shall
2 be construed as requiring the provision of inpatient
3 coverage if the attending physician and patient de-
4 termine that a shorter period of hospital stay is
5 medically appropriate.

6 (b) PROHIBITIONS.—A group health plan, and a
7 health insurance issuer offering group health insurance
8 coverage in connection with a group health plan, may
9 not—

10 (1) deny to a woman eligibility, or continued
11 eligibility, to enroll or to renew coverage under the
12 terms of the plan, solely for the purpose of avoiding
13 the requirements of this section;

14 (2) provide monetary payments or rebates to
15 women to encourage such women to accept less than
16 the minimum protections available under this sec-
17 tion;

18 (3) penalize or otherwise reduce or limit the re-
19 imbursement of an attending provider because such
20 provider provided care to an individual participant
21 or beneficiary in accordance with this section;

22 (4) provide incentives (monetary or otherwise)
23 to an attending provider to induce such provider to
24 provide care to an individual participant or bene-
25 ficiary in a manner inconsistent with this section; or

1 (5) subject to subsection (c)(3), restrict benefits
2 for any portion of a period within a hospital length
3 of stay required under subsection (a) in a manner
4 which is less favorable than the benefits provided for
5 any preceding portion of such stay.

6 (c) RULES OF CONSTRUCTION.—

7 (1) Nothing in this section shall be construed to
8 require a woman who is a participant or
9 beneficiary—

10 (A) to undergo a mastectomy, lumpectomy,
11 or lymph node dissection in a hospital; or

12 (B) to stay in the hospital for a fixed pe-
13 riod of time following a mastectomy,
14 lumpectomy, or lymph node dissection.

15 (2) This section shall not apply with respect to
16 any group health plan, or any group health insur-
17 ance coverage offered by a health insurance issuer,
18 which does not provide benefits for hospital lengths
19 of stay in connection with a mastectomy,
20 lumpectomy, or lymph node dissection for the treat-
21 ment of breast cancer.

22 (3) Nothing in this section shall be construed as
23 preventing a group health plan or issuer from impos-
24 ing deductibles, coinsurance, or other cost-sharing in
25 relation to benefits for hospital lengths of stay in

1 connection with a mastectomy or lymph node dissec-
2 tion for the treatment of breast cancer under the
3 plan (or under health insurance coverage offered in
4 connection with a group health plan), except that
5 such coinsurance or other cost-sharing for any por-
6 tion of a period within a hospital length of stay re-
7 quired under subsection (a) may not be greater than
8 such coinsurance or cost-sharing for any preceding
9 portion of such stay.

10 (d) LEVEL AND TYPE OF REIMBURSEMENTS.—Noth-
11 ing in this section shall be construed to prevent a group
12 health plan or a health insurance issuer offering group
13 health insurance coverage from negotiating the level and
14 type of reimbursement with a provider for care provided
15 in accordance with this section.

16 (e) EXCEPTION FOR HEALTH INSURANCE COVERAGE
17 IN CERTAIN STATES.—

18 (1) IN GENERAL.—The requirements of this
19 section shall not apply with respect to health insur-
20 ance coverage if there is a State law (as defined in
21 section 2723(d)(1) of the Public Health Service Act)
22 for a State that regulates such coverage that is de-
23 scribed in any of the following subparagraphs:

24 (A) Such State law requires such coverage
25 to provide for at least a 48-hour hospital length

1 of stay following a mastectomy performed for
2 treatment of breast cancer and at least a 24-
3 hour hospital length of stay following a lymph
4 node dissection for treatment of breast cancer.

5 (B) Such State law requires, in connection
6 with such coverage for surgical treatment of
7 breast cancer, that the hospital length of stay
8 for such care is left to the decision of (or re-
9 quired to be made by) the attending provider in
10 consultation with the woman involved.

11 (2) CONSTRUCTION.—Section 2723(a)(1) of the
12 Public Health Service Act and section 731(a)(1) of
13 the Employee Retirement Income Security Act of
14 1974 shall not be construed as superseding a State
15 law described in paragraph (1).

16 **Subtitle G—Definitions**

17 **SEC. 191. DEFINITIONS.**

18 (a) INCORPORATION OF GENERAL DEFINITIONS.—
19 The provisions of section 2971 of the Public Health Serv-
20 ice Act shall apply for purposes of this title in the same
21 manner as they apply for purposes of title XXVII of such
22 Act.

23 (b) SECRETARY.—Except as otherwise provided, the
24 term “Secretary” means the Secretary of Health and
25 Human Services, in consultation with the Secretary of

1 Labor and the Secretary of the Treasury and the term
2 “appropriate Secretary” means the Secretary of Health
3 and Human Services in relation to carrying out this title
4 under sections 2706 and 2751 of the Public Health Serv-
5 ice Act, the Secretary of Labor in relation to carrying out
6 this title under section 714 of the Employee Retirement
7 Income Security Act of 1974, and the Secretary of the
8 Treasury in relation to carrying out this title under chap-
9 ter 100 and section 4980D of the Internal Revenue Code
10 of 1986.

11 (c) ADDITIONAL DEFINITIONS.—For purposes of this
12 title:

13 (1) APPLICABLE AUTHORITY.—The term “ap-
14 plicable authority” means—

15 (A) in the case of a group health plan, the
16 Secretary of Health and Human Services and
17 the Secretary of Labor; and

18 (B) in the case of a health insurance issuer
19 with respect to a specific provision of this title,
20 the applicable State authority (as defined in
21 section 2791(d) of the Public Health Service
22 Act), or the Secretary of Health and Human
23 Services, if such Secretary is enforcing such
24 provision under section 2722(a)(2) or
25 2761(a)(2) of the Public Health Service Act.

1 (2) CLINICAL PEER.—The term “clinical peer”
2 means, with respect to a review or appeal, a physi-
3 cian (allopathic or osteopathic) or other health care
4 professional who holds a license, and who, in the
5 case of a physician, is appropriately certified by a
6 nationally recognized, peer reviewed accrediting body
7 in the same or similar specialty as typically manages
8 the medical condition, procedure, or treatment under
9 review or appeal and includes a pediatric specialist
10 where appropriate; except that only a physician may
11 be a clinical peer with respect to the review or ap-
12 peal of treatment recommended or rendered by a
13 physician.

14 (3) HEALTH CARE PROVIDER.—The term
15 “health care provider” includes a physician or other
16 health care professional, as well as an institutional
17 provider of health care services.

18 (4) NONPARTICIPATING.—The term “non-
19 participating” means, with respect to a health care
20 provider that provides health care items and services
21 to a participant, beneficiary, or enrollee under group
22 health plan or health insurance coverage, a health
23 care provider that is not a participating health care
24 provider with respect to such items and services.

1 (5) PARTICIPATING.—The term “participating”
2 mean, with respect to a health care provider that
3 provides health care items and services to a partici-
4 pant, beneficiary, or enrollee under group health
5 plan or health insurance coverage offered by a
6 health insurance issuer, a health care provider that
7 furnishes such items and services under a contract
8 or other arrangement with the plan or issuer.

9 **SEC. 192. PREEMPTION; STATE FLEXIBILITY; CONSTRUC-**
10 **TION.**

11 (a) CONTINUED APPLICABILITY OF STATE LAW
12 WITH RESPECT TO HEALTH INSURANCE ISSUERS.—

13 (1) IN GENERAL.—Subject to paragraph (2),
14 this title shall not be construed to supersede any
15 provision of State law which establishes, implements,
16 or continues in effect any standard or requirement
17 solely relating to health insurance issuers in connec-
18 tion with group health insurance coverage, except to
19 the extent that such standard or requirement pre-
20 vents the application of a requirement of this title,
21 or which requires (in connection with any litigation
22 against a health insurance issuer) that the dispute
23 be first, or simultaneously, considered through an al-
24 ternative dispute resolution system.

1 (2) CONTINUED PREEMPTION WITH RESPECT
2 TO GROUP HEALTH PLANS.—Nothing in this title
3 shall be construed to affect or modify the provisions
4 of section 514 of the Employee Retirement Income
5 Security Act of 1974 with respect to group health
6 plans.

7 (b) RULES OF CONSTRUCTION.—Except as provided
8 in section 152, nothing in this title shall be construed as
9 requiring a group health plan or health insurance coverage
10 to provide specific benefits under the terms of such plan
11 or coverage.

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

13 (1) STATE LAW.—The term “State law” in-
14 cludes all laws, decisions, rules, regulations, or other
15 State action having the effect of law, of any State.
16 A law of the United States applicable only to the
17 District of Columbia shall be treated as a State law
18 rather than a law of the United States.

19 (2) STATE.—The term “State” includes a
20 State, the Northern Mariana Islands, any political
21 subdivisions of a State or such Islands, or any agen-
22 cy or instrumentality of either.

23 **SEC. 193. REGULATIONS.**

24 The Secretaries of Health and Human Services and
25 Labor shall issue such regulations as may be necessary

1 or appropriate to carry out this title, other than section
 2 151. Such regulations shall be issued consistent with sec-
 3 tion 104 of Health Insurance Portability and Accountabil-
 4 ity Act of 1996. Such Secretaries may promulgate any in-
 5 terim final rules as the Secretaries determine are appro-
 6 priate to carry out this title.

7 **TITLE II—APPLICATION OF PA-**
 8 **TIENT PROTECTION STAND-**
 9 **ARDS TO GROUP HEALTH**
 10 **PLANS AND HEALTH INSUR-**
 11 **ANCE COVERAGE UNDER**
 12 **PUBLIC HEALTH SERVICE**
 13 **ACT**

14 **SEC. 201. APPLICATION TO GROUP HEALTH PLANS AND**
 15 **GROUP HEALTH INSURANCE COVERAGE.**

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

19 **“SEC. 2706. PATIENT PROTECTION STANDARDS.**

20 “(a) IN GENERAL.—Each group health plan shall
 21 comply with patient protection requirements under title I
 22 of the Managed Care Reform Act of 1999, and each health
 23 insurance issuer shall comply with patient protection re-
 24 quirements under such title with respect to group health

1 insurance coverage it offers, and such requirements shall
2 be deemed to be incorporated into this subsection.

3 “(b) NOTICE.—A group health plan shall comply with
4 the notice requirement under section 711(d) of the Em-
5 ployee Retirement Income Security Act of 1974 with re-
6 spect to the requirements referred to in subsection (a) and
7 a health insurance issuer shall comply with such notice
8 requirement as if such section applied to such issuer and
9 such issuer were a group health plan.”.

10 (b) CONFORMING AMENDMENT.—Section
11 2721(b)(2)(A) of such Act (42 U.S.C. 300gg–21(b)(2)(A))
12 is amended by inserting “(other than section 2706)” after
13 “requirements of such subparts”.

14 **SEC. 202. APPLICATION TO INDIVIDUAL HEALTH INSUR-**
15 **ANCE COVERAGE.**

16 Part B of title XXVII of the Public Health Service
17 Act is amended by inserting after section 2751 the follow-
18 ing new section:

19 **“SEC. 2752. PATIENT PROTECTION STANDARDS.**

20 “(a) IN GENERAL.—Each health insurance issuer
21 shall comply with patient protection requirements under
22 title I of the Managed Care Reform Act of 1999 with re-
23 spect to individual health insurance coverage it offers, and
24 such requirements shall be deemed to be incorporated into
25 this subsection.

1 “(b) NOTICE.—A health insurance issuer under this
 2 part shall comply with the notice requirement under sec-
 3 tion 711(d) of the Employee Retirement Income Security
 4 Act of 1974 with respect to the requirements of such title
 5 as if such section applied to such issuer and such issuer
 6 were a group health plan.”.

7 **TITLE III—AMENDMENTS TO**
 8 **THE EMPLOYEE RETIREMENT**
 9 **INCOME SECURITY ACT OF**
 10 **1974**

11 **SEC. 301. APPLICATION OF PATIENT PROTECTION STAND-**
 12 **ARDS TO GROUP HEALTH PLANS AND GROUP**
 13 **HEALTH INSURANCE COVERAGE UNDER THE**
 14 **EMPLOYEE RETIREMENT INCOME SECURITY**
 15 **ACT OF 1974.**

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

20 **“SEC. 714. PATIENT PROTECTION STANDARDS.**

21 “(a) IN GENERAL.—Subject to subsection (b), a
 22 group health plan (and a health insurance issuer offering
 23 group health insurance coverage in connection with such
 24 a plan) shall comply with the requirements of title I of
 25 the Managed Care Reform Act of 1999 (as in effect as

1 of the date of the enactment of such Act), and such re-
2 quirements shall be deemed to be incorporated into this
3 subsection.

4 “(b) PLAN SATISFACTION OF CERTAIN REQUIRE-
5 MENTS.—

6 “(1) SATISFACTION OF CERTAIN REQUIRE-
7 MENTS THROUGH INSURANCE.—For purposes of
8 subsection (a), insofar as a group health plan pro-
9 vides benefits in the form of health insurance cov-
10 erage through a health insurance issuer, the plan
11 shall be treated as meeting the following require-
12 ments of title I of the Managed Care Reform Act of
13 1999 with respect to such benefits and not be con-
14 sidered as failing to meet such requirements because
15 of a failure of the issuer to meet such requirements
16 so long as the plan sponsor or its representatives did
17 not cause such failure by the issuer:

18 “(A) Section 101 (relating to access to
19 emergency care).

20 “(B) Section 102(a)(1) (relating to offer-
21 ing option to purchase point-of-service cov-
22 erage), but only insofar as the plan is meeting
23 such requirement through an agreement with
24 the issuer to offer the option to purchase point-
25 of-service coverage under such section.

1 “(C) Section 103 (relating to choice of pro-
2 viders).

3 “(D) Section 104 (relating to access to
4 specialty care).

5 “(E) Section 105(a)(1) (relating to con-
6 tinuity in case of termination of provider con-
7 tract) and section 105(a)(2) (relating to con-
8 tinuity in case of termination of issuer con-
9 tract), but only insofar as a replacement issuer
10 assumes the obligation for continuity of care.

11 “(F) Section 106 (relating to coverage for
12 individuals participating in approved clinical
13 trials.)

14 “(G) Section 107 (relating to access to
15 needed prescription drugs).

16 “(H) Section 108 (relating to adequacy of
17 provider network).

18 “(I) Subtitle B (relating to quality assur-
19 ance).

20 “(J) Section 143 (relating to additional
21 rules regarding participation of health care pro-
22 fessionals).

23 “(K) Section 152 (relating to standards re-
24 lating to benefits for certain breast cancer
25 treatment).

1 “(2) INFORMATION.—With respect to informa-
2 tion required to be provided or made available under
3 section 121, in the case of a group health plan that
4 provides benefits in the form of health insurance
5 coverage through a health insurance issuer, the Sec-
6 retary shall determine the circumstances under
7 which the plan is not required to provide or make
8 available the information (and is not liable for the
9 issuer’s failure to provide or make available the in-
10 formation), if the issuer is obligated to provide and
11 make available (or provides and makes available)
12 such information.

13 “(3) GRIEVANCE AND INTERNAL APPEALS.—
14 With respect to the grievance system and internal
15 appeals process required to be established under sec-
16 tions 131 and 132, in the case of a group health
17 plan that provides benefits in the form of health in-
18 surance coverage through a health insurance issuer,
19 the Secretary shall determine the circumstances
20 under which the plan is not required to provide for
21 such system and process (and is not liable for the
22 issuer’s failure to provide for such system and proc-
23 ess), if the issuer is obligated to provide for (and
24 provides for) such system and process.

1 “(4) EXTERNAL APPEALS.—Pursuant to rules
2 of the Secretary, insofar as a group health plan en-
3 ters into a contract with a qualified external appeal
4 entity for the conduct of external appeal activities in
5 accordance with section 133, the plan shall be treat-
6 ed as meeting the requirement of such section and
7 is not liable for the entity’s failure to meet any re-
8 quirements under such section.

9 “(5) APPLICATION TO PROHIBITIONS.—Pursu-
10 ant to rules of the Secretary, if a health insurance
11 issuer offers health insurance coverage in connection
12 with a group health plan and takes an action in vio-
13 lation of any of the following sections, the group
14 health plan shall not be liable for such violation un-
15 less the plan caused such violation:

16 “(A) Section 141 (relating to prohibition of
17 interference with certain medical communica-
18 tions).

19 “(B) Section 142 (relating to prohibition
20 against transfer of indemnification or improper
21 incentive arrangements).

22 “(C) Section 144 (relating to prohibition
23 on retaliation).

24 “(D) Section 151 (relating to promoting
25 good medical practice).

1 “(6) CONSTRUCTION.—Nothing in this sub-
2 section shall be construed to affect or modify the re-
3 sponsibilities of the fiduciaries of a group health
4 plan under part 4 of subtitle B.

5 “(7) APPLICATION TO CERTAIN PROHIBITIONS
6 AGAINST RETALIATION.—With respect to compliance
7 with the requirements of section 144(b)(1) of the
8 Managed Care Reform Act of 1999, for purposes of
9 this subtitle the term ‘group health plan’ is deemed
10 to include a reference to an institutional health care
11 provider.

12 “(c) ENFORCEMENT OF CERTAIN REQUIREMENTS.—

13 “(1) COMPLAINTS.—Any protected health care
14 professional who believes that the professional has
15 been retaliated or discriminated against in violation
16 of section 144(b)(1) of the Managed Care Reform
17 Act of 1999 may file with the Secretary a complaint
18 within 180 days of the date of the alleged retaliation
19 or discrimination.

20 “(2) INVESTIGATION.—The Secretary shall in-
21 vestigate such complaints and shall determine if a
22 violation of such section has occurred and, if so,
23 shall issue an order to ensure that the protected
24 health care professional does not suffer any loss of
25 position, pay, or benefits in relation to the plan,

1 issuer, or provider involved, as a result of the viola-
2 tion found by the Secretary.

3 “(d) CONFORMING REGULATIONS.—The Secretary
4 may issue regulations to coordinate the requirements on
5 group health plans under this section with the require-
6 ments imposed under the other provisions of this title.”.

7 (b) SATISFACTION OF ERISA CLAIMS PROCEDURE
8 REQUIREMENT.—Section 503 of such Act (29 U.S.C.
9 1133) is amended by inserting “(a)” after “SEC. 503.”
10 and by adding at the end the following new subsection:

11 “(b) In the case of a group health plan (as defined
12 in section 733) compliance with the requirements of sub-
13 title D (and section 111) of title I of the Managed Care
14 Reform Act of 1999 in the case of a claims denial shall
15 be deemed compliance with subsection (a) with respect to
16 such claims denial.”.

17 (c) CONFORMING AMENDMENTS.—(1) Section 732(a)
18 of such Act (29 U.S.C. 1185(a)) is amended by striking
19 “section 711” and inserting “sections 711 and 714”.

20 (2) The table of contents in section 1 of such Act
21 is amended by inserting after the item relating to section
22 712 the following new item:

“Sec. 714. Patient protection standards.”.

23 (3) Section 502(b)(3) of such Act (29 U.S.C.
24 1132(b)(3)) is amended by inserting “(other than section
25 144(b))” after “part 7”.

1 **SEC. 302. ERISA PREEMPTION NOT TO APPLY TO CERTAIN**
2 **ACTIONS INVOLVING HEALTH INSURANCE**
3 **POLICYHOLDERS.**

4 (a) IN GENERAL.—Section 514 of the Employee Re-
5 tirement Income Security Act of 1974 (29 U.S.C. 1144)
6 is amended by adding at the end the following subsection:

7 “(e) PREEMPTION NOT TO APPLY TO CERTAIN AC-
8 TIONS ARISING OUT OF PROVISION OF HEALTH BENE-
9 FITS.—

10 “(1) NON-PREEMPTION OF CERTAIN CAUSES OF
11 ACTION.—

12 “(A) IN GENERAL.—Except as provided in
13 this subsection, nothing in this title shall be
14 construed to invalidate, impair, or supersede
15 any cause of action brought by a plan partici-
16 pant or beneficiary (or the estate of a plan par-
17 ticipant or beneficiary) under State law to re-
18 cover damages resulting from personal injury or
19 for wrongful death against any person—

20 “(i) in connection with the provision
21 of insurance, administrative services, or
22 medical services by such person to or for
23 a group health plan (as defined in section
24 733), or

25 “(ii) that arises out of the arrange-
26 ment by such person for the provision of

1 such insurance, administrative services, or
2 medical services by other persons.

3 “(B) LIMITATION ON PUNITIVE DAM-
4 AGES.—The plan or issuer is not liable for any
5 punitive, exemplary, or similar damages in the
6 case of a cause of action brought under sub-
7 paragraph (A) if—

8 “(i) it relates to an externally appeal-
9 able decision (as defined in subsection
10 (a)(2) of section 133 of the Managed Care
11 Reform Act of 1999);

12 “(ii) an external appeal with respect
13 to such decision was completed under such
14 section 133;

15 “(iii) in the case such external appeal
16 was initiated by the plan or issuer filing
17 the request for the external appeal, the re-
18 quest was filed on a timely basis before the
19 date the action was brought or, if later,
20 within 30 days after the date the exter-
21 nally appealable decision was made;

22 “(iv) the plan or issuer promptly fol-
23 lowed the recommendation of the qualified
24 external appeal entity involved; and

1 “(v) such recommendation is not va-
2 cated under subsection (d)(3) of such sec-
3 tion based upon an action of the plan or
4 issuer.

5 The provisions of this subparagraph supersede
6 any State law or common law to the contrary.

7 “(C) PERSONAL INJURY DEFINED.—For
8 purposes of this subsection, the term ‘personal
9 injury’ means a physical injury and includes an
10 injury arising out of the treatment (or failure
11 to treat) a mental illness or disease.

12 “(2) EXCEPTION FOR EMPLOYERS AND OTHER
13 PLAN SPONSORS.—

14 “(A) IN GENERAL.—Subject to subpara-
15 graph (B), paragraph (1) does not authorize—

16 “(i) any cause of action against an
17 employer or other plan sponsor maintain-
18 ing the group health plan (or against an
19 employee of such an employer or sponsor
20 acting within the scope of employment), or

21 “(ii) a right of recovery or indemnity
22 by a person against an employer or other
23 plan sponsor (or such an employee) for
24 damages assessed against the person pur-

1 suant to a cause of action under paragraph
2 (1).

3 “(B) SPECIAL RULE.—Subparagraph (A)
4 shall not preclude any cause of action described
5 in paragraph (1) against an employer or other
6 plan sponsor (or against an employee of such
7 an employer or sponsor acting within the scope
8 of employment) if—

9 “(i) such action is based on the em-
10 ployer’s or other plan sponsor’s (or em-
11 ployee’s) exercise of discretionary authority
12 to make a decision on a claim for benefits
13 covered under the plan or health insurance
14 coverage in the case at issue; and

15 “(ii) the exercise by such employer or
16 other plan sponsor (or employee) of such
17 authority resulted in personal injury or
18 wrongful death.

19 “(3) CONSTRUCTION.—Nothing in this sub-
20 section shall be construed as permitting a cause of
21 action under State law for the failure to provide an
22 item or service which is specifically excluded under
23 the group health plan involved.”.

24 (b) EFFECTIVE DATE.—The amendment made by
25 subsection (a) shall apply to acts and omissions occurring

1 on or after the date of the enactment of this Act from
2 which a cause of action arises.

3 **TITLE IV—EFFECTIVE DATES;**
4 **COORDINATION IN IMPLE-**
5 **MENTATION**

6 **SEC. 401. EFFECTIVE DATES.**

7 (a) GROUP HEALTH COVERAGE.—

8 (1) IN GENERAL.—Subject to paragraph (2),
9 the amendments made by sections 201(a) and 301
10 (and title I insofar as it relates to such sections)
11 shall apply with respect to group health plans, and
12 health insurance coverage offered in connection with
13 group health plans, for plan years beginning on or
14 after October 1, 2000 (in this section referred to as
15 the “general effective date”).

16 (2) TREATMENT OF COLLECTIVE BARGAINING
17 AGREEMENTS.—In the case of a group health plan
18 maintained pursuant to 1 or more collective bargain-
19 ing agreements between employee representatives
20 and 1 or more employers ratified before the date of
21 enactment of this Act, the amendments made by sec-
22 tions 201(a) and 301 (and title I insofar as it re-
23 lates to such sections) shall not apply to plan years
24 beginning before the later of—

1 (A) the date on which the last collective
2 bargaining agreements relating to the plan ter-
3 minates (determined without regard to any ex-
4 tension thereof agreed to after the date of en-
5 actment of this Act), or

6 (B) the general effective date.

7 For purposes of subparagraph (A), any plan amend-
8 ment made pursuant to a collective bargaining
9 agreement relating to the plan which amends the
10 plan solely to conform to any requirement added by
11 this Act shall not be treated as a termination of
12 such collective bargaining agreement.

13 (b) **INDIVIDUAL HEALTH INSURANCE COVERAGE.**—
14 The amendments made by section 202 shall apply with
15 respect to individual health insurance coverage offered,
16 sold, issued, renewed, in effect, or operated in the individ-
17 ual market on or after the general effective date.

18 **SEC. 402. COORDINATION IN IMPLEMENTATION.**

19 The Secretary of Health and Human Services and the
20 Secretary of Labor shall ensure, through the execution of
21 an interagency memorandum of understanding among
22 such Secretaries, that—

23 (1) regulations, rulings, and interpretations
24 issued by such Secretaries relating to the same mat-
25 ter over which two or more such Secretaries have re-

1 sponsibility under title I (and the amendments made
2 by titles II and III) are administered so as to have
3 the same effect at all times; and

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

○