

105TH CONGRESS
2D SESSION

H. R. 3605

To amend the Public Health Service Act, the Employee Retirement Income Security Act of 1974, and the Internal Revenue Code of 1986 to protect consumers in managed care plans and other health coverage.

IN THE HOUSE OF REPRESENTATIVES

MARCH 31, 1998

Mr. DINGELL (for himself, Mr. GEPHARDT, Mr. BROWN of Ohio, Mr. RANGEL, Mr. STARK, Mr. CLAY, Mr. PAYNE, Mr. FAZIO of California, Mr. WAXMAN, Mr. ABERCROMBIE, Mr. ALLEN, Mr. ANDREWS, Mr. BAESLER, Mr. BENTSEN, Mr. BERMAN, Mr. BOSWELL, Mr. BOUCHER, Ms. BROWN of Florida, Mr. BROWN of California, Mrs. CAPPS, Mr. CARDIN, Ms. CARSON, Ms. CHRISTIAN-GREEN, Mrs. CLAYTON, Mr. CLEMENT, Mr. COYNE, Mr. CUMMINGS, Ms. DEGETTE, Mr. DELAHUNT, Ms. DELAURO, Ms. ESHOO, Mr. EVANS, Mr. FILNER, Mr. FORD, Mr. FRANK of Massachusetts, Mr. FROST, Ms. FURSE, Mr. GEJDENSON, Mr. GREEN, Mr. HASTINGS of Florida, Mr. HILLIARD, Mr. HINCHEY, Mr. HOYER, Mr. JACKSON of Illinois, Ms. JACKSON-LEE of Texas, Ms. EDDIE BERNICE JOHNSON of Texas, Ms. KAPTUR, Mr. KENNEDY of Massachusetts, Mrs. KENNELLY of Connecticut, Mr. KLINK, Mr. LaFALCE, Mr. LANTOS, Mr. LEWIS of Georgia, Ms. LOFGREN, Mrs. MALONEY of New York, Mr. MANTON, Mr. MARKEY, Mr. MARTINEZ, Mr. MATSUI, Ms. MCCARTHY of Missouri, Mr. MCGOVERN, Ms. MCKINNEY, Mrs. MEEK of Florida, Mr. MENENDEZ, Mr. MILLER of California, Mr. MINGE, Mr. NADLER, Ms. NORTON, Mr. OLVER, Mr. OWENS, Mr. PALLONE, Mr. PASCRELL, Ms. PELOSI, Mr. PETERSON of Minnesota, Mr. RAHALL, Ms. RIVERS, Mr. ROMERO-BARCELÓ, Mr. SANDLIN, Mr. ROTHMAN, Mr. RUSH, Mr. SABO, Mr. SANDERS, Mr. SAWYER, Mr. SERRANO, Ms. STABENOW, Mr. STRICKLAND, Mr. STUPAK, Mr. THOMPSON, Mrs. THURMAN, Mr. TOWNS, Ms. VELÁZQUEZ, Mr. VENTO, Mr. WEXLER, Mr. WEYGAND, Mr. WISE, Ms. WOOLSEY, Mr. WYNN, and Mr. YATES) introduced the following bill; which was referred to the Committee on Commerce, and in addition to the Committees on Ways and Means, and Education and the Workforce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend the Public Health Service Act, the Employee Retirement Income Security Act of 1974, and the Internal Revenue Code of 1986 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 “Patients’ Bill of Rights Act of 1998”.

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—HEALTH INSURANCE BILL OF RIGHTS

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.
- Sec. 109. Nondiscrimination in delivery of services.

Subtitle B—Quality Assurance

- Sec. 111. Internal quality assurance program.
- Sec. 112. Collection of standardized data.
- Sec. 113. Process for selection of providers.
- Sec. 114. Drug utilization program.
- Sec. 115. Standards for utilization review activities.
- Sec. 116. Health Care Quality Advisory Board.

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.
- Sec. 153. Standards relating to benefits for reconstructive breast surgery.

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—APPLICATION TO GROUP HEALTH PLANS UNDER THE INTERNAL REVENUE CODE OF 1986

- Sec. 401. Amendments to the Internal Revenue Code of 1986.

TITLE V—EFFECTIVE DATES; COORDINATION IN IMPLEMENTATION

- Sec. 501. Effective dates.
- Sec. 502. Coordination in implementation.

1 **TITLE I—HEALTH INSURANCE**
2 **BILL OF RIGHTS**
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 pro-
20 vider—

21 (i) the participant, beneficiary, or en-
22 rollee is not liable for amounts that exceed
23 the amounts of liability that would be in-
24 curred if the services were provided by a
25 participating health care provider, and

1 (ii) the plan or issuer pays an amount
2 that is not less than the amount paid to a
3 participating health care provider for the
4 same services; and

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

14 (2) DEFINITIONS.—In this section:

15 (A) EMERGENCY MEDICAL CONDITION
16 BASED ON PRUDENT LAYPERSON STANDARD.—
17 The term “emergency medical condition” means
18 a medical condition manifesting itself by acute
19 symptoms of sufficient severity (including se-
20 vere pain) such that a prudent layperson, who
21 possesses an average knowledge of health and
22 medicine, could reasonably expect the absence
23 of immediate medical attention to result in a
24 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) if the services are maintenance care or
4 post-stabilization care covered under the guidelines estab-
5 lished under section 1852(d)(2) of the Social Security Act
6 (relating to promoting efficient and timely coordination of
7 appropriate maintenance and post-stabilization care of an
8 enrollee after an enrollee has been determined to be sta-
9 ble), or, in the absence of guidelines under such section,
10 such guidelines as the Secretary shall establish to carry
11 out this subsection.

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

14 (a) REQUIREMENT.—

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

1 rollment under the plan or coverage and at such
2 other times as the plan or issuer offers the partici-
3 pant a choice of coverage options.

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

7 (A) a choice of health insurance coverage
8 through more than one health insurance issuer;
9 or

10 (B) two or more coverage options that dif-
11 fer significantly with respect to the use of par-
12 ticipating health care providers or the networks
13 of such providers that are used.

14 (b) POINT-OF-SERVICE COVERAGE DEFINED.—In
15 this section, the term “point-of-service coverage” means,
16 with respect to benefits covered under a group health plan
17 or health insurance issuer, coverage of such benefits when
18 provided by a nonparticipating health care provider. Such
19 coverage need not include coverage of providers that the
20 plan or issuer excludes because of fraud, quality, or similar
21 reasons.

22 (c) CONSTRUCTION.—Nothing in this section shall be
23 construed—

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

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

5 (3) as preventing a group health plan or health
6 insurance issuer from imposing higher premiums or
7 cost-sharing on a participant for the exercise of a
8 point-of-service coverage option.

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

17 **SEC. 103. CHOICE OF PROVIDERS.**

18 (a) **PRIMARY CARE.**—A group health plan, and a
19 health insurance issuer that offers health insurance cov-
20 erage, shall permit each participant, beneficiary, and en-
21 rollee to receive primary care from any participating pri-
22 mary care provider who is available to accept such individ-
23 ual.

24 (b) **SPECIALISTS.**—

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

9 (2) LIMITATION.—Paragraph (1) shall not
10 apply to specialty care if the plan or issuer clearly
11 informs participants, beneficiaries, and enrollees of
12 the limitations on choice of participating providers
13 with respect to such care.

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

15 (a) OBSTETRICAL AND GYNECOLOGICAL CARE.—

16 (1) IN GENERAL.—If a group health plan, or a
17 health insurance issuer in connection with the provi-
18 sion of health insurance coverage, requires or pro-
19 vides for a participant, beneficiary, or enrollee to
20 designate a participating primary care provider—

21 (A) the plan or issuer shall permit such an
22 individual who is a female to designate a par-
23 ticipating physician who specializes in obstetrics
24 and gynecology as the individual’s primary care
25 provider; and

1 (B) if such an individual has not des-
2 ignated such a provider as a primary care pro-
3 vider, the plan or issuer—

4 (i) may not require authorization or a
5 referral by the individual's primary care
6 provider or otherwise for coverage of rou-
7 tine gynecological care (such as preventive
8 women's health examinations) and preg-
9 nancy-related services provided by a par-
10 ticipating health care professional who spe-
11 cializes in obstetrics and gynecology to the
12 extent such care is otherwise covered, and

13 (ii) may treat the ordering of other
14 gynecological care by such a participating
15 physician as the authorization of the pri-
16 mary care provider with respect to such
17 care under the plan or coverage.

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

22 (b) SPECIALTY CARE.—

23 (1) SPECIALTY CARE FOR COVERED SERV-
24 ICES.—

25 (A) IN GENERAL.—If—

1 (i) an individual is a participant or
2 beneficiary under a group health plan or
3 an enrollee who is covered under health in-
4 surance coverage offered by a health insur-
5 ance issuer,

6 (ii) the individual has a condition or
7 disease of sufficient seriousness and com-
8 plexity to require treatment by a specialist,
9 and

10 (iii) benefits for such treatment are
11 provided under the plan or coverage,

12 the plan or issuer shall make or provide for a
13 referral to a specialist who is available and ac-
14 cessible to provide the treatment for such condi-
15 tion or disease.

16 (B) SPECIALIST DEFINED.—For purposes
17 of this subsection, the term “specialist” means,
18 with respect to a condition, a health care practi-
19 tioner, facility, or center (such as a center of
20 excellence) that has adequate expertise through
21 appropriate training and experience (including,
22 in the case of a child, appropriate pediatric ex-
23 pertise) to provide high quality care in treating
24 the condition.

1 (C) CARE UNDER REFERRAL.—A group
2 health plan or health insurance issuer may re-
3 quire that the care provided to an individual
4 pursuant to such referral under subparagraph
5 (A) be—

6 (i) pursuant to a treatment plan, only
7 if the treatment plan is developed by the
8 specialist and approved by the plan or
9 issuer, in consultation with the designated
10 primary care provider or specialist and the
11 individual (or the individual's designee),
12 and

13 (ii) in accordance with applicable
14 quality assurance and utilization review
15 standards of the plan or issuer.

16 Nothing in this subsection shall be construed as
17 preventing such a treatment plan for an individ-
18 ual from requiring a specialist to provide the
19 primary care provider with regular updates on
20 the specialty care provided, as well as all nec-
21 essary medical information.

22 (D) REFERRALS TO PARTICIPATING PRO-
23 VIDERS.—A group health plan or health insur-
24 ance issuer is not required under subparagraph
25 (A) to provide for a referral to a specialist that

1 is not a participating provider, unless the plan
2 or issuer does not have an appropriate specialist
3 that is available and accessible to treat the indi-
4 vidual's condition and that is a participating
5 provider with respect to such treatment.

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

15 (2) SPECIALISTS AS PRIMARY CARE PROVID-
16 ERS.—

17 (A) IN GENERAL.—A group health plan, or
18 a health insurance issuer, in connection with
19 the provision of health insurance coverage, shall
20 have a procedure by which an individual who is
21 a participant, beneficiary, or enrollee and who
22 has an ongoing special condition (as defined in
23 subparagraph (C)) may receive a referral to a
24 specialist for such condition who shall be re-
25 sponsible for and capable of providing and co-

1 ordinating the individual’s primary and spe-
2 cialty care. If such an individual’s care would
3 most appropriately be coordinated by such a
4 specialist, such plan or issuer shall refer the in-
5 dividual to such specialist.

6 (B) TREATMENT AS PRIMARY CARE PRO-
7 VIDER.—Such specialist shall be permitted to
8 treat the individual without a referral from the
9 individual’s primary care provider and may au-
10 thorize such referrals, procedures, tests, and
11 other medical services as the individual’s pri-
12 mary care provider would otherwise be per-
13 mitted to provide or authorize, subject to the
14 terms of the treatment plan (referred to in
15 paragraph (1)(C)(i)).

16 (C) ONGOING SPECIAL CONDITION DE-
17 FINED.—In this paragraph, the term “special
18 condition” means a condition or disease that—

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

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

23 (D) TERMS OF REFERRAL.—The provi-
24 sions of subparagraphs (C) through (E) of
25 paragraph (1) apply with respect to referrals

1 under subparagraph (A) of this paragraph in
2 the same manner as they apply to referrals
3 under paragraph (1)(A).

4 (3) STANDING REFERRALS.—

5 (A) IN GENERAL.—A group health plan,
6 and a health insurance issuer in connection
7 with the provision of health insurance coverage,
8 shall have a procedure by which an individual
9 who is a participant, beneficiary, or enrollee
10 and who has a condition that requires ongoing
11 care from a specialist may receive a standing
12 referral to such specialist for treatment of such
13 condition. If the plan or issuer, or if the pri-
14 mary care provider in consultation with the
15 medical director of the plan or issuer and the
16 specialist (if any), determines that such a
17 standing referral is appropriate, the plan or
18 issuer shall make such a referral to such a spe-
19 cialist.

20 (B) TERMS OF REFERRAL.—The provi-
21 sions of subparagraphs (C) through (E) of
22 paragraph (1) apply with respect to referrals
23 under subparagraph (A) of this paragraph in
24 the same manner as they apply to referrals
25 under paragraph (1)(A).

1 **SEC. 105. CONTINUITY OF CARE.**

2 (a) IN GENERAL.—

3 (1) TERMINATION OF PROVIDER.—If a contract
4 between a group health plan, or a health insurance
5 issuer in connection with the provision of health in-
6 surance coverage, and a health care provider is ter-
7 minated (as defined in paragraph (3)), or benefits or
8 coverage provided by a health care provider are ter-
9 minated because of a change in the terms of pro-
10 vider participation in a group health plan, and an in-
11 dividual who is a participant, beneficiary, or enrollee
12 in the plan or coverage is undergoing a course of
13 treatment from the provider at the time of such ter-
14 mination, the plan or issuer shall—

15 (A) notify the individual on a timely basis
16 of such termination, and

17 (B) subject to subsection (c), permit the
18 individual to continue or be covered with re-
19 spect to the course of treatment with the pro-
20 vider during a transitional period (provided
21 under subsection (b)).

22 (2) TREATMENT OF TERMINATION OF CON-
23 TRACT WITH HEALTH INSURANCE ISSUER.—If a
24 contract for the provision of health insurance cov-
25 erage between a group health plan and a health in-
26 surance issuer is terminated and, as a result of such

1 termination, coverage of services of a health care
2 provider is terminated with respect to an individual,
3 the provisions of paragraph (1) (and the succeeding
4 provisions of this section) shall apply under the plan
5 in the same manner as if there had been a contract
6 between the plan and the provider that had been ter-
7 minated, but only with respect to benefits that are
8 covered under the plan after the contract termi-
9 nation.

10 (3) TERMINATION.—In this section, the term
11 “terminated” includes, with respect to a contract,
12 the expiration or nonrenewal of the contract, but
13 does not include a termination of the contract by the
14 plan or issuer for failure to meet applicable quality
15 standards or for fraud.

16 (b) TRANSITIONAL PERIOD.—

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

22 (2) INSTITUTIONAL CARE.—The transitional pe-
23 riod under this subsection for institutional or inpa-
24 tient care from a provider shall extend until the dis-
25 charge or termination of the period of institutional-

1 ization and also shall include institutional care pro-
2 vided within a reasonable time of the date of termi-
3 nation of the provider status if the care was sched-
4 uled before the date of the announcement of the ter-
5 mination of the provider status under subsection
6 (a)(1)(A) or if the individual on such date was on
7 an established waiting list or otherwise scheduled to
8 have such care.

9 (3) PREGNANCY.—If—

10 (A) a participant, beneficiary, or enrollee
11 has entered the second trimester of pregnancy
12 at the time of a provider’s termination of par-
13 ticipation, and

14 (B) the provider was treating the preg-
15 nancy before date of the termination,
16 the transitional period under this subsection with re-
17 spect to provider’s treatment of the pregnancy shall
18 extend through the provision of post-partum care di-
19 rectly related to the delivery.

20 (4) TERMINAL ILLNESS.—If—

21 (A) a participant, beneficiary, or enrollee
22 was determined to be terminally ill (as deter-
23 mined under section 1861(dd)(3)(A) of the So-
24 cial Security Act) at the time of a provider’s
25 termination of participation, and

1 (B) the provider was treating the terminal
2 illness before the date of termination,
3 the transitional period under this subsection shall
4 extend for the remainder of the individual's life for
5 care directly related to the treatment of the terminal
6 illness.

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

12 (1) The provider agrees to accept reimburse-
13 ment from the plan or issuer and individual involved
14 (with respect to cost-sharing) at the rates applicable
15 prior to the start of the transitional period as pay-
16 ment in full (or, in the case described in subsection
17 (a)(2), at the rates applicable under the replacement
18 plan or issuer after the date of the termination of
19 the contract with the health insurance issuer) and
20 not to impose cost-sharing with respect to the indi-
21 vidual in an amount that would exceed the cost-shar-
22 ing that could have been imposed if the contract re-
23 ferred to in subsection (a)(1) had not been termi-
24 nated.

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

4 (B) subject to subsection (c), may not deny
5 (or limit or impose additional conditions on) the
6 coverage of routine patient costs for items and
7 services furnished in connection with participa-
8 tion in the trial; and

9 (C) may not discriminate against the indi-
10 vidual on the basis of the enrollee's participa-
11 tion in such trial.

12 (2) EXCLUSION OF CERTAIN COSTS.—For pur-
13 poses of paragraph (1)(B), routine patient costs do
14 not include the cost of the tests or measurements
15 conducted primarily for the purpose of the clinical
16 trial involved.

17 (3) USE OF IN-NETWORK PROVIDERS.—If one
18 or more participating providers is participating in a
19 clinical trial, nothing in paragraph (1) shall be con-
20 strued as preventing a plan or issuer from requiring
21 that a qualified individual participate in the trial
22 through such a participating provider if the provider
23 will accept the individual as a participant in the
24 trial.

1 (b) QUALIFIED INDIVIDUAL DEFINED.—For pur-
2 poses of subsection (a), the term “qualified individual”
3 means an individual who is a participant or beneficiary
4 in a group health plan, or who is an enrollee under health
5 insurance coverage, and who meets the following condi-
6 tions:

7 (1)(A) The individual has a life-threatening or
8 serious illness for which no standard treatment is ef-
9 fective.

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

13 (C) The individual’s participation in the trial
14 offers meaningful potential for significant clinical
15 benefit for the individual.

16 (2) Either—

17 (A) the referring physician is a participat-
18 ing health care professional and has concluded
19 that the individual’s participation in such trial
20 would be appropriate based upon the individual
21 meeting the conditions described in paragraph
22 (1); or

23 (B) the participant, beneficiary, or enrollee
24 provides medical and scientific information es-
25 tablishing that the individual’s participation in

1 such trial would be appropriate based upon the
2 individual meeting the conditions described in
3 paragraph (1).

4 (c) PAYMENT.—

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

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

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

16 (B) a nonparticipating provider, the pay-
17 ment rate shall be at the rate the plan or issuer
18 would normally pay for comparable services
19 under subparagraph (A).

20 (d) APPROVED CLINICAL TRIAL DEFINED.—

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

1 (A) The National Institutes of Health.

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

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

6 (i) The Department of Veterans Af-
7 fairs.

8 (ii) The Department of Defense.

9 (2) CONDITIONS FOR DEPARTMENTS.—The
10 conditions described in this paragraph, for a study
11 or investigation conducted by a Department, are
12 that the study or investigation has been reviewed
13 and approved through a system of peer review that
14 the Secretary determines—

15 (A) to be comparable to the system of peer
16 review of studies and investigations used by the
17 National Institutes of Health, and

18 (B) assures unbiased review of the highest
19 scientific standards by qualified individuals who
20 have no interest in the outcome of the review.

21 (e) CONSTRUCTION.—Nothing in this section shall be
22 construed to limit a plan's or issuer's coverage with re-
23 spect to clinical trials.

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

2 (a) IN GENERAL.—If a group health plan, or health
3 insurance issuer that offers health insurance coverage,
4 provides benefits with respect to prescription drugs but
5 the coverage limits such benefits to drugs included in a
6 formulary, the plan or issuer shall—

7 (1) ensure participation of participating physi-
8 cians and pharmacists in the development of the for-
9 mulary;

10 (2) disclose to providers and, disclose upon re-
11 quest under section 121(c)(6) to participants, bene-
12 ficiaries, and enrollees, the nature of the formulary
13 restrictions; and

14 (3) consistent with the standards for a utiliza-
15 tion review program under section 115, provide for
16 exceptions from the formulary limitation when a
17 non-formulary alternative is medically indicated.

18 (b) COVERAGE OF APPROVED DRUGS AND MEDICAL
19 DEVICES.—

20 (1) IN GENERAL.—A group health plan (or
21 health insurance coverage offered in connection with
22 such a plan) that provides any coverage of prescrip-
23 tion drugs or medical devices shall not deny coverage
24 of such a drug or device on the basis that the use
25 is investigational, if the use—

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

1 (i) is included in the labeling author-
2 ized by the application in effect for the
3 drug pursuant to subsection (b) or (j) of
4 section 505 of the Federal Food, Drug,
5 and Cosmetic Act, without regard to any
6 postmarketing requirements that may
7 apply under such Act; or

8 (ii) is included in the labeling author-
9 ized by the application in effect for the
10 drug under section 351 of the Public
11 Health Service Act, without regard to any
12 postmarketing requirements that may
13 apply pursuant to such section; or

14 (B) in the case of a medical device, is in-
15 cluded in the labeling authorized by a regula-
16 tion under subsection (d) or (3) of section 513
17 of the Federal Food, Drug, and Cosmetic Act,
18 an order under subsection (f) of such section, or
19 an application approved under section 515 of
20 such Act, without regard to any postmarketing
21 requirements that may apply under such Act.

22 (2) CONSTRUCTION.—Nothing in this sub-
23 section shall be construed as requiring a group
24 health plan (or health insurance coverage offered in

1 connection with such a plan) to provide any coverage
2 of prescription drugs or medical devices.

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

4 (a) IN GENERAL.—Each group health plan, and each
5 health insurance issuer offering health insurance coverage,
6 that provides benefits, in whole or in part, through partici-
7 pating health care providers shall have (in relation to the
8 coverage) a sufficient number, distribution, and variety of
9 qualified participating health care providers to ensure that
10 all covered health care services, including specialty serv-
11 ices, will be available and accessible in a timely manner
12 to all participants, beneficiaries, and enrollees under the
13 plan or coverage.

14 (b) TREATMENT OF CERTAIN PROVIDERS.—The
15 qualified health care providers under subsection (a) may
16 include Federally qualified health centers, rural health
17 clinics, migrant health centers, and other essential com-
18 munity providers located in the service area of the plan
19 or issuer and shall include such providers if necessary to
20 meet the standards established to carry out such sub-
21 section.

22 **SEC. 109. NONDISCRIMINATION IN DELIVERY OF SERVICES.**

23 (a) APPLICATION TO DELIVERY OF SERVICES.—Sub-
24 ject to subsection (b), a group health plan, and health in-
25 surance issuer in relation to health insurance coverage,

1 may not discriminate against a participant, beneficiary, or
2 enrollee in the delivery of health care services consistent
3 with the benefits covered under the plan or coverage or
4 as required by law based on race, color, ethnicity, national
5 origin, religion, sex, age, mental or physical disability, sex-
6 ual orientation, genetic information, or source of payment.

7 (b) CONSTRUCTION.—Nothing in subsection (a) shall
8 be construed as relating to the eligibility to be covered,
9 or the offering (or guaranteeing the offer) of coverage,
10 under a plan or health insurance coverage, the application
11 of any pre-existing condition exclusion consistent with ap-
12 plicable law, or premiums charged under such plan or cov-
13 erage.

14 **Subtitle B—Quality Assurance**

15 **SEC. 111. INTERNAL QUALITY ASSURANCE PROGRAM.**

16 (a) REQUIREMENT.—A group health plan, and a
17 health insurance issuer that offers health insurance cov-
18 erage, shall establish and maintain an ongoing, internal
19 quality assurance and continuous quality improvement
20 program that meets the requirements of subsection (b).

21 (b) PROGRAM REQUIREMENTS.—The requirements of
22 this subsection for a quality improvement program of a
23 plan or issuer are as follows:

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

4 (2) WRITTEN PLAN.—The plan or issuer has a
5 written plan for the program that is updated annu-
6 ally and that specifies at least the following:

7 (A) The activities to be conducted.

8 (B) The organizational structure.

9 (C) The duties of the medical director.

10 (D) Criteria and procedures for the assess-
11 ment of quality.

12 (3) SYSTEMATIC REVIEW.—The program pro-
13 vides for systematic review of the type of health
14 services provided, consistency of services provided
15 with good medical practice, and patient outcomes.

16 (4) QUALITY CRITERIA.—The program—

17 (A) uses criteria that are based on per-
18 formance and patient outcomes where feasible
19 and appropriate;

20 (B) includes criteria that are directed spe-
21 cifically at meeting the needs of at-risk popu-
22 lations and covered individuals with chronic
23 conditions or severe illnesses, including gender-
24 specific criteria and pediatric-specific criteria
25 where available and appropriate;

1 (C) includes methods for informing covered
2 individuals of the benefit of preventive care and
3 what specific benefits with respect to preventive
4 care are covered under the plan or coverage;
5 and

6 (D) makes available to the public a de-
7 scription of the criteria used under subpara-
8 graph (A).

9 (5) SYSTEM FOR REPORTING.—The program
10 has procedures for reporting of possible quality con-
11 cerns by providers and enrollees and for remedial ac-
12 tions to correct quality problems, including written
13 procedures for responding to concerns and taking
14 appropriate corrective action.

15 (6) DATA ANALYSIS.—The program provides,
16 using data that include the data collected under sec-
17 tion 112, for an analysis of the plan's or issuer's
18 performance on quality measures.

19 (7) DRUG UTILIZATION REVIEW.—The program
20 provides for a drug utilization review program in ac-
21 cordance with section 114.

22 (c) DEEMING.—For purposes of subsection (a), the
23 requirements of—

24 (1) subsection (b) (other than paragraph (5))
25 are deemed to be met with respect to a health insur-

1 ance issuer that is a qualified health maintenance
2 organization (as defined in section 1310(c) of the
3 Public Health Service Act); or

4 (2) subsection (b) are deemed to be met with
5 respect to a health insurance issuer that is accred-
6 ited by a national accreditation organization that the
7 Secretary certifies as applying, as a condition of cer-
8 tification, standards at least as stringent as those re-
9 quired for a quality improvement program under
10 subsection (b).

11 (d) VARIATION PERMITTED.—The Secretary may
12 provide for variations in the application of the require-
13 ments of this section to group health plans and health in-
14 surance issuers based upon differences in the delivery sys-
15 tem among such plans and issuers as the Secretary deems
16 appropriate.

17 **SEC. 112. COLLECTION OF STANDARDIZED DATA.**

18 (a) IN GENERAL.—A group health plan and a health
19 insurance issuer that offers health insurance coverage
20 shall collect uniform quality data that include a minimum
21 uniform data set described in subsection (b).

22 (b) MINIMUM UNIFORM DATA SET.—The Secretary
23 shall specify (and may from time to time update) the data
24 required to be included in the minimum uniform data set

1 under subsection (a) and the standard format for such
2 data. Such data shall include at least—

3 (1) aggregate utilization data;

4 (2) data on the demographic characteristics of
5 participants, beneficiaries, and enrollees;

6 (3) data on disease-specific and age-specific
7 mortality rates and (to the extent feasible) morbidity
8 rates of such individuals;

9 (4) data on satisfaction of such individuals, in-
10 cluding data on voluntary disenrollment and griev-
11 ances; and

12 (5) data on quality indicators and health out-
13 comes, including, to the extent feasible and appro-
14 priate, data on pediatric cases and on a gender-spe-
15 cific basis.

16 (c) AVAILABILITY.—A summary of the data collected
17 under subsection (a) shall be disclosed under section
18 121(b)(9). The Secretary shall be provided access to all
19 the data so collected.

20 (d) VARIATION PERMITTED.—The Secretary may
21 provide for variations in the application of the require-
22 ments of this section to group health plans and health in-
23 surance issuers based upon differences in the delivery sys-
24 tem among such plans and issuers as the Secretary deems
25 appropriate.

1 **SEC. 113. PROCESS FOR SELECTION OF PROVIDERS.**

2 (a) IN GENERAL.—A group health plan and a health
3 insurance issuer that offers health insurance coverage
4 shall, if it provides benefits through participating health
5 care professionals, have a written process for the selection
6 of participating health care professionals, including mini-
7 mum professional requirements.

8 (b) VERIFICATION OF BACKGROUND.—Such process
9 shall include verification of a health care provider’s license
10 and a history of suspension or revocation.

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

15 (d) NONDISCRIMINATION BASED ON LICENSURE.—

16 (1) IN GENERAL.—Such process shall not dis-
17 criminate with respect to participation or indem-
18 nification as to any provider who is acting within the
19 scope of the provider’s license or certification under
20 applicable State law, solely on the basis of such li-
21 cense or certification.

22 (2) CONSTRUCTION.—Paragraph (1) shall not
23 be construed—

24 (A) as requiring the coverage under a plan
25 or coverage of particular benefits or services or
26 to prohibit a plan or issuer from including pro-

1 viders only to the extent necessary to meet the
2 needs of the plan’s or issuer’s participants,
3 beneficiaries, or enrollees or from establishing
4 any measure designed to maintain quality and
5 control costs consistent with the responsibilities
6 of the plan or issuer; or

7 (B) to override any State licensure or
8 scope-of-practice law.

9 (e) GENERAL NONDISCRIMINATION.—

10 (1) IN GENERAL.—Subject to paragraph (2),
11 such process shall not discriminate with respect to
12 selection of a health care professional to be a partici-
13 pating health care provider, or with respect to the
14 terms and conditions of such participation, based on
15 the professional’s race, color, religion, sex, national
16 origin, age, sexual orientation, or disability (consist-
17 ent with the Americans with Disabilities Act of
18 1990).

19 (2) RULES.—The appropriate Secretary may
20 establish such definitions, rules, and exceptions as
21 may be appropriate to carry out paragraph (1), tak-
22 ing into account comparable definitions, rules, and
23 exceptions in effect under employment-based non-
24 discrimination laws and regulations that relate to

1 each of the particular bases for discrimination de-
2 scribed in such paragraph.

3 **SEC. 114. DRUG UTILIZATION PROGRAM.**

4 A group health plan, and a health insurance issuer
5 that provides health insurance coverage, that includes ben-
6 efits for prescription drugs shall establish and maintain,
7 as part of its internal quality assurance and continuous
8 quality improvement program under section 111, a drug
9 utilization program which—

10 (1) encourages appropriate use of prescription
11 drugs by participants, beneficiaries, and enrollees
12 and providers, and

13 (2) takes appropriate action to reduce the inci-
14 dence of improper drug use and adverse drug reac-
15 tions and interactions.

16 **SEC. 115. STANDARDS FOR UTILIZATION REVIEW ACTIVI-**
17 **TIES.**

18 (a) COMPLIANCE WITH REQUIREMENTS.—

19 (1) IN GENERAL.—A group health plan, and a
20 health insurance issuer that provides health insur-
21 ance coverage, shall conduct utilization review activi-
22 ties in connection with the provision of benefits
23 under such plan or coverage only in accordance with
24 a utilization review program that meets the require-
25 ments of this section.

1 (2) USE OF OUTSIDE AGENTS.—Nothing in this
2 section shall be construed as preventing a group
3 health plan or health insurance issuer from arrang-
4 ing through a contract or otherwise for persons or
5 entities to conduct utilization review activities on be-
6 half of the plan or issuer, so long as such activities
7 are conducted in accordance with a utilization review
8 program that meets the requirements of this section.

9 (3) UTILIZATION REVIEW DEFINED.—For pur-
10 poses of this section, the terms “utilization review”
11 and “utilization review activities” mean procedures
12 used to monitor or evaluate the clinical necessity,
13 appropriateness, efficacy, or efficiency of health care
14 services, procedures or settings, and includes pro-
15 spective review, concurrent review, second opinions,
16 case management, discharge planning, or retrospec-
17 tive review.

18 (b) WRITTEN POLICIES AND CRITERIA.—

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

23 (2) USE OF WRITTEN CRITERIA.—

24 (A) IN GENERAL.—Such a program shall
25 utilize written clinical review criteria developed

1 pursuant to the program with the input of ap-
2 propriate physicians. Such criteria shall include
3 written clinical review criteria described in sec-
4 tion 111(b)(4)(B).

5 (B) CONTINUING USE OF STANDARDS IN
6 RETROSPECTIVE REVIEW.—If a health care
7 service has been specifically pre-authorized or
8 approved for an enrollee under such a program,
9 the program shall not, pursuant to retrospective
10 review, revise or modify the specific standards,
11 criteria, or procedures used for the utilization
12 review for procedures, treatment, and services
13 delivered to the enrollee during the same course
14 of treatment.

15 (c) CONDUCT OF PROGRAM ACTIVITIES.—

16 (1) ADMINISTRATION BY HEALTH CARE PRO-
17 FESSIONALS.—A utilization review program shall be
18 administered by qualified health care professionals
19 who shall oversee review decisions. In this sub-
20 section, the term “health care professional” means a
21 physician or other health care practitioner licensed,
22 accredited, or certified to perform specified health
23 services consistent with State law.

24 (2) USE OF QUALIFIED, INDEPENDENT PER-
25 SONNEL.—

1 (A) IN GENERAL.—A utilization review
2 program shall provide for the conduct of utiliza-
3 tion review activities only through personnel
4 who are qualified and, to the extent required,
5 who have received appropriate training in the
6 conduct of such activities under the program.

7 (B) PEER REVIEW OF SAMPLE OF AD-
8 VERSE CLINICAL DETERMINATIONS.—Such a
9 program shall provide that clinical peers (as de-
10 fined in section 191(c)(2)) shall evaluate the
11 clinical appropriateness of at least a sample of
12 adverse clinical determinations.

13 (C) PROHIBITION OF CONTINGENT COM-
14 PENSATION ARRANGEMENTS.—Such a program
15 shall not, with respect to utilization review ac-
16 tivities, permit or provide compensation or any-
17 thing of value to its employees, agents, or con-
18 tractors in a manner that—

19 (i) provides incentives, direct or indi-
20 rect, for such persons to make inappropri-
21 ate review decisions, or

22 (ii) is based, directly or indirectly, on
23 the quantity or type of adverse determina-
24 tions rendered.

1 (D) PROHIBITION OF CONFLICTS.—Such a
2 program shall not permit a health care profes-
3 sional who provides health care services to an
4 individual to perform utilization review activi-
5 ties in connection with the health care services
6 being provided to the individual.

7 (3) ACCESSIBILITY OF REVIEW.—Such a pro-
8 gram shall provide that appropriate personnel per-
9 forming utilization review activities under the pro-
10 gram are reasonably accessible by toll-free telephone
11 during normal business hours to discuss patient care
12 and allow response to telephone requests, and that
13 appropriate provision is made to receive and respond
14 promptly to calls received during other hours.

15 (4) LIMITS ON FREQUENCY.—Such a program
16 shall not provide for the performance of utilization
17 review activities with respect to a class of services
18 furnished to an individual more frequently than is
19 reasonably required to assess whether the services
20 under review are medically necessary or appropriate.

21 (5) LIMITATION ON INFORMATION REQUESTS.—
22 Under such a program, information shall be required
23 to be provided by health care providers only to the
24 extent it is necessary to perform the utilization re-
25 view activity involved.

1 (6) REVIEW OF PRELIMINARY UTILIZATION RE-
2 VIEW DECISION.—Under such program a partici-
3 pant, beneficiary, or enrollee or any provider acting
4 on behalf of such an individual with the individual's
5 consent, who is dissatisfied with a preliminary utili-
6 zation review decision has the opportunity to discuss
7 the decision with, and have such decision reviewed
8 by, the medical director of the plan or issuer in-
9 volved (or the director's designee) who has the au-
10 thority to reverse the decision.

11 (d) DEADLINE FOR DETERMINATIONS.—

12 (1) PRIOR AUTHORIZATION SERVICES.—Except
13 as provided in paragraph (2), in the case of a utili-
14 zation review activity involving the prior authoriza-
15 tion of health care items and services for an individ-
16 ual, the utilization review program shall make a de-
17 termination concerning such authorization, and pro-
18 vide notice of the determination to the individual or
19 the individual's designee and the individual's health
20 care provider by telephone and in printed form, as
21 soon as possible in accordance with the medical ex-
22 igencies of the cases, and in no event later than 3
23 business days after the date of receipt of information
24 that is reasonably necessary to make such deter-
25 mination.

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

20 (3) PREVIOUSLY PROVIDED SERVICES.—In the
21 case of a utilization review activity involving retro-
22 spective review of health care services previously pro-
23 vided for an individual, the utilization review pro-
24 gram shall make a determination concerning such
25 services, and provide notice of the determination to

1 the individual or the individual's designee and the
2 individual's health care provider by telephone and in
3 printed form, within 30 days of the date of receipt
4 of information that is reasonably necessary to make
5 such determination.

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

13 (e) NOTICE OF ADVERSE DETERMINATIONS.—

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

17 (A) the reasons for the determination (in-
18 cluding the clinical rationale);

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

21 (C) notice of the availability, upon request
22 of the individual (or the individual's designee)
23 of the clinical review criteria relied upon to
24 make such determination.

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

7 **SEC. 116. HEALTH CARE QUALITY ADVISORY BOARD.**

8 (a) ESTABLISHMENT.—The President shall establish
9 an advisory board to provide information to Congress and
10 the administration on issues relating to quality monitoring
11 and improvement in the health care provided under group
12 health plans and health insurance coverage.

13 (b) NUMBER AND APPOINTMENT.—The advisory
14 board shall be composed of the Secretary of Health and
15 Human Services (or the Secretary’s designee), the Sec-
16 retary of Labor (or the Secretary’s designee), and 20 addi-
17 tional members appointed by the President, in consulta-
18 tion with the Majority and Minority Leaders of the Senate
19 and House of Representatives. The members so appointed
20 shall include individuals with expertise in—

- 21 (1) consumer needs;
- 22 (2) education and training of health profes-
23 sionals;
- 24 (3) health care services;
- 25 (4) health plan management;

1 (5) health care accreditation, quality assurance,
2 improvement, measurement, and oversight;

3 (6) medical practice, including practicing physi-
4 cians;

5 (7) prevention and public health; and

6 (8) public and private group purchasing for
7 small and large employers or groups.

8 (c) DUTIES.—The advisory board shall—

9 (1) identify, update, and disseminate measures
10 of health care quality for group health plans and
11 health insurance issuers, including network and non-
12 network plans;

13 (2) advise the Secretary on the development
14 and maintenance of the minimum data set in section
15 112(b); and

16 (3) advise the Secretary on standardized for-
17 mats for information on group health plans and
18 health insurance coverage.

19 The measures identified under paragraph (1) may be used
20 on a voluntary basis by such plans and issuers. In carrying
21 out paragraph (1), the advisory board shall consult and
22 cooperate with national health care standard setting bod-
23 ies which define quality indicators, the Agency for Health
24 Care Policy and Research, the Institute of Medicine, and

1 other public and private entities that have expertise in
2 health care quality.

3 (d) REPORT.—The advisory board shall provide an
4 annual report to Congress and the President on the qual-
5 ity of the health care in the United States and national
6 and regional trends in health care quality. Such report
7 shall include a description of determinants of health care
8 quality and measurements of practice and quality varia-
9 bility within the United States.

10 (e) SECRETARIAL CONSULTATION.—In serving on
11 the advisory board, the Secretaries of Health and Human
12 Services and Labor (or their designees) shall consult with
13 the Secretaries responsible for other Federal health insur-
14 ance and health care programs.

15 (f) VACANCIES.—Any vacancy on the board shall be
16 filled in such manner as the original appointment. Mem-
17 bers of the board shall serve without compensation but
18 shall be reimbursed for travel, subsistence, and other nec-
19 essary expenses incurred by them in the performance of
20 their duties. Administrative support, scientific support,
21 and technical assistance for the advisory board shall be
22 provided by the Secretary of Health and Human Services.

23 (g) CONTINUATION.—Section 14(a)(2)(B) of the
24 Federal Advisory Committee Act (5 U.S.C. App.; relating

1 to the termination of advisory committees) shall not apply
2 to the advisory board.

3 **Subtitle C—Patient Information**

4 **SEC. 121. PATIENT INFORMATION.**

5 (a) DISCLOSURE REQUIREMENT.—

6 (1) GROUP HEALTH PLANS.—A group health
7 plan shall—

8 (A) provide to participants and bene-
9 ficiaries at the time of initial coverage under
10 the plan (or the effective date of this section, in
11 the case of individuals who are participants or
12 beneficiaries as of such date), and at least an-
13 nually thereafter, the information described in
14 subsection (b) in printed form;

15 (B) provide to participants and bene-
16 ficiaries, within a reasonable period (as speci-
17 fied by the appropriate Secretary) before or
18 after the date of significant changes in the in-
19 formation described in subsection (b), informa-
20 tion in printed form on such significant
21 changes; and

22 (C) upon request, make available to par-
23 ticipants and beneficiaries, the applicable au-
24 thority, and prospective participants and bene-

1 ficiaries, the information described in sub-
2 section (b) or (c) in printed form.

3 (2) HEALTH INSURANCE ISSUERS.—A health
4 insurance issuer in connection with the provision of
5 health insurance coverage shall—

6 (A) provide to individuals enrolled under
7 such coverage at the time of enrollment, and at
8 least annually thereafter, the information de-
9 scribed in subsection (b) in printed form;

10 (B) provide to enrollees, within a reason-
11 able period (as specified by the appropriate Sec-
12 retary) before or after the date of significant
13 changes in the information described in sub-
14 section (b), information in printed form on such
15 significant changes; and

16 (C) upon request, make available to the
17 applicable authority, to individuals who are pro-
18 spective enrollees, and to the public the infor-
19 mation described in subsection (b) or (c) in
20 printed form.

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

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

3 (2) BENEFITS.—Benefits offered under the
4 plan or coverage, including—

5 (A) covered benefits, including benefit lim-
6 its and coverage exclusions;

7 (B) cost sharing, such as deductibles, coin-
8 surance, and copayment amounts, including any
9 liability for balance billing, any maximum limi-
10 tations on out of pocket expenses, and the max-
11 imum out of pocket costs for services that are
12 provided by non participating providers or that
13 are furnished without meeting the applicable
14 utilization review requirements;

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

17 (D) the extent to which a participant, ben-
18 eficiary, or enrollee may select from among par-
19 ticipating providers and the types of providers
20 participating in the plan or issuer network;

21 (E) process for determining experimental
22 coverage; and

23 (F) use of a prescription drug formulary.

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

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

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

5 (C) Any point-of-service option (including
6 any supplemental premium or cost-sharing for
7 such option).

8 (D) The procedures for participants, bene-
9 ficiaries, and enrollees to select, access, and
10 change participating primary and specialty pro-
11 viders.

12 (E) The rights and procedures for obtain-
13 ing referrals (including standing referrals) to
14 participating and nonparticipating providers.

15 (F) The name, address, and telephone
16 number of participating health care providers
17 and an indication of whether each such provider
18 is available to accept new patients.

19 (G) Any limitations imposed on the selec-
20 tion of qualifying participating health care pro-
21 viders, including any limitations imposed under
22 section 103(b)(2).

23 (H) How the plan or issuer addresses the
24 needs of participants, beneficiaries, and enroll-
25 ees and others who do not speak English or

1 who have other special communications needs in
2 accessing providers under the plan or coverage,
3 including the provision of information described
4 in this subsection and subsection (c) to such in-
5 dividuals and including the provision of infor-
6 mation in a language other than English if 5
7 percent of the number of participants, bene-
8 ficiaries, and enrollees communicate in that lan-
9 guage instead of English.

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

12 (5) EMERGENCY COVERAGE.—Coverage of
13 emergency services, including—

14 (A) the appropriate use of emergency serv-
15 ices, including use of the 911 telephone system
16 or its local equivalent in emergency situations
17 and an explanation of what constitutes an
18 emergency situation;

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

21 (C) the locations of (i) emergency depart-
22 ments, and (ii) other settings, in which plan
23 physicians and hospitals provide emergency
24 services and post-stabilization care.

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

9 (7) PRIOR AUTHORIZATION RULES.—Rules re-
10 garding prior authorization or other review require-
11 ments that could result in noncoverage or non-
12 payment.

13 (8) GRIEVANCE AND APPEALS PROCEDURES.—
14 All appeal or grievance rights and procedures under
15 the plan or coverage, including the method for filing
16 grievances and the time frames and circumstances
17 for acting on grievances and appeals, who is the ap-
18 plicable authority with respect to the plan or issuer,
19 and the availability of assistance through an om-
20 budsman to individuals in relation to group health
21 plans and health insurance coverage.

22 (9) QUALITY ASSURANCE.—A summary descrip-
23 tion of the data on quality collected under section
24 112(a), including a summary description of the data
25 on satisfaction of participants, beneficiaries, and en-

1 rollees (including data on individual voluntary
2 disenrollment and grievances and appeals) described
3 in section 112(b)(4).

4 (10) SUMMARY OF PROVIDER FINANCIAL IN-
5 CENTIVES.—A summary description of the informa-
6 tion on the types of financial payment incentives
7 (described in section 1852(j)(4) of the Social Secu-
8 rity Act) provided by the plan or issuer under the
9 coverage.

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

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

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

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

1 section 115, including under any drug formulary
2 program under section 107.

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

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

14 (4) SPECIFIC INFORMATION ON CREDENTIALS
15 OF PARTICIPATING PROVIDERS.—In the case of each
16 participating provider, a description of the creden-
17 tials of the provider.

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 (5) Notification to the continuous quality im-
12 provement program under section 111(a) of all
13 grievances and appeals relating to quality of care.

14 **SEC. 132. INTERNAL APPEALS OF ADVERSE DETERMINA-**
15 **TIONS.**

16 (a) RIGHT OF APPEAL.—

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

1 provided with a written explanation of the appeal
2 process and the determination upon the conclusion
3 of the appeals process and as provided in section
4 121(b)(8).

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

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

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

19 (C) Failure to provide a choice of provider
20 under section 103.

21 (D) Failure to provide qualified health care
22 providers under section 103.

23 (E) Failure to provide access to specialty
24 and other care under section 104.

1 (F) Failure to provide continuation of care
2 under section 105.

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

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

8 (I) Discrimination in delivery of services in
9 violation of section 109.

10 (J) An adverse determination under a utili-
11 zation review program under section 115.

12 (K) The imposition of a limitation that is
13 prohibited under section 151.

14 (b) INTERNAL APPEAL PROCESS.—

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

24 (2) CONDUCT OF REVIEW.—

1 (A) IN GENERAL.—The process shall in-
2 clude a review of the decision by a physician or
3 other health care professional (or professionals)
4 who has been selected by the plan or issuer and
5 who has not been involved in the appealable de-
6 cision at issue in the appeal.

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

13 (3) DEADLINE.—

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

20 (i) 72 hours after the time of receipt
21 of an expedited appeal, and

22 (ii) except as provided in subpara-
23 graph (B), 15 business days after such
24 time in the case of all other appeals.

1 (B) EXTENSION.—A group health plan or
2 health insurance issuer may extend the deadline
3 for an appeal that does not relate to a decision
4 regarding an expedited appeal and that does
5 not involve medical exigencies up to an addi-
6 tional 10 business days where it can dem-
7 onstrate to the applicable authority reasonable
8 cause for the delay beyond its control and
9 where it provides, within the original deadline
10 under subparagraph (A), a written progress re-
11 port and explanation for the delay to such au-
12 thority and to the participant, beneficiary, or
13 enrollee and provider involved.

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

20 (c) EXPEDITED REVIEW PROCESS.—

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

1 mination could seriously jeopardize the life or health
2 of the participant, beneficiary, or enrollee or such an
3 individual's ability to regain maximum function.

4 (2) PROCESS.—Under such procedures—

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

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

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

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

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

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

7 (a) **RIGHT TO EXTERNAL APPEAL.—**

8 (1) **IN GENERAL.—**A group health plan, and a
9 health insurance issuer offering group health insur-
10 ance coverage, shall provide for an external appeals
11 process that meets the requirements of this section
12 in the case of an externally appealable decision de-
13 scribed in paragraph (2). The appropriate Secretary
14 shall establish standards to carry out such require-
15 ments.

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

20 (A) the amount involved exceeds a signifi-
21 cant threshold; or

22 (B) the patient's life or health is jeopard-
23 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:

1 (A) FAIR PROCESS; DE NOVO DETERMINA-
2 TION.—The process shall provide for a fair, de
3 novo determination.

4 (B) DETERMINATION CONCERNING EXTER-
5 NALLY APPEALABLE DECISIONS.—A qualified
6 external appeal entity shall determine whether a
7 decision is an externally appealable decision and
8 related decisions, including—

9 (i) whether such a decision involves an
10 expedited appeal;

11 (ii) the appropriate deadlines for in-
12 ternal review process required due to medi-
13 cal exigencies in a case; and

14 (iii) whether such a process has been
15 completed.

16 (C) OPPORTUNITY TO SUBMIT EVIDENCE,
17 HAVE REPRESENTATION, AND MAKE ORAL
18 PRESENTATION.—Each party to an externally
19 appealable decision—

20 (i) may submit and review evidence
21 related to the issues in dispute,

22 (ii) may use the assistance or rep-
23 resentation of one or more individuals (any
24 of whom may be an attorney), and

25 (iii) may make an oral presentation.

1 (D) PROVISION OF INFORMATION.—The
2 plan or issuer involved shall provide timely ac-
3 cess to all its records relating to the matter of
4 the externally appealable decision and to all
5 provisions of the plan or health insurance cov-
6 erage (including any coverage manual) relating
7 to the matter.

8 (E) TIMELY DECISIONS.—A determination
9 by the external appeal entity on the decision
10 shall—

11 (i) be made orally or in writing and,
12 if it is made orally, shall be supplied to the
13 parties in writing as soon as possible;

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

15 (iii) be made in accordance with the
16 medical exigencies of the case involved, but
17 in no event later than 60 days (or 72
18 hours in the case of an expedited appeal)
19 from the date of completion of the filing of
20 notice of external appeal of the decision;

21 (iv) state, in layperson's language, the
22 basis for the determination, including, if
23 relevant, any basis in the terms or condi-
24 tions of the plan or coverage; and

1 (v) inform the participant, beneficiary,
2 or enrollee of the individual's rights to seek
3 further review by the courts (or other proc-
4 ess) of the external appeal determination.

5 (c) QUALIFICATIONS OF EXTERNAL APPEAL ENTI-
6 TIES.—

7 (1) IN GENERAL.—For purposes of this section,
8 the term “qualified external appeal entity” means,
9 in relation to a plan or issuer, an entity (which may
10 be a governmental entity) that is certified under
11 paragraph (2) as meeting the following require-
12 ments:

13 (A) There is no real or apparent conflict of
14 interest that would impede the entity conduct-
15 ing external appeal activities independent of the
16 plan or issuer.

17 (B) The entity conducts external appeal
18 activities through clinical peers.

19 (C) The entity has sufficient medical, legal,
20 and other expertise and sufficient staffing to
21 conduct external appeal activities for the plan
22 or issuer on a timely basis consistent with sub-
23 section (b)(3)(E).

1 (D) The entity meets such other require-
2 ments as the appropriate Secretary may im-
3 pose.

4 (2) CERTIFICATION OF EXTERNAL APPEAL EN-
5 TITIES.—

6 (A) IN GENERAL.—In order to be treated
7 as a qualified external appeal entity with re-
8 spect to—

9 (i) a group health plan, the entity
10 must be certified (and, in accordance with
11 subparagraph (B), periodically recertified)
12 as meeting the requirements of paragraph
13 (1) by the Secretary of Labor (or under a
14 process recognized or approved by the Sec-
15 retary of Labor); or

16 (ii) a health insurance issuer operat-
17 ing in a State, the entity must be certified
18 (and, in accordance with subparagraph
19 (B), periodically recertified) as meeting
20 such requirements by the applicable State
21 authority (or, if the States has not estab-
22 lished an adequate certification and recer-
23 tification process, by the Secretary of
24 Health and Human Services, or under a

1 process recognized or approved by such
2 Secretary).

3 (B) RECERTIFICATION PROCESS.—The ap-
4 propriate Secretary shall develop standards for
5 the recertification of external appeal entities.
6 Such standards shall include a specification
7 of—

8 (i) the information required to be sub-
9 mitted as a condition of recertification on
10 the entity's performance of external appeal
11 activities, which information shall include
12 the number of cases reviewed, a summary
13 of the disposition of those cases, the length
14 of time in making determinations on those
15 cases, and such information as may be nec-
16 essary to assure the independence of the
17 entity from the plans or issuers for which
18 external appeal activities are being con-
19 ducted; and

20 (ii) the periodicity which recertifi-
21 cation will be required.

22 (d) CONTINUING LEGAL RIGHTS OF ENROLLEES.—
23 Nothing in this title shall be construed as removing any
24 legal rights of participants, beneficiaries, enrollees, and

1 others under State or Federal law, including the right to
2 file judicial actions to enforce rights.

3 **Subtitle E—Protecting the Doctor-**
4 **Patient Relationship**

5 **SEC. 141. PROHIBITION OF INTERFERENCE WITH CERTAIN**
6 **MEDICAL COMMUNICATIONS.**

7 (a) PROHIBITION.—

8 (1) GENERAL RULE.—The provisions of any
9 contract or agreement, or the operation of any con-
10 tract or agreement, between a group health plan or
11 health insurance issuer in relation to health insur-
12 ance coverage (including any partnership, associa-
13 tion, or other organization that enters into or ad-
14 ministers such a contract or agreement) and a
15 health care provider (or group of health care provid-
16 ers) shall not prohibit or restrict the provider from
17 engaging in medical communications with the pro-
18 vider’s patient.

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

22 (b) RULES OF CONSTRUCTION.—Nothing in this sec-
23 tion shall be construed—

24 (1) to prohibit the enforcement, as part of a
25 contract or agreement to which a health care pro-

1 vider is a party, of any mutually agreed upon terms
2 and conditions, including terms and conditions re-
3 quiring a health care provider to participate in, and
4 cooperate with, all programs, policies, and proce-
5 dures developed or operated by a group health plan
6 or health insurance issuer to assure, review, or im-
7 prove the quality and effective utilization of health
8 care services (if such utilization is according to
9 guidelines or protocols that are based on clinical or
10 scientific evidence and the professional judgment of
11 the provider) but only if the guidelines or protocols
12 under such utilization do not prohibit or restrict
13 medical communications between providers and their
14 patients; or

15 (2) to permit a health care provider to mis-
16 represent the scope of benefits covered under the
17 group health plan or health insurance coverage or to
18 otherwise require a group health plan health insur-
19 ance issuer to reimburse providers for benefits not
20 covered under the plan or coverage.

21 (c) MEDICAL COMMUNICATION DEFINED.—In this
22 section:

23 (1) IN GENERAL.—The term “medical commu-
24 nication” means any communication made by a
25 health care provider with a patient of the health care

1 provider (or the guardian or legal representative of
2 such patient) with respect to—

3 (A) the patient’s health status, medical
4 care, or treatment options;

5 (B) any utilization review requirements
6 that may affect treatment options for the pa-
7 tient; or

8 (C) any financial incentives that may af-
9 fect the treatment of the patient.

10 (2) MISREPRESENTATION.—The term “medical
11 communication” does not include a communication
12 by a health care provider with a patient of the
13 health care provider (or the guardian or legal rep-
14 resentative of such patient) if the communication in-
15 volves a knowing or willful misrepresentation by
16 such provider.

17 **SEC. 142. PROHIBITION AGAINST TRANSFER OF INDEM-**
18 **NIFICATION OR IMPROPER INCENTIVE AR-**
19 **RANGEMENTS.**

20 (a) PROHIBITION OF TRANSFER OF INDEMNIFICA-
21 TION.—

22 (1) IN GENERAL.—No contract or agreement
23 between a group health plan or health insurance
24 issuer (or any agent acting on behalf of such a plan
25 or issuer) and a health care provider shall contain

1 any provision purporting to transfer to the health
2 care provider by indemnification or otherwise any li-
3 ability relating to activities, actions, or omissions of
4 the plan, issuer, or agent (as opposed to the pro-
5 vider).

6 (2) NULLIFICATION.—Any contract or agree-
7 ment provision described in paragraph (1) shall be
8 null and void.

9 (b) PROHIBITION OF IMPROPER PHYSICIAN INCEN-
10 TIVE PLANS.—

11 (1) IN GENERAL.—A group health plan and a
12 health insurance issuer offering health insurance
13 coverage may not operate any physician incentive
14 plan (as defined in subparagraph (B) of section
15 1876(i)(8) of the Social Security Act) unless the re-
16 quirements described in subparagraph (A) of such
17 section are met with respect to such a plan.

18 (2) APPLICATION.—For purposes of carrying
19 out paragraph (1), any reference in section
20 1876(i)(8) of the Social Security Act to the Sec-
21 retary, an eligible organization, or an individual en-
22 rolled with the organization shall be treated as a ref-
23 erence to the applicable authority, a group health
24 plan or health insurance issuer, respectively, and a

1 participant, beneficiary, or enrollee with the plan or
2 organization, respectively.

3 **SEC. 143. ADDITIONAL RULES REGARDING PARTICIPATION**
4 **OF HEALTH CARE PROFESSIONALS.**

5 (a) PROCEDURES.—Insofar as a group health plan,
6 or health insurance issuer that offers health insurance cov-
7 erage, provides benefits through participating health care
8 professionals, the plan or issuer shall establish reasonable
9 procedures relating to the participation (under an agree-
10 ment between a professional and the plan or issuer) of
11 such professionals under the plan or coverage. Such proce-
12 dures shall include—

13 (1) providing notice of the rules regarding par-
14 ticipation;

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

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

21 (b) CONSULTATION IN MEDICAL POLICIES.—A group
22 health plan, and health insurance issuer that offers health
23 insurance coverage, shall consult with participating physi-
24 cians (if any) regarding the plan's or issuer's medical pol-
25 icy, quality, and medical management procedures.

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

2 (a) PROTECTION FOR USE OF UTILIZATION REVIEW
3 AND GRIEVANCE PROCESS.—A group health plan, and a
4 health insurance issuer with respect to the provision of
5 health insurance coverage, may not retaliate against a par-
6 ticipant, beneficiary, enrollee, or health care provider
7 based on the participant's, beneficiary's, enrollee's or pro-
8 vider's use of, or participation in, a utilization review proc-
9 ess or a grievance process of the plan or issuer (including
10 an internal or external review or appeal process) under
11 this title.

12 (b) PROTECTION FOR QUALITY ADVOCACY BY
13 HEALTH CARE PROFESSIONALS.—

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

18 (A) discloses information relating to the
19 care, services, or conditions affecting one or
20 more participants, beneficiaries, or enrollees of
21 the plan or issuer to an appropriate public reg-
22 ulatory agency, an appropriate private accredi-
23 tation body, or appropriate management per-
24 sonnel of the plan or issuer; or

25 (B) initiates, cooperates, or otherwise par-
26 ticipates in an investigation or proceeding by

1 such an agency with respect to such care, serv-
2 ices, or conditions.

3 If an institutional health care provider is a partici-
4 pating provider with such a plan or issuer or other-
5 wise receives payments for benefits provided by such
6 a plan or issuer, the provisions of the previous sen-
7 tence shall apply to the provider in relation to care,
8 services, or conditions affecting one or more patients
9 within an institutional health care provider in the
10 same manner as they apply to the plan or issuer in
11 relation to care, services, or conditions provided to
12 one or more participants, beneficiaries, or enrollees;
13 and for purposes of applying this sentence, any ref-
14 erence to a plan or issuer is deemed a reference to
15 the institutional health care provider.

16 (2) GOOD FAITH ACTION.—For purposes of
17 paragraph (1), a protected health care professional
18 is considered to be acting in good faith with respect
19 to disclosure of information or participation if, with
20 respect to the information disclosed as part of the
21 action—

22 (A) the disclosure is made on the basis of
23 personal knowledge and is consistent with that
24 degree of learning and skill ordinarily possessed
25 by health care professionals with the same li-

1 censure or certification and the same experi-
2 ence;

3 (B) the professional reasonably believes the
4 information to be true;

5 (C) the information evidences either a vio-
6 lation of a law, rule, or regulation, of an appli-
7 cable accreditation standard, or of a generally
8 recognized professional or clinical standard or
9 that a patient is in imminent hazard of loss of
10 life or serious injury; and

11 (D) subject to subparagraphs (B) and (C)
12 of paragraph (3), the professional has followed
13 reasonable internal procedures of the plan,
14 issuer, or institutional health care provider es-
15 tablished or the purpose of addressing quality
16 concerns before making the disclosure.

17 (3) EXCEPTION AND SPECIAL RULE.—

18 (A) GENERAL EXCEPTION.—Paragraph (1)
19 does not protect disclosures that would violate
20 Federal or State law or diminish or impair the
21 rights of any person to the continued protection
22 of confidentiality of communications provided
23 by such law.

24 (B) NOTICE OF INTERNAL PROCEDURES.—
25 Subparagraph (D) of paragraph (2) shall not

1 apply unless the internal procedures involved
2 are reasonably expected to be known to the
3 health care professional involved. For purposes
4 of this subparagraph, a health care professional
5 is reasonably expected to know of internal pro-
6 cedures if those procedures have been made
7 available to the professional through distribu-
8 tion or posting.

9 (C) INTERNAL PROCEDURE EXCEPTION.—

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

12 (i) the disclosure relates to an immi-
13 nent hazard of loss of life or serious injury
14 to a patient;

15 (ii) the disclosure is made to an ap-
16 propriate private accreditation body pursu-
17 ant to disclosure procedures established by
18 the body; or

19 (iii) the disclosure is in response to an
20 inquiry made in an investigation or pro-
21 ceeding of an appropriate public regulatory
22 agency and the information disclosed is
23 limited to the scope of the investigation or
24 proceeding.

1 (4) ADDITIONAL CONSIDERATIONS.—It shall
2 not be a violation of paragraph (1) to take an ad-
3 verse action against a protected health care profes-
4 sional if the plan, issuer, or provider taking the ad-
5 verse action involved demonstrates that it would
6 have taken the same adverse action even in the ab-
7 sence of the activities protected under such para-
8 graph.

9 (5) NOTICE.—A group health plan, health in-
10 surance issuer, and institutional health care provider
11 shall post a notice, to be provided or approved by
12 the Secretary of Labor, setting forth excerpts from,
13 or summaries of, the pertinent provisions of this
14 subsection and information pertaining to enforce-
15 ment of such provisions.

16 (6) CONSTRUCTIONS.—

17 (A) DETERMINATIONS OF COVERAGE.—
18 Nothing in this subsection shall be construed to
19 prohibit a plan or issuer from making a deter-
20 mination not to pay for a particular medical
21 treatment or service or the services of a type of
22 health care professional.

23 (B) ENFORCEMENT OF PEER REVIEW PRO-
24 TOCOLS AND INTERNAL PROCEDURES.—Noth-
25 ing in this subsection shall be construed to pro-

1 hibit a plan, issuer, or provider from establish-
2 ing and enforcing reasonable peer review or uti-
3 lization review protocols or determining whether
4 a protected health care professional has com-
5 plied with those protocols or from establishing
6 and enforcing internal procedures for the pur-
7 pose of addressing quality concerns.

8 (C) RELATION TO OTHER RIGHTS.—Noth-
9 ing in this subsection shall be construed to
10 abridge rights of participants, beneficiaries, en-
11 rollees, and protected health care professionals
12 under other applicable Federal or State laws.

13 (7) PROTECTED HEALTH CARE PROFESSIONAL
14 DEFINED.—For purposes of this subsection, the
15 term “protected health care professional” means an
16 individual who is a licensed or certified health care
17 professional and who—

18 (A) with respect to a group health plan or
19 health insurance issuer, is an employee of the
20 plan or issuer or has a contract with the plan
21 or issuer for provision of services for which ben-
22 efits are available under the plan or issuer; or

23 (B) with respect to an institutional health
24 care provider, is an employee of the provider or
25 has a contract or other arrangement with the

1 provider respecting the provision of health care
2 services.

3 **Subtitle F—Promoting Good**
4 **Medical Practice**

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

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

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

17 (2) CONSTRUCTION.—Paragraph (1) shall not
18 be construed as prohibiting a plan or issuer from
19 limiting the delivery of services to one or more
20 health care providers within a network of such pro-
21 viders.

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) **REQUIREMENTS FOR MINIMUM HOSPITAL STAY**
11 **FOLLOWING MASTECTOMY OR LYMPH NODE DISSEC-**
12 **TION.**—

13 (1) **IN GENERAL.**—A group health plan, and a
14 health insurance issuer offering group health insur-
15 ance coverage, may not—

16 (A) except as provided in paragraph (2)—

17 (i) restrict benefits for any hospital
18 length of stay in connection with a mastec-
19 tomy for the treatment of breast cancer to
20 less than 48 hours, or

21 (ii) restrict benefits for any hospital
22 length of stay in connection with a lymph
23 node dissection for the treatment of breast
24 cancer to less than 24 hours, or

1 (B) require that a provider obtain author-
2 zation from the plan or the issuer for prescrib-
3 ing any length of stay required under subpara-
4 graph (A) (without regard to paragraph (2)).

5 (2) EXCEPTION.—Paragraph (1)(A) shall not
6 apply in connection with any group health plan or
7 health insurance issuer in any case in which the de-
8 cision to discharge the woman involved prior to the
9 expiration of the minimum length of stay otherwise
10 required under paragraph (1)(A) is made by the at-
11 tending provider in consultation with the woman or
12 in a case involving a partial mastectomy without
13 lymph node dissection.

14 (b) PROHIBITIONS.—A group health plan, and a
15 health insurance issuer offering group health insurance
16 coverage in connection with a group health plan, may
17 not—

18 (1) deny to a woman eligibility, or continued
19 eligibility, to enroll or to renew coverage under the
20 terms of the plan, solely for the purpose of avoiding
21 the requirements of this section;

22 (2) provide monetary payments or rebates to
23 women to encourage such women to accept less than
24 the minimum protections available under this sec-
25 tion;

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

5 (4) provide incentives (monetary or otherwise)
6 to an attending provider to induce such provider to
7 provide care to an individual participant or bene-
8 ficiary in a manner inconsistent with this section; or

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

14 (c) RULES OF CONSTRUCTION.—

15 (1) Nothing in this section shall be construed to
16 require a woman who is a participant or bene-
17 ficiary—

18 (A) to undergo a mastectomy or lymph
19 node dissection in a hospital; or

20 (B) to stay in the hospital for a fixed pe-
21 riod of time following a mastectomy or lymph
22 node dissection.

23 (2) This section shall not apply with respect to
24 any group health plan, or any group health insur-
25 ance coverage offered by a health insurance issuer,

1 which does not provide benefits for hospital lengths
2 of stay in connection with a mastectomy or lymph
3 node dissection for the treatment of breast cancer.

4 (3) Nothing in this section shall be construed as
5 preventing a group health plan or issuer from impos-
6 ing deductibles, coinsurance, or other cost-sharing in
7 relation to benefits for hospital lengths of stay in
8 connection with a mastectomy or lymph node dissec-
9 tion for the treatment of breast cancer under the
10 plan (or under health insurance coverage offered in
11 connection with a group health plan), except that
12 such coinsurance or other cost-sharing for any por-
13 tion of a period within a hospital length of stay re-
14 quired under subsection (a) may not be greater than
15 such coinsurance or cost-sharing for any preceding
16 portion of such stay.

17 (d) LEVEL AND TYPE OF REIMBURSEMENTS.—Noth-
18 ing in this section shall be construed to prevent a group
19 health plan or a health insurance issuer offering group
20 health insurance coverage from negotiating the level and
21 type of reimbursement with a provider for care provided
22 in accordance with this section.

23 (e) EXCEPTION FOR HEALTH INSURANCE COVERAGE
24 IN CERTAIN STATES.—

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

7 (A) Such State law requires such coverage
8 to provide for at least a 48-hour hospital length
9 of stay following a mastectomy performed for
10 treatment of breast cancer and at least a 24-
11 hour hospital length of stay following a lymph
12 node dissection for treatment of breast cancer.

13 (B) Such State law requires, in connection
14 with such coverage for surgical treatment of
15 breast cancer, that the hospital length of stay
16 for such care is left to the decision of (or re-
17 quired to be made by) the attending provider in
18 consultation with the woman involved.

19 (2) CONSTRUCTION.—Section 2723(a)(1) of the
20 Public Health Service Act and section 731(a)(1) of
21 the Employee Retirement Income Security Act of
22 1974 shall not be construed as superseding a State
23 law described in paragraph (1).

1 **SEC. 153. STANDARDS RELATING TO BENEFITS FOR RECON-**
2 **STRUCTIVE BREAST SURGERY.**

3 (a) **REQUIREMENTS FOR RECONSTRUCTIVE BREAST**
4 **SURGERY.—**

5 (1) **IN GENERAL.**—A group health plan, and a
6 health insurance issuer offering group health insur-
7 ance coverage, that provides coverage for breast sur-
8 gery in connection with a mastectomy shall provide
9 coverage for reconstructive breast surgery resulting
10 from the mastectomy. Such coverage shall include
11 coverage for all stages of reconstructive breast sur-
12 gery performed on a nondiseased breast to establish
13 symmetry with the diseased when reconstruction on
14 the diseased breast is performed and coverage of
15 prostheses and complications of mastectomy includ-
16 ing lymphedema.

17 (2) **RECONSTRUCTIVE BREAST SURGERY DE-**
18 **FINED.**—In this section, the term “reconstructive
19 breast surgery” means surgery performed as a result
20 of a mastectomy to reestablish symmetry between
21 two breasts, and includes augmentation
22 mammoplasty, reduction mammoplasty, and
23 mastopexy.

24 (3) **MASTECTOMY DEFINED.**—In this section,
25 the term “mastectomy” means the surgical removal
26 of all or part of a breast.

1 (b) PROHIBITIONS.—

2 (1) DENIAL OF COVERAGE BASED ON COSMETIC
3 SURGERY.—A group health plan, and a health insur-
4 ance issuer offering group health insurance coverage
5 in connection with a group health plan, may not
6 deny coverage described in subsection (a)(1) on the
7 basis that the coverage is for cosmetic surgery.

8 (2) APPLICATION OF SIMILAR PROHIBITIONS.—
9 Paragraphs (2) through (5) of section 152 shall
10 apply under this section in the same manner as they
11 apply with respect to section 152.

12 (c) RULES OF CONSTRUCTION.—

13 (1) Nothing in this section shall be construed to
14 require a woman who is a participant or beneficiary
15 to undergo reconstructive breast surgery.

16 (2) This section shall not apply with respect to
17 any group health plan, or any group health insur-
18 ance coverage offered by a health insurance issuer,
19 which does not provide benefits for mastectomies.

20 (3) Nothing in this section shall be construed as
21 preventing a group health plan or issuer from impos-
22 ing deductibles, coinsurance, or other cost-sharing in
23 relation to benefits for reconstructive breast surgery
24 under the plan (or under health insurance coverage
25 offered in connection with a group health plan), ex-

1 cept that such coinsurance or other cost-sharing for
2 any portion may not be greater than such coinsur-
3 ance or cost-sharing that is otherwise applicable with
4 respect to benefits for mastectomies.

5 (e) LEVEL AND TYPE OF REIMBURSEMENTS.—Noth-
6 ing in this section shall be construed to prevent a group
7 health plan or a health insurance issuer offering group
8 health insurance coverage from negotiating the level and
9 type of reimbursement with a provider for care provided
10 in accordance with this section.

11 (f) EXCEPTION FOR HEALTH INSURANCE COVERAGE
12 IN CERTAIN STATES.—

13 (1) IN GENERAL.—The requirements of this
14 section shall not apply with respect to health insur-
15 ance coverage if there is a State law (as defined in
16 section 2723(d)(1) of the Public Health Service Act)
17 for a State that regulates such coverage and that re-
18 quires coverage of at least the coverage of recon-
19 structive breast surgery otherwise required under
20 this section.

21 (2) CONSTRUCTION.—Section 2723(a)(1) of the
22 Public Health Service Act and section 731(a)(1) of
23 the Employee Retirement Income Security Act of
24 1974 shall not be construed as superseding a State
25 law described in paragraph (1).

1 **Subtitle G—Definitions**

2 **SEC. 191. DEFINITIONS.**

3 (a) **INCORPORATION OF GENERAL DEFINITIONS.—**

4 The provisions of section 2971 of the Public Health Serv-
5 ice Act shall apply for purposes of this title in the same
6 manner as they apply for purposes of title XXVII of such
7 Act.

8 (b) **SECRETARY.—**Except as otherwise provided, the
9 term “Secretary” means the Secretary of Health and
10 Human Services, in consultation with the Secretary of
11 Labor and the Secretary of the Treasury and the term
12 “appropriate Secretary” means the Secretary of Health
13 and Human Services in relation to carrying out this title
14 under sections 2706 and 2751 of the Public Health Serv-
15 ice Act, the Secretary of Labor in relation to carrying out
16 this title under section 713 of the Employee Retirement
17 Income Security Act of 1974, and the Secretary of the
18 Treasury in relation to carrying out this title under chap-
19 ter 100 and section 4980D of the Internal Revenue Code
20 of 1986.

21 (c) **ADDITIONAL DEFINITIONS.—**For purposes of this
22 title:

23 (1) **APPLICABLE AUTHORITY.—**The term “ap-
24 plicable authority” means—

1 (A) in the case of a group health plan, the
2 Secretary of Health and Human Services and
3 the Secretary of Labor; and

4 (B) in the case of a health insurance issuer
5 with respect to a specific provision of this title,
6 the applicable State authority (as defined in
7 section 2791(d) of the Public Health Service
8 Act), or the Secretary of Health and Human
9 Services, if such Secretary is enforcing such
10 provision under section 2722(a)(2) or
11 2761(a)(2) of the Public Health Service Act.

12 (2) CLINICAL PEER.—The term “clinical peer”
13 means, with respect to a review or appeal, a physi-
14 cian (allopathic or osteopathic) or other health care
15 professional who holds a non-restricted license in a
16 State and who is appropriately credentialed in the
17 same or similar specialty as typically manages the
18 medical condition, procedure, or treatment under re-
19 view or appeal and includes a pediatric specialist
20 where appropriate; except that only a physician may
21 be a clinical peer with respect to the review or ap-
22 peal of treatment rendered by a physician.

23 (3) HEALTH CARE PROVIDER.—The term
24 “health care provider” includes a physician or other

1 health care professional, as well as an institutional
2 provider of health care services.

3 (4) NONPARTICIPATING.—The term “non-
4 participating” means, with respect to a health care
5 provider that provides health care items and services
6 to a participant, beneficiary, or enrollee under group
7 health plan or health insurance coverage, a health
8 care provider that is not a participating health care
9 provider with respect to such items and services.

10 (5) PARTICIPATING.—The term “participating”
11 mean, with respect to a health care provider that
12 provides health care items and services to a partici-
13 pant, beneficiary, or enrollee under group health
14 plan or health insurance coverage offered by a
15 health insurance issuer, a health care provider that
16 furnishes such items and services under a contract
17 or other arrangement with the plan or issuer.

18 **SEC. 192. PREEMPTION; STATE FLEXIBILITY; CONSTRUC-**
19 **TION.**

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

22 (1) IN GENERAL.—Subject to paragraph (2),
23 this title shall not be construed to supersede any
24 provision of State law which establishes, implements,
25 or continues in effect any standard or requirement

1 solely relating to health insurance issuers in connec-
2 tion with group health insurance coverage except to
3 the extent that such standard or requirement pre-
4 vents the application of a requirement of this title.

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

11 (b) RULES OF CONSTRUCTION.—Except as provided
12 in sections 152 and 153, nothing in this title shall be con-
13 strued as requiring a group health plan or health insur-
14 ance coverage to provide specific benefits under the terms
15 of such plan or coverage.

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

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

23 (2) STATE.—The term “State” includes a
24 State, the Northern Mariana Islands, any political

1 subdivisions of a State or such Islands, or any agen-
2 cy or instrumentality of either.

3 **SEC. 193. REGULATIONS.**

4 The Secretaries of Health and Human Services,
5 Labor, and the Treasury shall issue such regulations as
6 may be necessary or appropriate to carry out this title.
7 Such regulations shall be issued consistent with section
8 104 of Health Insurance Portability and Accountability
9 Act of 1996. Such Secretaries may promulgate any in-
10 terim final rules as the Secretaries determine are appro-
11 priate to carry out this title.

12 **TITLE II—APPLICATION OF PA-**
13 **TIENT PROTECTION STAND-**
14 **ARDS TO GROUP HEALTH**
15 **PLANS AND HEALTH INSUR-**
16 **ANCE COVERAGE UNDER**
17 **PUBLIC HEALTH SERVICE**
18 **ACT**

19 **SEC. 201. APPLICATION TO GROUP HEALTH PLANS AND**
20 **GROUP HEALTH INSURANCE COVERAGE.**

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

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

2 “(a) IN GENERAL.—Each group health plan shall
3 comply with patient protection requirements under title I
4 of the Patients’ Bill of Rights Act of 1998, and each
5 health insurance issuer shall comply with patient protec-
6 tion requirements under such title with respect to group
7 health insurance coverage it offers, and such requirements
8 shall be deemed to be incorporated into this subsection.

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

16 (b) CONFORMING AMENDMENT.—Section
17 2721(b)(1)(A) of such Act (42 U.S.C. 300gg–21(b)(1)(A))
18 is amended by inserting “(other than section 2706)” after
19 “requirements of such subparts”.

20 **SEC. 202. APPLICATION TO INDIVIDUAL HEALTH INSUR-**
21 **ANCE COVERAGE.**

22 Part B of title XXVII of the Public Health Service
23 Act is amended by inserting after section 2751 the follow-
24 ing new section:

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

2 “(a) IN GENERAL.—Each health insurance issuer
3 shall comply with patient protection requirements under
4 title I of the Patients’ Bill of Rights Act of 1998 with
5 respect to individual health insurance coverage it offers,
6 and such requirements shall be deemed to be incorporated
7 into this subsection.

8 “(b) NOTICE.—A health insurance issuer under this
9 part shall comply with the notice requirement under sec-
10 tion 711(d) of the Employee Retirement Income Security
11 Act of 1974 with respect to the requirements of such title
12 as if such section applied to such issuer and such issuer
13 were a group health plan.”.

14 **TITLE III—AMENDMENTS TO**
15 **THE EMPLOYEE RETIREMENT**
16 **INCOME SECURITY ACT OF**
17 **1974**

18 **SEC. 301. APPLICATION OF PATIENT PROTECTION STAND-**
19 **ARDS TO GROUP HEALTH PLANS AND GROUP**
20 **HEALTH INSURANCE COVERAGE UNDER THE**
21 **EMPLOYEE RETIREMENT INCOME SECURITY**
22 **ACT OF 1974.**

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

1 **“SEC. 713. PATIENT PROTECTION STANDARDS.**

2 “(a) IN GENERAL.—Subject to subsection (b), a
3 group health plan (and a health insurance issuer offering
4 group health insurance coverage in connection with such
5 a plan) shall comply with the requirements of title I of
6 the Patients’ Bill of Rights Act of 1998 (as in effect as
7 of the date of the enactment of such Act), and such re-
8 quirements shall be deemed to be incorporated into this
9 subsection.

10 “(b) PLAN SATISFACTION OF CERTAIN REQUIRE-
11 MENTS.—

12 “(1) SATISFACTION OF CERTAIN REQUIRE-
13 MENTS THROUGH INSURANCE.—For purposes of
14 subsection (a), insofar as a group health plan pro-
15 vides benefits in the form of health insurance cov-
16 erage through a health insurance issuer, the plan
17 shall be treated as meeting the following require-
18 ments of title I of the Patients’ Bill of Rights Act
19 of 1998 with respect to such benefits and not be
20 considered as failing to meet such requirements be-
21 cause of a failure of the issuer to meet such require-
22 ments so long as the plan sponsor or its representa-
23 tives did not cause such failure by the issuer:

24 “(A) Section 101 (relating to access to
25 emergency care).

1 “(B) Section 102(a)(1) (relating to offer-
2 ing option to purchase point-of-service cov-
3 erage), but only insofar as the plan is meeting
4 such requirement through an agreement with
5 the issuer to offer the option to purchase point-
6 of-service coverage under such section.

7 “(C) Section 103 (relating to choice of pro-
8 viders).

9 “(D) Section 104 (relating to access to
10 specialty care).

11 “(E) Section 105(a)(1) (relating to con-
12 tinuity in case of termination of provider con-
13 tract) and section 105(a)(2) (relating to con-
14 tinuity in case of termination of issuer con-
15 tract), but only insofar as a replacement issuer
16 assumes the obligation for continuity of care.

17 “(F) Section 106 (relating to coverage for
18 individuals participating in approved clinical
19 trials.)

20 “(G) Section 107 (relating to access to
21 needed prescription drugs).

22 “(H) Section 108 (relating to adequacy of
23 provider network).

24 “(I) Subtitle B (relating to quality assur-
25 ance).

1 “(J) Section 143 (relating to additional
2 rules regarding participation of health care pro-
3 fessionals).

4 “(K) Section 152 (relating to standards re-
5 lating to benefits for certain breast cancer
6 treatment).

7 “(L) Section 153 (relating to standards re-
8 lating to benefits for reconstructive breast sur-
9 gery).

10 “(2) INFORMATION.—With respect to informa-
11 tion required to be provided or made available under
12 section 121, in the case of a group health plan that
13 provides benefits in the form of health insurance
14 coverage through a health insurance issuer, the Sec-
15 retary shall determine the circumstances under
16 which the plan is not required to provide or make
17 available the information (and is not liable for the
18 issuer’s failure to provide or make available the in-
19 formation), if the issuer is obligated to provide and
20 make available (or provides and makes available)
21 such information.

22 “(3) GRIEVANCE AND INTERNAL APPEALS.—
23 With respect to the grievance system and internal
24 appeals process required to be established under sec-
25 tions 131 and 132, in the case of a group health

1 plan that provides benefits in the form of health in-
2 surance coverage through a health insurance issuer,
3 the Secretary shall determine the circumstances
4 under which the plan is not required to provide for
5 such system and process (and is not liable for the
6 issuer's failure to provide for such system and proc-
7 ess), if the issuer is obligated to provide for (and
8 provides for) such system and process.

9 “(4) EXTERNAL APPEALS.—Pursuant to rules
10 of the Secretary, insofar as a group health plan en-
11 ters into a contract with a qualified external appeal
12 entity for the conduct of external appeal activities in
13 accordance with section 133, the plan shall be treat-
14 ed as meeting the requirement of such section and
15 is not liable for the entity's failure to meet any re-
16 quirements under such section.

17 “(5) APPLICATION TO PROHIBITIONS.—Pursu-
18 ant to rules of the Secretary, if a health insurance
19 issuer offers health insurance coverage in connection
20 with a group health plan and takes an action in vio-
21 lation of any of the following sections, the group
22 health plan shall not be liable for such violation un-
23 less the plan caused such violation:

24 “(A) Section 109 (relating to non-
25 discrimination in delivery of services).

1 “(B) Section 141 (relating to prohibition
2 of interference with certain medical communica-
3 tions).

4 “(C) Section 142 (relating to prohibition
5 against transfer of indemnification or improper
6 incentive arrangements).

7 “(D) Section 144 (relating to prohibition
8 on retaliation).

9 “(E) Section 151 (relating to promoting
10 good medical practice).

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

15 “(7) APPLICATION TO CERTAIN PROHIBITIONS
16 AGAINST RETALIATION.—With respect to compliance
17 with the requirements of section 144(b)(1) of the
18 Patients’ Bill of Rights Act of 1998, for purposes of
19 this subtitle the term ‘group health plan’ is deemed
20 to include a reference to an institutional health care
21 provider.

22 “(c) ENFORCEMENT OF CERTAIN REQUIREMENTS.—

23 “(1) COMPLAINTS.—Any protected health care
24 professional who believes that the professional has
25 been retaliated or discriminated against in violation

1 of section 144(b)(1) of the Patients' Bill of Rights
2 Act of 1998 may file with the Secretary a complaint
3 within 180 days of the date of the alleged retaliation
4 or discrimination.

5 “(2) INVESTIGATION.—The Secretary shall in-
6 vestigate such complaints and shall determine if a
7 violation of such section has occurred and, if so,
8 shall issue an order to ensure that the protected
9 health care professional does not suffer any loss of
10 position, pay, or benefits in relation to the plan,
11 issuer, or provider involved, as a result of the viola-
12 tion found by the Secretary.

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

17 (b) SATISFACTION OF ERISA CLAIMS PROCEDURE
18 REQUIREMENT.—Section 503 of such Act (29 U.S.C.
19 1133) is amended by inserting “(a)” after “SEC. 503.”
20 and by adding at the end the following new subsection:

21 “(b) In the case of a group health plan (as defined
22 in section 733) compliance with the requirements of sub-
23 title D (and section 115) of title I of the Patients' Bill
24 of Rights Act of 1998 in the case of a claims denial shall

1 be deemed compliance with subsection (a) with respect to
2 such claims denial.”.

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

6 (2) The table of contents in section 1 of such Act
7 is amended by inserting after the item relating to section
8 712 the following new item:

“Sec. 713. Patient protection standards.”.

9 (3) Section 502(b)(3) of such Act (29 U.S.C.
10 1132(b)(3)) is amended by inserting “(other than section
11 144(b))” after “part 7”.

12 **SEC. 302. ERISA PREEMPTION NOT TO APPLY TO CERTAIN**
13 **ACTIONS INVOLVING HEALTH INSURANCE**
14 **POLICYHOLDERS.**

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

18 “(e) PREEMPTION NOT TO APPLY TO CERTAIN AC-
19 TIONS ARISING OUT OF PROVISION OF HEALTH BENE-
20 FITS.—

21 “(1) IN GENERAL.—Except as provided in this
22 subsection, nothing in this title shall be construed to
23 invalidate, impair, or supersede any cause of action
24 under State law to recover damages resulting from

1 personal injury or for wrongful death against any
2 person—

3 “(A) in connection with the provision of in-
4 surance, administrative services, or medical
5 services by such person to or for a group health
6 plan (as defined in section 733), or

7 “(B) that arises out of the arrangement by
8 such person for the provision of such insurance,
9 administrative services, or medical services by
10 other persons.

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

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

15 “(i) any cause of action against an
16 employer or other plan sponsor maintain-
17 ing the group health plan, or

18 “(ii) a right of recovery or indemnity
19 by a person against an employer or other
20 plan sponsor for damages assessed against
21 the person pursuant to a cause of action
22 under paragraph (1).

23 “(B) SPECIAL RULE.—Subparagraph (A)
24 shall not preclude any cause of action described

1 in paragraph (1) against an employer or other
2 plan sponsor if—

3 “(i) such action is based on the em-
4 ployer’s or other plan sponsor’s exercise of
5 discretionary authority to make a decision
6 on a claim for benefits covered under the
7 plan or health insurance coverage in the
8 case at issue; and

9 “(ii) the exercise by such employer or
10 other plan sponsor of such authority re-
11 sulted in personal injury or wrongful
12 death.”.

13 (b) EFFECTIVE DATE.—The amendment made by
14 subsection (a) shall apply to acts and omissions occurring
15 on or after the date of the enactment of this Act from
16 which a cause of action arises.

17 **TITLE IV—APPLICATION TO**
18 **GROUP HEALTH PLANS**
19 **UNDER THE INTERNAL REVE-**
20 **NUE CODE OF 1986.**

21 **SEC. 401. AMENDMENTS TO THE INTERNAL REVENUE CODE**
22 **OF 1986.**

23 Subchapter B of chapter 100 of the Internal Revenue
24 Code of 1986 (as amended by section 1531(a) of the Tax-
25 payer Relief Act of 1997) is amended—

1 (1) in the table of sections, by inserting after
 2 the item relating to section 9812 the following new
 3 item:

“Sec. 9813. Standard relating to patient freedom of choice.”;
 and

4 (2) by inserting after section 9812 the follow-
 5 ing:

6 **“SEC. 9813. STANDARD RELATING TO PATIENTS’ BILL OF**
 7 **RIGHTS.**

8 “A group health plan shall comply with the require-
 9 ments of title I of the Patients’ Bill of Rights Act of 1998
 10 (as in effect as of the date of the enactment of such Act),
 11 and such requirements shall be deemed to be incorporated
 12 into this section.”.

13 **TITLE V—EFFECTIVE DATES; CO-**
 14 **ORDINATION IN IMPLEMEN-**
 15 **TATION**

16 **SEC. 501. EFFECTIVE DATES.**

17 (a) GROUP HEALTH COVERAGE.—

18 (1) IN GENERAL.—Subject to paragraph (2),
 19 the amendments made by sections 201(a), 301, and
 20 401 (and title I insofar as it relates to such sections)
 21 shall apply with respect to group health plans, and
 22 health insurance coverage offered in connection with
 23 group health plans, for plan years beginning on or
 24 after January 1, 1999 (in this section referred to as

1 the “general effective date”) and also shall apply to
2 portions of plan years occurring on and after such
3 date.

4 (2) TREATMENT OF COLLECTIVE BARGAINING
5 AGREEMENTS.—In the case of a group health plan
6 maintained pursuant to 1 or more collective bargain-
7 ing agreements between employee representatives
8 and 1 or more employers ratified before the date of
9 enactment of this Act, the amendments made by sec-
10 tions 201(a), 301, and 401 (and title I insofar as it
11 relates to such sections) shall not apply to plan
12 years beginning before the later of—

13 (A) the date on which the last collective
14 bargaining agreements relating to the plan ter-
15 minates (determined without regard to any ex-
16 tension thereof agreed to after the date of en-
17 actment of this Act), or

18 (B) the general effective date.

19 For purposes of subparagraph (A), any plan amend-
20 ment made pursuant to a collective bargaining
21 agreement relating to the plan which amends the
22 plan solely to conform to any requirement added by
23 this Act shall not be treated as a termination of
24 such collective bargaining agreement.

1 (b) INDIVIDUAL HEALTH INSURANCE COVERAGE.—
2 The amendments made by section 202 shall apply with
3 respect to individual health insurance coverage offered,
4 sold, issued, renewed, in effect, or operated in the individ-
5 ual market on or after the general effective date.

6 **SEC. 502. COORDINATION IN IMPLEMENTATION.**

7 Section 104(1) of Health Insurance Portability and
8 Accountability Act of 1996 is amended by striking “this
9 subtitle (and the amendments made by this subtitle and
10 section 401)” and inserting “the provisions of part 7 of
11 subtitle B of title I of the Employee Retirement Income
12 Security Act of 1974, the provisions of parts A and C of
13 title XXVII of the Public Health Service Act, chapter 100
14 of the Internal Revenue Code of 1986, and title I of the
15 Patients’ Bill of Rights Act of 1998”.

○