

106TH CONGRESS
1ST SESSION

H. R. 358

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

JANUARY 19, 1999

Mr. DINGELL (for himself, Mr. GEPHARDT, Mr. BROWN of Ohio, Mr. RANGEL, Mr. STARK, Mr. CLAY, Mr. ANDREWS, Mr. PALLONE, Ms. ESHOO, Mr. BERRY, Mr. WAXMAN, Mr. ABERCROMBIE, Mr. ACKERMAN, Mr. ALLEN, Ms. BALDWIN, Mr. BARRETT of Wisconsin, Mr. BENTSEN, Ms. BERKLEY, Mr. BERMAN, Mr. BISHOP, Mr. BLAGOJEVICH, Mr. BLUMENAUER, Mr. BONIOR, Mr. BORSKI, Mr. BOUCHER, Mr. BRADY of Pennsylvania, Ms. BROWN of Florida, Mr. BROWN of California, Mrs. CAPPS, Mr. CAPUANO, Mr. CARDIN, Ms. CARSON, Mrs. CLAYTON, Mr. CLEMENT, Mr. CONYERS, Mr. COSTELLO, Mr. COYNE, Mr. CROWLEY, Mr. CUMMINGS, Mr. DAVIS of Florida, Ms. DEGETTE, Mr. DELAHUNT, Ms. DELAURO, Mr. DIXON, Mr. DOYLE, Mr. ENGEL, Mr. EVANS, Mr. FALCONE, Mr. FARR of California, Mr. FILNER, Mr. FORD, Mr. FRANK of Massachusetts, Mr. FROST, Mr. GEJDENSON, Mr. GONZALEZ, Mr. GREEN of Texas, Mr. HASTINGS of Florida, Mr. HILL of Indiana, Mr. HINCHEY, Mr. HOEFFEL, Mr. HOYER, Mr. INSLEE, Mr. JACKSON of Illinois, Ms. JACKSON-LEE of Texas, Mr. JEFFERSON, Ms. EDDIE BERNICE JOHNSON of Texas, Mr. KANJORSKI, Ms. KAPTUR, Mr. KENNEDY, Mr. KILDEE, Ms. KILPATRICK, Mr. KLECZKA, Mr. KLINK, Mr. LAFALCE, Mr. LAMPSON, Mr. LANTOS, Ms. LEE, Mr. LEVIN, Mr. LEWIS of Georgia, Mrs. LOWEY, Mr. LUTHER, Mrs. MALONEY of New York, Mr. MALONEY of Connecticut, Mr. MARKEY, Mr. MASCARA, Mr. MATSUI, Mrs. MCCARTHY of New York, Ms. MCCARTHY of Missouri, Mr. McDERMOTT, Mr. MCGOVERN, Ms. MCKINNEY, Mr. MEEHAN, Mr. MEEKS of New York, Mr. MENENDEZ, Ms. MILLENDER-MCDONALD, Mr. GEORGE MILLER of California, Mrs. MINK of Hawaii, Mr. MOAKLEY, Mr. MOORE, Mr. MURTHA, Mr. NADLER, Mrs. NAPOLITANO, Mr. NEAL of Massachusetts, Ms. NORTON, Mr. OLVER, Mr. OWENS, Mr. PASCRELL, Mr. PASTOR, Mr. PAYNE, Ms. PELOSI, Mr. PHELPS, Mr. PRICE of North Carolina, Ms. RIVERS, Mr. RODRIGUEZ, Mr. ROMERO-BARCELÓ, Mr. ROTHMAN, Ms. ROYBAL-ALLARD, Mr. RUSH, Mr. SABO, Mr. SANDLIN, Mr. SAWYER, Ms. SCHAKOWSKY, Mr. SERRANO, Mr. SHERMAN, Mr. SHOWS, Ms. SLAUGHTER, Mr. SNYDER, Mr. SPRATT, Ms. STABENOW,

Mr. STRICKLAND, Mr. STUPAK, Mr. THOMPSON of Mississippi, Mr. THOMPSON of California, Mrs. THURMAN, Mr. TOWNS, Mr. UDALL of Colorado, Mr. UDALL of New Mexico, Mr. UNDERWOOD, Ms. VELÁZQUEZ, Mr. VENTO, Mr. VISCLOSKEY, Mr. WEINER, Mr. WEXLER, Mr. WEYGAND, Mr. WISE, Ms. WOOLSEY, Mr. WU, Mr. WYNN, Ms. CHRISTIAN-CHRISTENSEN, Mr. BALDACCI, Mr. GORDON, Mr. TIERNEY, Mr. BECERRA, Ms. LOFGREN, Mr. HALL of Ohio, Mrs. TAUSCHER, Mr. SCOTT, Mr. BARCIA, Mr. HALL of Texas, Mr. OBEY, Mr. GUTIERREZ, Mr. HILLIARD, Mr. KUCINICH, Mr. BAIRD, Mrs. JONES of Ohio, and Mr. BOSWELL) 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 1999”.

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

Sec. 1. Short title; table of contents.

TITLE I—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.

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 COV- ERAGE 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 and related rules.

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-

1 rollee by a nonparticipating health care provider
2 without prior authorization by the plan or
3 issuer, the participant, beneficiary, or enrollee
4 is not liable for amounts that exceed the
5 amounts of liability that would be incurred if
6 the services were provided by a participating
7 health care provider with prior authorization by
8 the plan or issuer; and

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

18 (2) DEFINITIONS.—In this section:

19 (A) EMERGENCY MEDICAL CONDITION
20 BASED ON PRUDENT LAYPERSON STANDARD.—
21 The term “emergency medical condition” means
22 a medical condition manifesting itself by acute
23 symptoms of sufficient severity (including se-
24 vere pain) such that a prudent layperson, who
25 possesses an average knowledge of health and

1 medicine, could reasonably expect the absence
2 of immediate medical attention to result in a
3 condition described in clause (i), (ii), or (iii) of
4 section 1867(e)(1)(A) of the Social Security
5 Act.

6 (B) EMERGENCY SERVICES.—The term
7 “emergency services” means—

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

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

22 (b) REIMBURSEMENT FOR MAINTENANCE CARE AND
23 POST-STABILIZATION CARE.—In the case of services
24 (other than emergency services) for which benefits are
25 available under a group health plan, or under health insur-

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

16 **SEC. 102. OFFERING OF CHOICE OF COVERAGE OPTIONS**
17 **UNDER GROUP HEALTH PLANS.**

18 (a) REQUIREMENT.—

19 (1) OFFERING OF POINT-OF-SERVICE COV-
20 ERAGE OPTION.—Except as provided in paragraph
21 (2), if a group health plan (or health insurance cov-
22 erage offered by a health insurance issuer in connec-
23 tion with a group health plan) provides benefits only
24 through participating health care providers, the plan
25 or issuer shall offer the participant the option to

1 purchase point-of-service coverage (as defined in
2 subsection (b)) for all such benefits for which cov-
3 erage is otherwise so limited. Such option shall be
4 made available to the participant at the time of en-
5 rollment under the plan or coverage and at such
6 other times as the plan or issuer offers the partici-
7 pant a choice of coverage options.

8 (2) EXCEPTION.—Paragraph (1) shall not
9 apply with respect to a participant in a group health
10 plan if the plan offers the participant—

11 (A) a choice of health insurance coverage
12 through more than one health insurance issuer;
13 or

14 (B) two or more coverage options that dif-
15 fer significantly with respect to the use of par-
16 ticipating health care providers or the networks
17 of such providers that are used.

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

1 (c) CONSTRUCTION.—Nothing in this section shall be
2 construed—

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

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

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

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

21 **SEC. 103. CHOICE OF PROVIDERS.**

22 (a) PRIMARY CARE.—A group health plan, and a
23 health insurance issuer that offers health insurance cov-
24 erage, shall permit each participant, beneficiary, and en-
25 rollee to receive primary care from any participating pri-

1 mary care provider who is available to accept such individ-
2 ual.

3 (b) SPECIALISTS.—

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

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

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

18 (a) OBSTETRICAL AND GYNECOLOGICAL CARE.—

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

24 (A) the plan or issuer shall permit such an
25 individual who is a female to designate a par-

1 participating physician who specializes in obstetrics
2 and gynecology as the individual's primary care
3 provider; and

4 (B) if such an individual has not des-
5 igned such a provider as a primary care pro-
6 vider, the plan or issuer—

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

16 (ii) may treat the ordering of other
17 gynecological care by such a participating
18 health professional as the authorization of
19 the primary care provider with respect to
20 such care under the plan or coverage.

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

1 (b) PEDIATRIC CARE.—If a group health plan, or a
2 health insurance issuer in connection with the provision
3 of health insurance coverage, requires or provides for a
4 participant, beneficiary, or enrollee to designate a partici-
5 pating primary care provider for a child of such partici-
6 pant, beneficiary, or enrollee, the plan or issuer shall per-
7 mit the participant, beneficiary, or enrollee to designate
8 a physician who specializes in pediatrics as the child’s pri-
9 mary care provider.

10 (c) SPECIALTY CARE.—

11 (1) SPECIALTY CARE FOR COVERED SERV-
12 ICES.—

13 (A) IN GENERAL.—If—

14 (i) an individual is a participant or
15 beneficiary under a group health plan or
16 an enrollee who is covered under health in-
17 surance coverage offered by a health insur-
18 ance issuer,

19 (ii) the individual has a condition or
20 disease of sufficient seriousness and com-
21 plexity to require treatment by a specialist,
22 and

23 (iii) benefits for such treatment are
24 provided under the plan or coverage,

1 the plan or issuer shall make or provide for a
2 referral to a specialist who is available and ac-
3 cessible to provide the treatment for such condi-
4 tion or disease.

5 (B) SPECIALIST DEFINED.—For purposes
6 of this subsection, the term “specialist” means,
7 with respect to a condition, a health care practi-
8 tioner, facility, or center (such as a center of
9 excellence) that has adequate expertise through
10 appropriate training and experience (including,
11 in the case of a child, appropriate pediatric ex-
12 pertise) to provide high quality care in treating
13 the condition.

14 (C) CARE UNDER REFERRAL.—A group
15 health plan or health insurance issuer may re-
16 quire that the care provided to an individual
17 pursuant to such referral under subparagraph
18 (A) be—

19 (i) pursuant to a treatment plan, only
20 if the treatment plan is developed by the
21 specialist and approved by the plan or
22 issuer, in consultation with the designated
23 primary care provider or specialist and the
24 individual (or the individual’s designee),
25 and

1 (ii) in accordance with applicable
2 quality assurance and utilization review
3 standards of the plan or issuer.

4 Nothing in this subsection shall be construed as
5 preventing such a treatment plan for an individ-
6 ual from requiring a specialist to provide the
7 primary care provider with regular updates on
8 the specialty care provided, as well as all nec-
9 essary medical information.

10 (D) REFERRALS TO PARTICIPATING PRO-
11 VIDERS.—A group health plan or health insur-
12 ance issuer is not required under subparagraph
13 (A) to provide for a referral to a specialist that
14 is not a participating provider, unless the plan
15 or issuer does not have an appropriate specialist
16 that is available and accessible to treat the indi-
17 vidual's condition and that is a participating
18 provider with respect to such treatment.

19 (E) TREATMENT OF NONPARTICIPATING
20 PROVIDERS.—If a plan or issuer refers an indi-
21 vidual to a nonparticipating specialist pursuant
22 to subparagraph (A), services provided pursu-
23 ant to the approved treatment plan (if any)
24 shall be provided at no additional cost to the in-
25 dividual beyond what the individual would oth-

1 otherwise pay for services received by such a spe-
2 cialist that is a participating provider.

3 (2) SPECIALISTS AS PRIMARY CARE PROVID-
4 ERS.—

5 (A) IN GENERAL.—A group health plan, or
6 a health insurance issuer, in connection with
7 the provision of health insurance coverage, shall
8 have a procedure by which an individual who is
9 a participant, beneficiary, or enrollee and who
10 has an ongoing special condition (as defined in
11 subparagraph (C)) may receive a referral to a
12 specialist for such condition who shall be re-
13 sponsible for and capable of providing and co-
14 ordinating the individual's primary and spe-
15 cialty care. If such an individual's care would
16 most appropriately be coordinated by such a
17 specialist, such plan or issuer shall refer the in-
18 dividual to such specialist.

19 (B) TREATMENT AS PRIMARY CARE PRO-
20 VIDER.—Such specialist shall be permitted to
21 treat the individual without a referral from the
22 individual's primary care provider and may au-
23 thorize such referrals, procedures, tests, and
24 other medical services as the individual's pri-
25 mary care provider would otherwise be per-

1 mitted to provide or authorize, subject to the
2 terms of the treatment plan (referred to in
3 paragraph (1)(C)(i)).

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

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

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

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

17 (3) STANDING REFERRALS.—

18 (A) IN GENERAL.—A group health plan,
19 and a health insurance issuer in connection
20 with the provision of health insurance coverage,
21 shall have a procedure by which an individual
22 who is a participant, beneficiary, or enrollee
23 and who has a condition that requires ongoing
24 care from a specialist may receive a standing
25 referral to such specialist for treatment of such

1 condition. If the plan or issuer, or if the pri-
2 mary care provider in consultation with the
3 medical director of the plan or issuer and the
4 specialist (if any), determines that such a
5 standing referral is appropriate, the plan or
6 issuer shall make such a referral to such a spe-
7 cialist.

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

14 **SEC. 105. CONTINUITY OF CARE.**

15 (a) IN GENERAL.—

16 (1) TERMINATION OF PROVIDER.—If a contract
17 between a group health plan, or a health insurance
18 issuer in connection with the provision of health in-
19 surance coverage, and a health care provider is ter-
20 minated (as defined in paragraph (3)), or benefits
21 or coverage provided by a health care provider are
22 terminated because of a change in the terms of pro-
23 vider participation in a group health plan, and an
24 individual who is a participant, beneficiary, or en-
25 rollee in the plan or coverage is undergoing a course

1 of treatment from the provider at the time of such
2 termination, the plan or issuer shall—

3 (A) notify the individual on a timely basis
4 of such termination, and

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

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

24 (3) TERMINATION.—In this section, the term
25 “terminated” includes, with respect to a contract,

1 the expiration or nonrenewal of the contract, but
2 does not include a termination of the contract by the
3 plan or issuer for failure to meet applicable quality
4 standards or for fraud.

5 (b) TRANSITIONAL PERIOD.—

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

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

23 (3) PREGNANCY.—If—

24 (A) a participant, beneficiary, or enrollee
25 has entered the second trimester of pregnancy

1 at the time of a provider's termination of par-
2 ticipation, and

3 (B) the provider was treating the preg-
4 nancy before date of the termination,

5 the transitional period under this subsection with re-
6 spect to provider's treatment of the pregnancy shall
7 extend through the provision of post-partum care di-
8 rectly related to the delivery.

9 (4) TERMINAL ILLNESS.—If—

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

15 (B) the provider was treating the terminal
16 illness before the date of termination,

17 the transitional period under this subsection shall
18 extend for the remainder of the individual's life for
19 care directly related to the treatment of the terminal
20 illness.

21 (c) PERMISSIBLE TERMS AND CONDITIONS.—A

22 group health plan or health insurance issuer may condi-
23 tion coverage of continued treatment by a provider under
24 subsection (a)(1)(B) upon the provider agreeing to the fol-
25 lowing terms and conditions:

1 (1) The provider agrees to accept reimburse-
2 ment from the plan or issuer and individual involved
3 (with respect to cost-sharing) at the rates applicable
4 prior to the start of the transitional period as pay-
5 ment in full (or, in the case described in subsection
6 (a)(2), at the rates applicable under the replacement
7 plan or issuer after the date of the termination of
8 the contract with the health insurance issuer) and
9 not to impose cost-sharing with respect to the indi-
10 vidual in an amount that would exceed the cost-shar-
11 ing that could have been imposed if the contract re-
12 ferred to in subsection (a)(1) had not been termi-
13 nated.

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

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

1 (d) CONSTRUCTION.—Nothing in this section shall be
2 construed to require the coverage of benefits which would
3 not have been covered if the provider involved remained
4 a participating provider.

5 **SEC. 106. COVERAGE FOR INDIVIDUALS PARTICIPATING IN**
6 **APPROVED CLINICAL TRIALS.**

7 (a) COVERAGE.—

8 (1) IN GENERAL.—If a group health plan, or
9 health insurance issuer that is providing health in-
10 surance coverage, provides coverage to a qualified in-
11 dividual (as defined in subsection (b)), the plan or
12 issuer—

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

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

21 (C) may not discriminate against the indi-
22 vidual on the basis of the enrollee's participa-
23 tion in such trial.

24 (2) EXCLUSION OF CERTAIN COSTS.—For pur-
25 poses of paragraph (1)(B), routine patient costs do

1 not include the cost of the tests or measurements
2 conducted primarily for the purpose of the clinical
3 trial involved.

4 (3) USE OF IN-NETWORK PROVIDERS.—If one
5 or more participating providers is participating in a
6 clinical trial, nothing in paragraph (1) shall be con-
7 strued as preventing a plan or issuer from requiring
8 that a qualified individual participate in the trial
9 through such a participating provider if the provider
10 will accept the individual as a participant in the
11 trial.

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

18 (1)(A) The individual has a life-threatening or
19 serious illness for which no standard treatment is ef-
20 fective.

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

1 (C) The individual's participation in the trial
2 offers meaningful potential for significant clinical
3 benefit for the individual.

4 (2) Either—

5 (A) the referring physician is a participat-
6 ing health care professional and has concluded
7 that the individual's participation in such trial
8 would be appropriate based upon the individual
9 meeting the conditions described in paragraph
10 (1); or

11 (B) the participant, beneficiary, or enrollee
12 provides medical and scientific information es-
13 tablishing that the individual's participation in
14 such trial would be appropriate based upon the
15 individual meeting the conditions described in
16 paragraph (1).

17 (c) PAYMENT.—

18 (1) IN GENERAL.—Under this section a group
19 health plan or health insurance issuer shall provide
20 for payment for routine patient costs described in
21 subsection (a)(2) but is not required to pay for costs
22 of items and services that are reasonably expected
23 (as determined by the Secretary) to be paid for by
24 the sponsors of an approved clinical trial.

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

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

5 (B) a nonparticipating provider, the pay-
6 ment rate shall be at the rate the plan or issuer
7 would normally pay for comparable services
8 under subparagraph (A).

9 (d) APPROVED CLINICAL TRIAL DEFINED.—

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

15 (A) The National Institutes of Health.

16 (B) A cooperative group or center of the
17 National Institutes of Health.

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

20 (i) The Department of Veterans Af-
21 fairs.

22 (ii) The Department of Defense.

23 (2) CONDITIONS FOR DEPARTMENTS.—The
24 conditions described in this paragraph, for a study
25 or investigation conducted by a Department, are

1 that the study or investigation has been reviewed
2 and approved through a system of peer review that
3 the Secretary determines—

4 (A) to be comparable to the system of peer
5 review of studies and investigations used by the
6 National Institutes of Health, and

7 (B) assures unbiased review of the highest
8 scientific standards by qualified individuals who
9 have no interest in the outcome of the review.

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

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

14 (a) IN GENERAL.—If a group health plan, or health
15 insurance issuer that offers health insurance coverage,
16 provides benefits with respect to prescription drugs but
17 the coverage limits such benefits to drugs included in a
18 formulary, the plan or issuer shall—

19 (1) ensure participation of participating physi-
20 cians and pharmacists in the development of the for-
21 mulary;

22 (2) disclose to providers and, disclose upon re-
23 quest under section 121(e)(6) to participants, bene-
24 ficiaries, and enrollees, the nature of the formulary
25 restrictions; and

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

5 (b) COVERAGE OF APPROVED DRUGS AND MEDICAL
6 DEVICES.—

7 (1) IN GENERAL.—A group health plan (or
8 health insurance coverage offered in connection with
9 such a plan) that provides any coverage of prescrip-
10 tion drugs or medical devices shall not deny coverage
11 of such a drug or device on the basis that the use
12 is investigational, if the use—

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

14 (i) is included in the labeling author-
15 ized by the application in effect for the
16 drug pursuant to subsection (b) or (j) of
17 section 505 of the Federal Food, Drug,
18 and Cosmetic Act, without regard to any
19 postmarketing requirements that may
20 apply under such Act; or

21 (ii) is included in the labeling author-
22 ized by the application in effect for the
23 drug under section 351 of the Public
24 Health Service Act, without regard to any

1 postmarketing requirements that may
2 apply pursuant to such section; or

3 (B) in the case of a medical device, is in-
4 cluded in the labeling authorized by a regula-
5 tion under subsection (d) or (3) of section 513
6 of the Federal Food, Drug, and Cosmetic Act,
7 an order under subsection (f) of such section, or
8 an application approved under section 515 of
9 such Act, without regard to any postmarketing
10 requirements that may apply under such Act.

11 (2) CONSTRUCTION.—Nothing in this sub-
12 section shall be construed as requiring a group
13 health plan (or health insurance coverage offered in
14 connection with such a plan) to provide any coverage
15 of prescription drugs or medical devices.

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

17 (a) IN GENERAL.—Each group health plan, and each
18 health insurance issuer offering health insurance coverage,
19 that provides benefits, in whole or in part, through partici-
20 pating health care providers shall have (in relation to the
21 coverage) a sufficient number, distribution, and variety of
22 qualified participating health care providers to ensure that
23 all covered health care services, including specialty serv-
24 ices, will be available and accessible in a timely manner
25 to all participants, beneficiaries, and enrollees under the

1 plan or coverage. This subsection shall only apply to a
2 plan's or issuer's application of restrictions on the partici-
3 pation of health care providers in a network and shall not
4 be construed as requiring a plan or issuer to create or
5 establish new health care providers in an area.

6 (b) TREATMENT OF CERTAIN PROVIDERS.—The
7 qualified health care providers under subsection (a) may
8 include federally qualified health centers, rural health clin-
9 ics, migrant health centers, and other essential community
10 providers located in the service area of the plan or issuer
11 and shall include such providers if necessary to meet the
12 standards established to carry out such subsection.

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

14 (a) APPLICATION TO DELIVERY OF SERVICES.—Sub-
15 ject to subsection (b), a group health plan, and health in-
16 surance issuer in relation to health insurance coverage,
17 may not discriminate against a participant, beneficiary, or
18 enrollee in the delivery of health care services consistent
19 with the benefits covered under the plan or coverage or
20 as required by law based on race, color, ethnicity, national
21 origin, religion, sex, age, mental or physical disability, sex-
22 ual orientation, genetic information, or source of payment.

23 (b) CONSTRUCTION.—Nothing in subsection (a) shall
24 be construed as relating to the eligibility to be covered,
25 or the offering (or guaranteeing the offer) of coverage,

1 under a plan or health insurance coverage, the application
2 of any pre-existing condition exclusion consistent with ap-
3 plicable law, or premiums charged under such plan or cov-
4 erage. Pursuant to section 192(b), except as provided in
5 section 152, nothing in this title shall be construed as re-
6 quiring a group health plan or health insurance issuer to
7 provide specific benefits under the terms of such plan or
8 coverage.

9 **Subtitle B—Quality Assurance**

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

11 (a) **REQUIREMENT.**—A group health plan, and a
12 health insurance issuer that offers health insurance cov-
13 erage, shall establish and maintain an ongoing, internal
14 quality assurance and continuous quality improvement
15 program that meets the requirements of subsection (b).

16 (b) **PROGRAM REQUIREMENTS.**—The requirements of
17 this subsection for a quality improvement program of a
18 plan or issuer are as follows:

19 (1) **ADMINISTRATION.**—The plan or issuer has
20 a separate identifiable unit with responsibility for
21 administration of the program.

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

25 (A) The activities to be conducted.

1 (B) The organizational structure.

2 (C) The duties of the medical director.

3 (D) Criteria and procedures for the assess-
4 ment of quality.

5 (3) SYSTEMATIC REVIEW.—The program pro-
6 vides for systematic review of the type of health
7 services provided, consistency of services provided
8 with good medical practice, and patient outcomes.

9 (4) QUALITY CRITERIA.—The program—

10 (A) uses criteria that are based on per-
11 formance and patient outcomes where feasible
12 and appropriate;

13 (B) includes criteria that are directed spe-
14 cifically at meeting the needs of at-risk popu-
15 lations and covered individuals with chronic
16 conditions or severe illnesses, including gender-
17 specific criteria and pediatric-specific criteria
18 where available and appropriate;

19 (C) includes methods for informing covered
20 individuals of the benefit of preventive care and
21 what specific benefits with respect to preventive
22 care are covered under the plan or coverage;
23 and

1 (D) makes available to the public a de-
2 scription of the criteria used under subpara-
3 graph (A).

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

10 (6) DATA ANALYSIS.—The program provides,
11 using data that include the data collected under sec-
12 tion 112, for an analysis of the plan’s or issuer’s
13 performance on quality measures.

14 (7) DRUG UTILIZATION REVIEW.—The program
15 provides for a drug utilization review program in ac-
16 cordance with section 114.

17 (c) DEEMING.—For purposes of subsection (a), the
18 requirements of—

19 (1) subsection (b) (other than paragraph (5))
20 are deemed to be met with respect to a health insur-
21 ance issuer that is a qualified health maintenance
22 organization (as defined in section 1310(c) of the
23 Public Health Service Act); or

24 (2) subsection (b) are deemed to be met with
25 respect to a health insurance issuer that is accred-

1 ited by a national accreditation organization that the
2 Secretary certifies as applying, as a condition of cer-
3 tification, standards at least as stringent as those re-
4 quired for a quality improvement program under
5 subsection (b).

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

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

13 (a) IN GENERAL.—A group health plan and a health
14 insurance issuer that offers health insurance coverage
15 shall collect uniform quality data that include a minimum
16 uniform data set described in subsection (b).

17 (b) MINIMUM UNIFORM DATA SET.—The Secretary
18 shall specify (and may from time to time update) the data
19 required to be included in the minimum uniform data set
20 under subsection (a) and the standard format for such
21 data. Such data shall include at least—

22 (1) aggregate utilization data;

23 (2) data on the demographic characteristics of
24 participants, beneficiaries, and enrollees;

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

4 (4) data on satisfaction (including satisfaction
5 with respect to services to children) of such individ-
6 uals, including data on voluntary disenrollment and
7 grievances; and

8 (5) data on quality indicators and health out-
9 comes, including, to the extent feasible and appro-
10 priate, data on pediatric cases and on a gender-spe-
11 cific basis.

12 (c) AVAILABILITY.—A summary of the data collected
13 under subsection (a) shall be disclosed under section
14 121(b)(9). The Secretary shall be provided access to all
15 the data so collected.

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

22 (e) EXCEPTION FOR NONMEDICAL, RELIGIOUS CARE
23 PROVIDERS.—The requirements of subsection (a), insofar
24 as they may apply to a provider of health care, do not
25 apply to a provider that provides no medical care and that

1 provides only a religious method of healing or religious
2 nonmedical nursing care.

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

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

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

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

17 (d) NONDISCRIMINATION BASED ON LICENSURE.—

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

24 (2) CONSTRUCTION.—Paragraph (1) shall not
25 be construed—

1 (A) as requiring the coverage under a plan
2 or coverage of particular benefits or services or
3 to prohibit a plan or issuer from including pro-
4 viders only to the extent necessary to meet the
5 needs of the plan's or issuer's participants,
6 beneficiaries, or enrollees or from establishing
7 any measure designed to maintain quality and
8 control costs consistent with the responsibilities
9 of the plan or issuer; or

10 (B) to override any State licensure or
11 scope-of-practice law.

12 (e) GENERAL NONDISCRIMINATION.—

13 (1) IN GENERAL.—Subject to paragraph (2),
14 such process shall not discriminate with respect to
15 selection of a health care professional to be a partici-
16 pating health care provider, or with respect to the
17 terms and conditions of such participation, based on
18 the professional's race, color, religion, sex, national
19 origin, age, sexual orientation, or disability (consist-
20 ent with the Americans with Disabilities Act of
21 1990).

22 (2) RULES.—The appropriate Secretary may
23 establish such definitions, rules, and exceptions as
24 may be appropriate to carry out paragraph (1), tak-
25 ing into account comparable definitions, rules, and

1 exceptions in effect under employment-based non-
2 discrimination laws and regulations that relate to
3 each of the particular bases for discrimination de-
4 scribed in such paragraph.

5 **SEC. 114. DRUG UTILIZATION PROGRAM.**

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

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

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

18 **SEC. 115. STANDARDS FOR UTILIZATION REVIEW ACTIVI-**
19 **TIES.**

20 (a) COMPLIANCE WITH REQUIREMENTS.—

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

1 a utilization review program that meets the require-
2 ments of this section.

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

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

20 (b) WRITTEN POLICIES AND CRITERIA.—

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

25 (2) USE OF WRITTEN CRITERIA.—

1 (A) IN GENERAL.—Such a program shall
2 utilize written clinical review criteria developed
3 pursuant to the program with the input of ap-
4 propriate physicians. Such criteria shall include
5 written clinical review criteria described in sec-
6 tion 111(b)(4)(B).

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

17 (c) CONDUCT OF PROGRAM ACTIVITIES.—

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

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

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

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

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

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

1 (ii) is based, directly or indirectly, on
2 the quantity or type of adverse determina-
3 tions rendered.

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

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

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

24 (5) LIMITATION ON INFORMATION REQUESTS.—
25 Under such a program, information shall be required

1 to be provided by health care providers only to the
2 extent it is necessary to perform the utilization re-
3 view activity involved.

4 (d) DEADLINE FOR DETERMINATIONS.—

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

19 (2) CONTINUED CARE.—In the case of a utiliza-
20 tion review activity involving authorization for con-
21 tinued or extended health care services for an indi-
22 vidual, or additional services for an individual under-
23 going a course of continued treatment prescribed by
24 a health care provider, the utilization review pro-
25 gram shall make a determination concerning such

1 authorization, and provide notice of the determina-
2 tion to the individual or the individual's designee
3 and the individual's health care provider by tele-
4 phone and in printed form, as soon as possible in ac-
5 cordance with the medical exigencies of the cases,
6 and in no event later than 1 business day after the
7 date of receipt of information that is reasonably nec-
8 essary to make such determination. Such notice shall
9 include, with respect to continued or extended health
10 care services, the number of extended services ap-
11 proved, the new total of approved services, the date
12 of onset of services, and the next review date, if any.

13 (3) PREVIOUSLY PROVIDED SERVICES.—In the
14 case of a utilization review activity involving retro-
15 spective review of health care services previously pro-
16 vided for an individual, the utilization review pro-
17 gram shall make a determination concerning such
18 services, and provide notice of the determination to
19 the individual or the individual's designee and the
20 individual's health care provider by telephone and in
21 printed form, within 30 days of the date of receipt
22 of information that is reasonably necessary to make
23 such determination.

24 (4) REFERENCE TO SPECIAL RULES FOR EMER-
25 GENCY SERVICES, MAINTENANCE CARE, AND POST-

1 STABILIZATION CARE.—For waiver of prior author-
2 ization requirements in certain cases involving emer-
3 gency services and maintenance care and post-sta-
4 bilization care, see subsections (a)(1) and (b) of sec-
5 tion 101, respectively.

6 (e) NOTICE OF ADVERSE DETERMINATIONS.—

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

10 (A) the reasons for the determination (in-
11 cluding the clinical rationale);

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

14 (C) notice of the availability, upon request
15 of the individual (or the individual's designee)
16 of the clinical review criteria relied upon to
17 make such determination.

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

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

2 (a) ESTABLISHMENT.—The President shall establish
3 an advisory board to provide information to Congress and
4 the administration on issues relating to quality monitoring
5 and improvement in the health care provided under group
6 health plans and health insurance coverage.

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

- 15 (1) consumer needs;
- 16 (2) education and training of health profes-
17 sionals;
- 18 (3) health care services;
- 19 (4) health plan management;
- 20 (5) health care accreditation, quality assurance,
21 improvement, measurement, and oversight;
- 22 (6) medical practice, including practicing physi-
23 cians;
- 24 (7) prevention and public health; and
- 25 (8) public and private group purchasing for
26 small and large employers or groups.

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

2 (1) identify, update, and disseminate measures
3 of health care quality for group health plans and
4 health insurance issuers, including network and non-
5 network plans;

6 (2) advise the Secretary on the development
7 and maintenance of the minimum data set in section
8 112(b); and

9 (3) advise the Secretary on standardized for-
10 mats for information on group health plans and
11 health insurance coverage.

12 The measures identified under paragraph (1) may be used
13 on a voluntary basis by such plans and issuers. In carrying
14 out paragraph (1), the advisory board shall consult and
15 cooperate with national health care standard setting bod-
16 ies which define quality indicators, the Agency for Health
17 Care Policy and Research, the Institute of Medicine, and
18 other public and private entities that have expertise in
19 health care quality.

20 (d) REPORT.—The advisory board shall provide an
21 annual report to Congress and the President on the qual-
22 ity of the health care in the United States and national
23 and regional trends in health care quality. Such report
24 shall include a description of determinants of health care

1 quality and measurements of practice and quality varia-
2 bility within the United States.

3 (e) SECRETARIAL CONSULTATION.—In serving on
4 the advisory board, the Secretaries of Health and Human
5 Services and Labor (or their designees) shall consult with
6 the Secretaries responsible for other Federal health insur-
7 ance and health care programs.

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

16 (g) CONTINUATION.—Section 14(a)(2)(B) of the
17 Federal Advisory Committee Act (5 U.S.C. App.; relating
18 to the termination of advisory committees) shall not apply
19 to the advisory board.

20 **Subtitle C—Patient Information**

21 **SEC. 121. PATIENT INFORMATION.**

22 (a) DISCLOSURE REQUIREMENT.—

23 (1) GROUP HEALTH PLANS.—A group health
24 plan shall—

1 (A) provide to participants and bene-
2 ficiaries at the time of initial coverage under
3 the plan (or the effective date of this section, in
4 the case of individuals who are participants or
5 beneficiaries as of such date), and at least an-
6 nually thereafter, the information described in
7 subsection (b) in printed form;

8 (B) provide to participants and bene-
9 ficiaries, within a reasonable period (as speci-
10 fied by the appropriate Secretary) before or
11 after the date of significant changes in the in-
12 formation described in subsection (b), informa-
13 tion in printed form on such significant
14 changes; and

15 (C) upon request, make available to par-
16 ticipants and beneficiaries, the applicable au-
17 thority, and prospective participants and bene-
18 ficiaries, the information described in sub-
19 section (b) or (c) in printed form.

20 (2) HEALTH INSURANCE ISSUERS.—A health
21 insurance issuer in connection with the provision of
22 health insurance coverage shall—

23 (A) provide to individuals enrolled under
24 such coverage at the time of enrollment, and at

1 least annually thereafter, the information de-
2 scribed in subsection (b) in printed form;

3 (B) provide to enrollees, within a reason-
4 able period (as specified by the appropriate Sec-
5 retary) before or after the date of significant
6 changes in the information described in sub-
7 section (b), information in printed form on such
8 significant changes; and

9 (C) upon request, make available to the
10 applicable authority, to individuals who are pro-
11 spective enrollees, and to the public the infor-
12 mation described in subsection (b) or (c) in
13 printed form.

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

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

20 (2) BENEFITS.—Benefits offered under the
21 plan or coverage, including—

22 (A) covered benefits, including benefit lim-
23 its and coverage exclusions;

24 (B) cost sharing, such as deductibles, coin-
25 surance, and copayment amounts, including any

1 liability for balance billing, any maximum limi-
2 tations on out of pocket expenses, and the max-
3 imum out of pocket costs for services that are
4 provided by nonparticipating providers or that
5 are furnished without meeting the applicable
6 utilization review requirements;

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

9 (D) the extent to which a participant, ben-
10 efiary, or enrollee may select from among par-
11 ticipating providers and the types of providers
12 participating in the plan or issuer network;

13 (E) process for determining experimental
14 coverage; and

15 (F) use of a prescription drug formulary.

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

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

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

21 (C) Any point-of-service option (including
22 any supplemental premium or cost-sharing for
23 such option).

24 (D) The procedures for participants, bene-
25 ficiaries, and enrollees to select, access, and

1 change participating primary and specialty pro-
2 viders.

3 (E) The rights and procedures for obtain-
4 ing referrals (including standing referrals) to
5 participating and nonparticipating providers.

6 (F) The name, address, and telephone
7 number of participating health care providers
8 and an indication of whether each such provider
9 is available to accept new patients.

10 (G) Any limitations imposed on the selec-
11 tion of qualifying participating health care pro-
12 viders, including any limitations imposed under
13 section 103(b)(2).

14 (H) How the plan or issuer addresses the
15 needs of participants, beneficiaries, and enroll-
16 ees and others who do not speak English or
17 who have other special communications needs in
18 accessing providers under the plan or coverage,
19 including the provision of information described
20 in this subsection and subsection (c) to such in-
21 dividuals and including the provision of infor-
22 mation in a language other than English if 5
23 percent of the number of participants, bene-
24 ficiaries, and enrollees communicate in that lan-
25 guage instead of English.

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

3 (5) EMERGENCY COVERAGE.—Coverage of
4 emergency services, including—

5 (A) the appropriate use of emergency serv-
6 ices, including use of the 911 telephone system
7 or its local equivalent in emergency situations
8 and an explanation of what constitutes an
9 emergency situation;

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

12 (C) the locations of (i) emergency depart-
13 ments, and (ii) other settings, in which plan
14 physicians and hospitals provide emergency
15 services and post-stabilization care.

16 (6) PERCENTAGE OF PREMIUMS USED FOR
17 BENEFITS (LOSS-RATIOS).—In the case of health in-
18 surance coverage only (and not with respect to group
19 health plans that do not provide coverage through
20 health insurance coverage), a description of the over-
21 all loss-ratio for the coverage (as defined in accord-
22 ance with rules established or recognized by the Sec-
23 retary of Health and Human Services).

24 (7) PRIOR AUTHORIZATION RULES.—Rules re-
25 garding prior authorization or other review require-

1 ments that could result in noncoverage or non-
2 payment.

3 (8) GRIEVANCE AND APPEALS PROCEDURES.—

4 All appeal or grievance rights and procedures under
5 the plan or coverage, including the method for filing
6 grievances and the time frames and circumstances
7 for acting on grievances and appeals, who is the ap-
8 plicable authority with respect to the plan or issuer,
9 and the availability of assistance through an om-
10 budsman to individuals in relation to group health
11 plans and health insurance coverage.

12 (9) QUALITY ASSURANCE.—A summary descrip-

13 tion of the data on quality collected under section
14 112(a), including a summary description of the data
15 on satisfaction of participants, beneficiaries, and en-
16 rollees (including data on individual voluntary
17 disenrollment and grievances and appeals) described
18 in section 112(b)(4).

19 (10) SUMMARY OF PROVIDER FINANCIAL IN-

20 CENTIVES.—A summary description of the informa-
21 tion on the types of financial payment incentives
22 (described in section 1852(j)(4) of the Social Secu-
23 rity Act) provided by the plan or issuer under the
24 coverage.

1 (11) INFORMATION ON ISSUER.—Notice of ap-
2 propriate mailing addresses and telephone numbers
3 to be used by participants, beneficiaries, and enroll-
4 ees in seeking information or authorization for treat-
5 ment.

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

9 (c) INFORMATION MADE AVAILABLE UPON RE-
10 QUEST.—The information described in this subsection is
11 the following:

12 (1) UTILIZATION REVIEW ACTIVITIES.—A de-
13 scription of procedures used and requirements (in-
14 cluding circumstances, time frames, and appeal
15 rights) under any utilization review program under
16 section 115, including under any drug formulary
17 program under section 107.

18 (2) GRIEVANCE AND APPEALS INFORMATION.—
19 Information on the number of grievances and ap-
20 peals and on the disposition in the aggregate of such
21 matters.

22 (3) METHOD OF PHYSICIAN COMPENSATION.—
23 An overall summary description as to the method of
24 compensation of participating physicians, including
25 information on the types of financial payment incen-

1 tives (described in section 1852(j)(4) of the Social
2 Security Act) provided by the plan or issuer under
3 the coverage.

4 (4) SPECIFIC INFORMATION ON CREDENTIALS
5 OF PARTICIPATING PROVIDERS.—In the case of each
6 participating provider, a description of the creden-
7 tials of the provider.

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

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

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

15 (d) FORM OF DISCLOSURE.—

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

23 (2) INFORMATION INTO HANDBOOK.—Nothing
24 in this section shall be construed as preventing a
25 group health plan or health insurance issuer from

1 making the information under subsections (b) and
2 (c) available to participants, beneficiaries, and en-
3 rollees through an enrollee handbook or similar pub-
4 lication.

5 (3) UPDATING PARTICIPATING PROVIDER IN-
6 FORMATION.—The information on participating
7 health care providers described in subsection
8 (b)(3)(C) shall be updated within such reasonable
9 period as determined appropriate by the Secretary.
10 Nothing in this section shall prevent an issuer from
11 changing or updating other information made avail-
12 able under this section.

13 (e) CONSTRUCTION.—Nothing in this section shall be
14 construed as requiring public disclosure of individual con-
15 tracts or financial arrangements between a group health
16 plan or health insurance issuer and any provider.

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

18 Insofar as a group health plan, or a health insurance
19 issuer that offers health insurance coverage, maintains
20 medical records or other health information regarding par-
21 ticipants, beneficiaries, and enrollees, the plan or issuer
22 shall establish procedures—

23 (1) to safeguard the privacy of any individually
24 identifiable enrollee information;

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

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

5 **SEC. 123. HEALTH INSURANCE OMBUDSMEN.**

6 (a) IN GENERAL.—Each State that obtains a grant
7 under subsection (c) shall provide for creation and oper-
8 ation of a Health Insurance Ombudsman through a con-
9 tract with a not-for-profit organization that operates inde-
10 pendent of group health plans and health insurance
11 issuers. Such Ombudsman shall be responsible for at least
12 the following:

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

16 (2) To provide counseling and assistance to en-
17 rollees dissatisfied with their treatment by health in-
18 surance issuers and group health plans in regard to
19 such coverage or plans and with respect to griev-
20 ances and appeals regarding determinations under
21 such coverage or plans.

22 (b) FEDERAL ROLE.—In the case of any State that
23 does not provide for such an Ombudsman under sub-
24 section (a), the Secretary shall provide for the creation
25 and operation of a Health Insurance Ombudsman through

1 a contract with a not-for-profit organization that operates
2 independent of group health plans and health insurance
3 issuers and that is responsible for carrying out with re-
4 spect to that State the functions otherwise provided under
5 subsection (a) by a Health Insurance Ombudsman.

6 (c) AUTHORIZATION OF APPROPRIATIONS.—There
7 are authorized to be appropriated to the Secretary of
8 Health and Human Services such amounts as may be nec-
9 essary to provide for grants to States for contracts for
10 Health Insurance Ombudsmen under subsection (a) or
11 contracts for such Ombudsmen under subsection (b).

12 (d) CONSTRUCTION.—Nothing in this section shall be
13 construed to prevent the use of other forms of enrollee
14 assistance.

15 **Subtitle D—Grievance and Appeals** 16 **Procedures**

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

18 (a) ESTABLISHMENT OF GRIEVANCE SYSTEM.—

19 (1) IN GENERAL.—A group health plan, and a
20 health insurance issuer in connection with the provi-
21 sion of health insurance coverage, shall establish and
22 maintain a system to provide for the presentation
23 and resolution of oral and written grievances
24 brought by individuals who are participants, bene-
25 ficiaries, or enrollees, or health care providers or

1 other individuals acting on behalf of an individual
2 and with the individual's consent, regarding any as-
3 pect of the plan's or issuer's services.

4 (2) SCOPE.—The system shall include griev-
5 ances regarding access to and availability of services,
6 quality of care, choice and accessibility of providers,
7 network adequacy, and compliance with the require-
8 ments of this title.

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

12 (1) Written notification to all such individuals
13 and providers of the telephone numbers and business
14 addresses of the plan or issuer personnel responsible
15 for resolution of grievances and appeals.

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

19 (3) A process providing for timely processing
20 and resolution of grievances.

21 (4) Procedures for follow-up action, including
22 the methods to inform the person making the griev-
23 ance of the resolution of the grievance.

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

4 **SEC. 132. INTERNAL APPEALS OF ADVERSE DETERMINA-**
5 **TIONS.**

6 (a) RIGHT OF APPEAL.—

7 (1) IN GENERAL.—A participant or beneficiary
8 in a group health plan, and an enrollee in health in-
9 surance coverage offered by a health insurance
10 issuer, and any provider or other person acting on
11 behalf of such an individual with the individual’s
12 consent, may appeal any appealable decision (as de-
13 fined in paragraph (2)) under the procedures de-
14 scribed in this section and (to the extent applicable)
15 section 133. Such individuals and providers shall be
16 provided with a written explanation of the appeal
17 process and the determination upon the conclusion
18 of the appeals process and as provided in section
19 121(b)(8).

20 (2) APPEALABLE DECISION DEFINED.—In this
21 section, the term “appealable decision” means any of
22 the following:

23 (A) Denial, reduction, or termination of, or
24 failure to provide or make payment (in whole or
25 in part) for a benefit, including a failure to

1 cover an item or service for which benefits are
2 otherwise provided because it is determined to
3 be experimental or investigational or not medi-
4 cally necessary or appropriate.

5 (B) Failure to provide coverage of emer-
6 gency services or reimbursement of mainte-
7 nance care or post-stabilization care under sec-
8 tion 101.

9 (C) Failure to provide a choice of provider
10 under section 103.

11 (D) Failure to provide qualified health care
12 providers under section 103.

13 (E) Failure to provide access to specialty
14 and other care under section 104.

15 (F) Failure to provide continuation of care
16 under section 105.

17 (G) Failure to provide coverage of routine
18 patient costs in connection with an approval
19 clinical trial under section 106.

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

22 (I) Discrimination in delivery of services in
23 violation of section 109.

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

1 (K) The imposition of a limitation that is
2 prohibited under section 151.

3 (b) INTERNAL APPEAL PROCESS.—

4 (1) IN GENERAL.—Each group health plan and
5 health insurance issuer shall establish and maintain
6 an internal appeal process under which any partici-
7 pant, beneficiary, or enrollee, or any provider or
8 other person acting on behalf of such an individual
9 with the individual’s consent, who is dissatisfied with
10 any appealable decision has the opportunity to ap-
11 peal the decision through an internal appeal process.
12 The appeal may be communicated orally.

13 (2) CONDUCT OF REVIEW.—

14 (A) IN GENERAL.—The process shall in-
15 clude a review of the decision by a physician or
16 other health care professional (or professionals)
17 who has been selected by the plan or issuer and
18 who has not been involved in the appealable de-
19 cision at issue in the appeal.

20 (B) AVAILABILITY AND PARTICIPATION OF
21 CLINICAL PEERS.—The individuals conducting
22 such review shall include one or more clinical
23 peers (as defined in section 191(c)(2)) who have
24 not been involved in the appealable decision at
25 issue in the appeal.

1 (3) DEADLINE.—

2 (A) Subject to subsection (c), the plan or
3 issuer shall conclude each appeal as soon as
4 possible after the time of the receipt of the ap-
5 peal in accordance with medical exigencies of
6 the case involved, but in no event later than—

7 (i) 72 hours after the time of receipt
8 of an expedited appeal, and

9 (ii) except as provided in subpara-
10 graph (B), 30 business days after such
11 time (or, if the participant, beneficiary, en-
12 rollee supplies additional information that
13 was not available to the plan or issuer at
14 the time of the receipt of the appeal, after
15 the date of supplying such additional infor-
16 mation) in the case of all other appeals.

17 (B) EXTENSION.—In the case of an appeal
18 that does not relate to a decision regarding an
19 expedited appeal and that does not involve med-
20 ical exigencies, if a group health plan or health
21 insurance issuer is unable to conclude the ap-
22 peal within the time period provided under sub-
23 paragraph (A)(ii) due to circumstances beyond
24 the control of the plan or issuer, the deadline
25 shall be extended for up to an additional 10

1 business days if the plan or issuer provides, on
2 or before 10 days before the deadline otherwise
3 applicable, written notice to the participant,
4 beneficiary, or enrollee and the provider in-
5 volved of the extension and the reasons for the
6 extension.

7 (4) NOTICE.—If a plan or issuer denies an ap-
8 peal, the plan or issuer shall provide the participant,
9 beneficiary, or enrollee and provider involved with
10 notice in printed form of the denial and the reasons
11 therefore, together with a notice in printed form of
12 rights to any further appeal.

13 (c) EXPEDITED REVIEW PROCESS.—

14 (1) IN GENERAL.—A group health plan, and a
15 health insurance issuer, shall establish procedures in
16 writing for the expedited consideration of appeals
17 under subsection (b) in situations in which the appli-
18 cation of the normal timeframe for making a deter-
19 mination could seriously jeopardize the life or health
20 of the participant, beneficiary, or enrollee (including
21 in the case of a child, development) or such an indi-
22 vidual's ability to regain maximum function.

23 (2) PROCESS.—Under such procedures—

24 (A) the request for expedited appeal may
25 be submitted orally or in writing by an individ-

1 ual or provider who is otherwise entitled to re-
2 quest the appeal;

3 (B) all necessary information, including
4 the plan's or issuer's decision, shall be trans-
5 mitted between the plan or issuer and the re-
6 quester by telephone, facsimile, or other simi-
7 larly expeditious available method; and

8 (C) the plan or issuer shall expedite the
9 appeal if the request for an expedited appeal is
10 submitted under subparagraph (A) by a physi-
11 cian and the request indicates that the situation
12 described in paragraph (1) exists.

13 (d) DIRECT USE OF FURTHER APPEALS.—In the
14 event that the plan or issuer fails to comply with any of
15 the deadlines for completion of appeals under this section
16 or in the event that the plan or issuer for any reason ex-
17 pressly waives its rights to an internal review of an appeal
18 under subsection (b), the participant, beneficiary, or en-
19 rollee involved and the provider involved shall be relieved
20 of any obligation to complete the appeal involved and may,
21 at such an individual's or provider's option, proceed di-
22 rectly to seek further appeal through any applicable exter-
23 nal appeals process.

1 **SEC. 133. EXTERNAL APPEALS OF ADVERSE DETERMINA-**
2 **TIONS.**

3 (a) **RIGHT TO EXTERNAL APPEAL.—**

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

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

16 (A) the amount involved exceeds a signifi-
17 cant threshold; or

18 (B) the patient’s life or health is jeopard-
19 ized (including, in the case of a child, develop-
20 ment) as a consequence of the decision.

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

24 (3) **EXHAUSTION OF INTERNAL APPEALS PROC-**
25 **ESS.—**A plan or issuer may condition the use of an
26 external appeal process in the case of an externally

1 appealable decision upon completion of the internal
2 review process provided under section 132, but only
3 if the decision is made in a timely basis consistent
4 with the deadlines provided under this subtitle.

5 (b) GENERAL ELEMENTS OF EXTERNAL APPEALS
6 PROCESS.—

7 (1) CONTRACT WITH QUALIFIED EXTERNAL AP-
8 PEAL ENTITY.—

9 (A) CONTRACT REQUIREMENT.—Subject to
10 subparagraph (B), the external appeal process
11 under this section of a plan or issuer shall be
12 conducted under a contract between the plan or
13 issuer and one or more qualified external appeal
14 entities (as defined in subsection (c)).

15 (B) RESTRICTIONS ON QUALIFIED EXTER-
16 NAL APPEAL ENTITY.—

17 (i) BY STATE FOR HEALTH INSUR-
18 ANCE ISSUERS.—With respect to health in-
19 surance issuers in a State, the State may
20 provide for external review activities to be
21 conducted by a qualified external appeal
22 entity that is designated by the State or
23 that is selected by the State in such a
24 manner as to assure an unbiased deter-
25 mination.

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

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

18 (I) shall assure that the selection
19 process will not create any incentives
20 for external appeal entities to make a
21 decision in a biased manner, and

22 (II) shall implement procedures
23 for auditing a sample of decisions by
24 such entities to assure that no such

1 decisions are made in a biased man-
2 ner.

3 (C) OTHER TERMS AND CONDITIONS.—

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

15 (2) ELEMENTS OF PROCESS.—An external ap-
16 peal process shall be conducted consistent with
17 standards established by the appropriate Secretary
18 that include at least the following:

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

22 (B) DETERMINATION CONCERNING EXTER-
23 NALLY APPEALABLE DECISIONS.—A qualified
24 external appeal entity shall determine whether a

1 decision is an externally appealable decision and
2 related decisions, including—

3 (i) whether such a decision involves an
4 expedited appeal;

5 (ii) the appropriate deadlines for in-
6 ternal review process required due to medi-
7 cal exigencies in a case; and

8 (iii) whether such a process has been
9 completed.

10 (C) OPPORTUNITY TO SUBMIT EVIDENCE,
11 HAVE REPRESENTATION, AND MAKE ORAL
12 PRESENTATION.—Each party to an externally
13 appealable decision—

14 (i) may submit and review evidence
15 related to the issues in dispute,

16 (ii) may use the assistance or rep-
17 resentation of one or more individuals (any
18 of whom may be an attorney), and

19 (iii) may make an oral presentation.

20 (D) PROVISION OF INFORMATION.—The
21 plan or issuer involved shall provide timely ac-
22 cess to all its records relating to the matter of
23 the externally appealable decision and to all
24 provisions of the plan or health insurance cov-

1 erage (including any coverage manual) relating
2 to the matter.

3 (E) TIMELY DECISIONS.—A determination
4 by the external appeal entity on the decision
5 shall—

6 (i) be made orally or in writing and,
7 if it is made orally, shall be supplied to the
8 parties in writing as soon as possible;

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

10 (iii) be made in accordance with the
11 medical exigencies of the case involved, but
12 in no event later than 60 days (or 72
13 hours in the case of an expedited appeal)
14 from the date of completion of the filing of
15 notice of external appeal of the decision;

16 (iv) state, in layperson’s language, the
17 basis for the determination, including, if
18 relevant, any basis in the terms or condi-
19 tions of the plan or coverage; and

20 (v) inform the participant, beneficiary,
21 or enrollee of the individual’s rights to seek
22 further review by the courts (or other proc-
23 ess) of the external appeal determination.

24 (c) QUALIFICATIONS OF EXTERNAL APPEAL ENTI-
25 TIES.—

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

7 (A) There is no real or apparent conflict of
8 interest that would impede the entity conduct-
9 ing external appeal activities independent of the
10 plan or issuer.

11 (B) The entity conducts external appeal
12 activities through clinical peers.

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

18 (D) The entity meets such other require-
19 ments as the appropriate Secretary may im-
20 pose.

21 (2) CERTIFICATION OF EXTERNAL APPEAL EN-
22 TITIES.—

23 (A) IN GENERAL.—In order to be treated
24 as a qualified external appeal entity with re-
25 spect to—

1 (i) a group health plan, the entity
2 must be certified (and, in accordance with
3 subparagraph (B), periodically recertified)
4 as meeting the requirements of paragraph
5 (1) by the Secretary of Labor (or under a
6 process recognized or approved by the Sec-
7 retary of Labor); or

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

19 (B) RECERTIFICATION PROCESS.—The ap-
20 propriate Secretary shall develop standards for
21 the recertification of external appeal entities.
22 Such standards shall include a specification
23 of—

24 (i) the information required to be sub-
25 mitted as a condition of recertification on

1 the entity's performance of external appeal
 2 activities, which information shall include
 3 the number of cases reviewed, a summary
 4 of the disposition of those cases, the length
 5 of time in making determinations on those
 6 cases, and such information as may be nec-
 7 essary to assure the independence of the
 8 entity from the plans or issuers for which
 9 external appeal activities are being con-
 10 ducted; and

11 (ii) the periodicity which recertifi-
 12 cation will be required.

13 (d) CONTINUING LEGAL RIGHTS OF ENROLLEES.—
 14 Nothing in this title shall be construed as removing any
 15 legal rights of participants, beneficiaries, enrollees, and
 16 others under State or Federal law, including the right to
 17 file judicial actions to enforce rights.

18 **Subtitle E—Protecting the Doctor-** 19 **Patient Relationship**

20 **SEC. 141. PROHIBITION OF INTERFERENCE WITH CERTAIN** 21 **MEDICAL COMMUNICATIONS.**

22 (a) PROHIBITION.—

23 (1) GENERAL RULE.—The provisions of any
 24 contract or agreement, or the operation of any con-
 25 tract or agreement, between a group health plan or

1 health insurance issuer in relation to health insur-
2 ance coverage (including any partnership, associa-
3 tion, or other organization that enters into or ad-
4 ministers such a contract or agreement) and a
5 health care provider (or group of health care provid-
6 ers) shall not prohibit or restrict the provider from
7 engaging in medical communications with the pro-
8 vider's patient.

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

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

15 (1) to prohibit the enforcement, as part of a
16 contract or agreement to which a health care pro-
17 vider is a party, of any mutually agreed upon terms
18 and conditions, including terms and conditions re-
19 quiring a health care provider to participate in, and
20 cooperate with, all programs, policies, and proce-
21 dures developed or operated by a group health plan
22 or health insurance issuer to assure, review, or im-
23 prove the quality and effective utilization of health
24 care services (if such utilization is according to
25 guidelines or protocols that are based on clinical or

1 scientific evidence and the professional judgment of
2 the provider) but only if the guidelines or protocols
3 under such utilization do not prohibit or restrict
4 medical communications between providers and their
5 patients; or

6 (2) to permit a health care provider to mis-
7 represent the scope of benefits covered under the
8 group health plan or health insurance coverage or to
9 otherwise require a group health plan health insur-
10 ance issuer to reimburse providers for benefits not
11 covered under the plan or coverage.

12 (c) MEDICAL COMMUNICATION DEFINED.—In this
13 section:

14 (1) IN GENERAL.—The term “medical commu-
15 nication” means any communication made by a
16 health care provider with a patient of the health care
17 provider (or the guardian or legal representative of
18 such patient) with respect to—

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

21 (B) any utilization review requirements
22 that may affect treatment options for the pa-
23 tient; or

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

1 (2) MISREPRESENTATION.—The term “medical
2 communication” does not include a communication
3 by a health care provider with a patient of the
4 health care provider (or the guardian or legal rep-
5 resentative of such patient) if the communication in-
6 volves a knowing or willful misrepresentation by
7 such provider.

8 **SEC. 142. PROHIBITION AGAINST TRANSFER OF INDEM-**
9 **NIFICATION OR IMPROPER INCENTIVE AR-**
10 **RANGEMENTS.**

11 (a) PROHIBITION OF TRANSFER OF INDEMNIFICA-
12 TION.—

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

22 (2) NULLIFICATION.—Any contract or agree-
23 ment provision that violates paragraph (1) shall be
24 null and void.

1 (b) PROHIBITION OF IMPROPER PHYSICIAN INCEN-
2 TIVE PLANS.—

3 (1) IN GENERAL.—A group health plan and a
4 health insurance issuer offering health insurance
5 coverage may not operate any physician incentive
6 plan (as defined in subparagraph (B) of section
7 1876(i)(8) of the Social Security Act) unless the re-
8 quirements described in subparagraph (A) of such
9 section are met with respect to such a plan.

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

19 **SEC. 143. ADDITIONAL RULES REGARDING PARTICIPATION**
20 **OF HEALTH CARE PROFESSIONALS.**

21 (a) PROCEDURES.—Insofar as a group health plan,
22 or health insurance issuer that offers health insurance cov-
23 erage, provides benefits through participating health care
24 professionals, the plan or issuer shall establish reasonable
25 procedures relating to the participation (under an agree-

1 ment between a professional and the plan or issuer) of
2 such professionals under the plan or coverage. Such proce-
3 dures shall include—

4 (1) providing notice of the rules regarding par-
5 ticipation;

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

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

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

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

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

1 an internal or external review or appeal process) under
2 this title.

3 (b) PROTECTION FOR QUALITY ADVOCACY BY
4 HEALTH CARE PROFESSIONALS.—

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

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

16 (B) initiates, cooperates, or otherwise par-
17 ticipates in an investigation or proceeding by
18 such an agency with respect to such care, serv-
19 ices, or conditions.

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

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

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

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

20 (B) the professional reasonably believes the
21 information to be true;

22 (C) the information evidences either a vio-
23 lation of a law, rule, or regulation, of an appli-
24 cable accreditation standard, or of a generally
25 recognized professional or clinical standard or

1 that a patient is in imminent hazard of loss of
2 life or serious injury; and

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

9 (3) EXCEPTION AND SPECIAL RULE.—

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

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

1 (C) INTERNAL PROCEDURE EXCEPTION.—

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

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

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

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

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

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

8 (6) CONSTRUCTIONS.—

9 (A) DETERMINATIONS OF COVERAGE.—

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

15 (B) ENFORCEMENT OF PEER REVIEW PRO-

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

10 (a) **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
17 beneficiary—

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 **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 nonrestricted 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 means, 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 section 152, nothing in this title shall be construed as
13 requiring a group health plan or health insurance coverage
14 to provide specific benefits under the terms of such plan
15 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 1999, 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)(2)(A) of such Act (42 U.S.C. 300gg–21(b)(2)(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 1999 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 1999 (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 1999 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 “(2) INFORMATION.—With respect to informa-
8 tion required to be provided or made available under
9 section 121, in the case of a group health plan that
10 provides benefits in the form of health insurance
11 coverage through a health insurance issuer, the Sec-
12 retary shall determine the circumstances under
13 which the plan is not required to provide or make
14 available the information (and is not liable for the
15 issuer’s failure to provide or make available the in-
16 formation), if the issuer is obligated to provide and
17 make available (or provides and makes available)
18 such information.

19 “(3) GRIEVANCE AND INTERNAL APPEALS.—
20 With respect to the grievance system and internal
21 appeals process required to be established under sec-
22 tions 131 and 132, in the case of a group health
23 plan that provides benefits in the form of health in-
24 surance coverage through a health insurance issuer,
25 the Secretary shall determine the circumstances

1 under which the plan is not required to provide for
2 such system and process (and is not liable for the
3 issuer's failure to provide for such system and proc-
4 ess), if the issuer is obligated to provide for (and
5 provides for) such system and process.

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

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

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

23 “(B) Section 141 (relating to prohibition
24 of interference with certain medical communica-
25 tions).

1 “(C) Section 142 (relating to prohibition
2 against transfer of indemnification or improper
3 incentive arrangements).

4 “(D) Section 144 (relating to prohibition
5 on retaliation).

6 “(E) Section 151 (relating to promoting
7 good medical practice).

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

12 “(7) APPLICATION TO CERTAIN PROHIBITIONS
13 AGAINST RETALIATION.—With respect to compliance
14 with the requirements of section 144(b)(1) of the
15 Patients’ Bill of Rights Act of 1999, for purposes of
16 this subtitle the term ‘group health plan’ is deemed
17 to include a reference to an institutional health care
18 provider.

19 “(c) ENFORCEMENT OF CERTAIN REQUIREMENTS.—

20 “(1) COMPLAINTS.—Any protected health care
21 professional who believes that the professional has
22 been retaliated or discriminated against in violation
23 of section 144(b)(1) of the Patients’ Bill of Rights
24 Act of 1999 may file with the Secretary a complaint

1 within 180 days of the date of the alleged retaliation
2 or discrimination.

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

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

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

19 “(b) In the case of a group health plan (as defined
20 in section 733) compliance with the requirements of sub-
21 title D (and section 115) of title I of the Patients’ Bill
22 of Rights Act of 1999 in the case of a claims denial shall
23 be deemed compliance with subsection (a) with respect to
24 such claims denial.”.

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

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

“Sec. 713. Patient protection standards.”.

7 (3) Section 502(b)(3) of such Act (29 U.S.C.
 8 1132(b)(3)) is amended by inserting “(other than section
 9 144(b))” after “part 7”.

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

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

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

19 “(1) IN GENERAL.—Except as provided in this
 20 subsection, nothing in this title shall be construed to
 21 invalidate, impair, or supersede any cause of action
 22 brought by a plan participant or beneficiary (or the
 23 estate of a plan participant or beneficiary) under
 24 State law to recover damages resulting from per-

1 sonal 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 against an
18 employee of such an employer or sponsor
19 acting within the scope of employment, or

20 “(ii) a right of recovery or indemnity
21 by a person against an employer or other
22 plan sponsor (or employee of such author-
23 ity) for damages assessed against the per-
24 son pursuant to a cause of action under
25 paragraph (1).

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

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

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

17 “(3) CONSTRUCTION.—Nothing in this sub-
18 section shall be construed as permitting a cause of
19 action under State law for the failure to provide an
20 item or service which is not covered under the group
21 health plan involved.

22 “(4) PERSONAL INJURY DEFINED.—For pur-
23 poses of this subsection, the term ‘personal injury’
24 means a physical injury and includes an injury aris-

1 (as in effect as of the date of the enactment of such Act),
2 and such requirements shall be deemed to be incorporated
3 into this section.”.

4 **TITLE V—EFFECTIVE DATES; CO-**
5 **ORDINATION IN IMPLEMEN-**
6 **TATION**

7 **SEC. 501. EFFECTIVE DATES AND RELATED RULES.**

8 (a) GROUP HEALTH COVERAGE.—

9 (1) IN GENERAL.—Subject to paragraph (2),
10 the amendments made by sections 201(a), 301, and
11 401 (and title I insofar as it relates to such sections)
12 shall apply with respect to group health plans, and
13 health insurance coverage offered in connection with
14 group health plans, for plan years beginning on or
15 after January 1, 2000 (in this section referred to as
16 the “general effective date”).

17 (2) TREATMENT OF COLLECTIVE BARGAINING
18 AGREEMENTS.—In the case of a group health plan
19 maintained pursuant to 1 or more collective bargain-
20 ing agreements between employee representatives
21 and 1 or more employers ratified before the date of
22 enactment of this Act, the amendments made by sec-
23 tions 201(a), 301, and 401 (and title I insofar as it
24 relates to such sections) shall not apply to plan
25 years beginning before the later of—

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

6 (B) the general effective date.

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

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

18 (c) TREATMENT OF RELIGIOUS NONMEDICAL PRO-
19 VIDERS.—

20 (1) IN GENERAL.—Nothing in this Act (or the
21 amendments made thereby) shall be construed to—

22 (A) restrict or limit the right of group
23 health plans, and of health insurance issuers of-
24 fering health insurance coverage, to include as
25 providers religious nonmedical providers;

1 (B) require such plans or issuers to—

2 (i) utilize medically based eligibility
3 standards or criteria in deciding provider
4 status of religious nonmedical providers;

5 (ii) use medical professionals or cri-
6 teria to decide patient access to religious
7 nonmedical providers;

8 (iii) utilize medical professionals or
9 criteria in making decisions in internal or
10 external appeals regarding coverage for
11 care by religious nonmedical providers; or

12 (iv) compel a participant or bene-
13 ficiary to undergo a medical examination
14 or test as a condition of receiving health
15 insurance coverage for treatment by a reli-
16 gious nonmedical provider; or

17 (C) require such plans or issuers to ex-
18 clude religious nonmedical providers because
19 they do not provide medical or other required
20 data, if such data is inconsistent with the reli-
21 gious nonmedical treatment or nursing care
22 provided by the provider.

23 (2) RELIGIOUS NONMEDICAL PROVIDER.—For
24 purposes of this subsection, the term “religious non-
25 medical provider” means a provider who provides no

1 medical care but who provides only religious non-
2 medical treatment or religious nonmedical nursing
3 care.

4 **SEC. 502. COORDINATION IN IMPLEMENTATION.**

5 Section 104(1) of Health Insurance Portability and
6 Accountability Act of 1996 is amended by striking “this
7 subtitle (and the amendments made by this subtitle and
8 section 401)” and inserting “the provisions of part 7 of
9 subtitle B of title I of the Employee Retirement Income
10 Security Act of 1974, the provisions of parts A and C of
11 title XXVII of the Public Health Service Act, chapter 100
12 of the Internal Revenue Code of 1986, and title I of the
13 Patients’ Bill of Rights Act of 1999”.

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