

109TH CONGRESS
1ST SESSION

H. R. 2650

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

MAY 26, 2005

Mr. NORWOOD introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Education and the Workforce and Ways and Means, 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 “Patient Protection Act of 2005”.

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

Sec. 1. Short title; table of contents.

TITLE I—IMPROVING MANAGED CARE

Subtitle A—Utilization review; claims; and internal and external appeals

- Sec. 101. Utilization review activities.
- Sec. 102. Procedures for initial claims for benefits and prior authorization determinations.
- Sec. 103. Internal appeals of claims denials.
- Sec. 104. Independent external appeals procedures.
- Sec. 105. Health care consumer assistance fund.

Subtitle B—Access to care

- Sec. 111. Consumer choice option.
- Sec. 112. Choice of health care professional.
- Sec. 113. Access to emergency care.
- Sec. 114. Timely access to specialists.
- Sec. 115. Patient access to obstetrical and gynecological care.
- Sec. 116. Access to pediatric care.
- Sec. 117. Continuity of care.
- Sec. 118. Access to needed prescription drugs.
- Sec. 119. Coverage for individuals participating in approved clinical trials.
- Sec. 120. Required coverage for minimum hospital stay for mastectomies and lymph node dissections for the treatment of breast cancer and coverage for secondary consultations.

Subtitle C—Access to information

- Sec. 121. Patient access to information.

Subtitle D—Protecting the doctor-patient relationship

- Sec. 131. Prohibition of interference with certain medical communications.
- Sec. 132. Prohibition of discrimination against providers based on licensure.
- Sec. 133. Prohibition against improper incentive arrangements.
- Sec. 134. Payment of claims.
- Sec. 135. Protection for patient advocacy.

Subtitle E—Definitions

- Sec. 151. Definitions.
- Sec. 152. Preemption; State flexibility; construction.
- Sec. 153. Exclusions.
- Sec. 154. Treatment of excepted benefits.
- Sec. 155. Regulations.
- Sec. 156. Incorporation into plan or coverage documents.

Sec. 157. Preservation of protections.

TITLE II—APPLICATION OF QUALITY CARE STANDARDS TO
GROUP HEALTH PLANS AND HEALTH INSURANCE COVERAGE
UNDER THE PUBLIC HEALTH SERVICE ACT

Sec. 201. Application to group health plans and group health insurance coverage.

Sec. 202. Application to individual health insurance coverage.

Sec. 203. Cooperation between Federal and State authorities.

TITLE III—APPLICATION OF PATIENT PROTECTION STANDARDS
TO FEDERAL HEALTH INSURANCE PROGRAMS

Sec. 301. Application of patient protection standards to Federal health insurance programs.

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

Sec. 401. Application of patient protection standards to group health plans and group health insurance coverage under the Employee Retirement Income Security Act of 1974.

Sec. 402. Cooperation between Federal and State authorities.

Sec. 403. Sense of the Congress concerning the importance of certain unpaid services.

TITLE V—AMENDMENTS TO THE INTERNAL REVENUE CODE OF
1986

Sec. 501. Application of requirements to group health plans under the Internal Revenue Code of 1986.

Sec. 502. Conforming enforcement for women's health and cancer rights.

TITLE VI—EFFECTIVE DATES; COORDINATION IN
IMPLEMENTATION

Sec. 601. Effective dates.

Sec. 602. Coordination in implementation.

Sec. 603. Severability.

TITLE VII—MISCELLANEOUS PROVISIONS

Sec. 701. No impact on Social Security Trust Fund.

Sec. 702. Sense of Congress with respect to participation in clinical trials and access to specialty care.

Sec. 703. Sense of the Congress regarding fair review process.

Sec. 704. Annual review.

1 **TITLE I—IMPROVING MANAGED**
2 **CARE**
3 **Subtitle A—Utilization Review;**
4 **Claims; and Internal and Exter-**
5 **nal Appeals**

6 **SEC. 101. UTILIZATION REVIEW ACTIVITIES.**

7 (a) COMPLIANCE WITH REQUIREMENTS.—

8 (1) IN GENERAL.—A group health plan, and a
9 health insurance issuer that provides health insur-
10 ance coverage, shall conduct utilization review activi-
11 ties in connection with the provision of benefits
12 under such plan or coverage only in accordance with
13 a utilization review program that meets the require-
14 ments of this section and section 102.

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

23 (3) UTILIZATION REVIEW DEFINED.—For pur-
24 poses of this section, the terms “utilization review”
25 and “utilization review activities” mean procedures

1 used to monitor or evaluate the use or coverage,
2 clinical necessity, appropriateness, efficacy, or effi-
3 ciency of health care services, procedures or settings,
4 and includes prospective review, concurrent review,
5 second opinions, case management, discharge plan-
6 ning, or retrospective review.

7 (b) WRITTEN POLICIES AND CRITERIA.—

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

12 (2) USE OF WRITTEN CRITERIA.—

13 (A) IN GENERAL.—Such a program shall
14 utilize written clinical review criteria developed
15 with input from a range of appropriate actively
16 practicing health care professionals, as deter-
17 mined by the plan, pursuant to the program.
18 Such criteria shall include written clinical re-
19 view criteria that are based on valid clinical evi-
20 dence where available and that are directed spe-
21 cifically at meeting the needs of at-risk popu-
22 lations and covered individuals with chronic
23 conditions or severe illnesses, including gender-
24 specific criteria and pediatric-specific criteria
25 where available and appropriate.

1 (B) CONTINUING USE OF STANDARDS IN
2 RETROSPECTIVE REVIEW.—If a health care
3 service has been specifically pre-authorized or
4 approved for a participant, beneficiary, or en-
5 rollee under such a program, the program shall
6 not, pursuant to retrospective review, revise or
7 modify the specific standards, criteria, or proce-
8 dures used for the utilization review for proce-
9 dures, treatment, and services delivered to the
10 enrollee during the same course of treatment.

11 (C) REVIEW OF SAMPLE OF CLAIMS DENI-
12 ALS.—Such a program shall provide for a peri-
13 odic evaluation of the clinical appropriateness of
14 at least a sample of denials of claims for bene-
15 fits.

16 (c) CONDUCT OF PROGRAM ACTIVITIES.—

17 (1) ADMINISTRATION BY HEALTH CARE PRO-
18 FESSIONALS.—A utilization review program shall be
19 administered by qualified health care professionals
20 who shall oversee review decisions.

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

23 (A) IN GENERAL.—A utilization review
24 program shall provide for the conduct of utiliza-
25 tion review activities only through personnel

1 who are qualified and have received appropriate
2 training in the conduct of such activities under
3 the program.

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

11 (C) PROHIBITION OF CONFLICTS.—Such a
12 program shall not permit a health care profes-
13 sional who is providing health care services to
14 an individual to perform utilization review ac-
15 tivities in connection with the health care serv-
16 ices being provided to the individual.

17 (3) ACCESSIBILITY OF REVIEW.—Such a pro-
18 gram shall provide that appropriate personnel per-
19 forming utilization review activities under the pro-
20 gram, including the utilization review administrator,
21 are reasonably accessible by toll-free telephone dur-
22 ing normal business hours to discuss patient care
23 and allow response to telephone requests, and that
24 appropriate provision is made to receive and respond
25 promptly to calls received during other hours.

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

8 **SEC. 102. PROCEDURES FOR INITIAL CLAIMS FOR BENE-**
9 **FITS AND PRIOR AUTHORIZATION DETER-**
10 **MINATIONS.**

11 (a) PROCEDURES OF INITIAL CLAIMS FOR BENE-
12 FITS.—

13 (1) IN GENERAL.—A group health plan, and a
14 health insurance issuer offering health insurance
15 coverage, shall—

16 (A) make a determination on an initial
17 claim for benefits by a participant, beneficiary,
18 or enrollee (or authorized representative) re-
19 garding payment or coverage for items or serv-
20 ices under the terms and conditions of the plan
21 or coverage involved, including any cost-sharing
22 amount that the participant, beneficiary, or en-
23 rollee is required to pay with respect to such
24 claim for benefits; and

1 (B) notify a participant, beneficiary, or en-
2 rollee (or authorized representative) and the
3 treating health care professional involved re-
4 garding a determination on an initial claim for
5 benefits made under the terms and conditions
6 of the plan or coverage, including any cost-shar-
7 ing amounts that the participant, beneficiary,
8 or enrollee may be required to make with re-
9 spect to such claim for benefits, and of the
10 right of the participant, beneficiary, or enrollee
11 to an internal appeal under section 103.

12 (2) ACCESS TO INFORMATION.—

13 (A) TIMELY PROVISION OF NECESSARY IN-
14 FORMATION.—With respect to an initial claim
15 for benefits, the participant, beneficiary, or en-
16 rollee (or authorized representative) and the
17 treating health care professional (if any) shall
18 provide the plan or issuer with access to infor-
19 mation requested by the plan or issuer that is
20 necessary to make a determination relating to
21 the claim. Such access shall be provided not
22 later than 5 days after the date on which the
23 request for information is received, or, in a case
24 described in subparagraph (B) or (C) of sub-
25 section (b)(1), by such earlier time as may be

1 necessary to comply with the applicable timeline
2 under such subparagraph.

3 (B) LIMITED EFFECT OF FAILURE ON
4 PLAN OR ISSUER'S OBLIGATIONS.—Failure of
5 the participant, beneficiary, or enrollee to com-
6 ply with the requirements of subparagraph (A)
7 shall not remove the obligation of the plan or
8 issuer to make a decision in accordance with
9 the medical exigencies of the case and as soon
10 as possible, based on the available information,
11 and failure to comply with the time limit estab-
12 lished by this paragraph shall not remove the
13 obligation of the plan or issuer to comply with
14 the requirements of this section.

15 (3) ORAL REQUESTS.—In the case of a claim
16 for benefits involving an expedited or concurrent de-
17 termination, a participant, beneficiary, or enrollee
18 (or authorized representative) may make an initial
19 claim for benefits orally, but a group health plan, or
20 health insurance issuer offering health insurance
21 coverage, may require that the participant, bene-
22 ficiary, or enrollee (or authorized representative)
23 provide written confirmation of such request in a
24 timely manner on a form provided by the plan or
25 issuer. In the case of such an oral request for bene-

1 fits, the making of the request (and the timing of
2 such request) shall be treated as the making at that
3 time of a claim for such benefits without regard to
4 whether and when a written confirmation of such re-
5 quest is made.

6 (b) TIMELINE FOR MAKING DETERMINATIONS.—

7 (1) PRIOR AUTHORIZATION DETERMINATION.—

8 (A) IN GENERAL.—A group health plan,
9 and a health insurance issuer offering health in-
10 surance coverage, shall make a prior authoriza-
11 tion determination on a claim for benefits
12 (whether oral or written) in accordance with the
13 medical exigencies of the case and as soon as
14 possible, but in no case later than 14 days from
15 the date on which the plan or issuer receives in-
16 formation that is reasonably necessary to enable
17 the plan or issuer to make a determination on
18 the request for prior authorization and in no
19 case later than 28 days after the date of the
20 claim for benefits is received.

21 (B) EXPEDITED DETERMINATION.—Not-
22 withstanding subparagraph (A), a group health
23 plan, and a health insurance issuer offering
24 health insurance coverage, shall expedite a prior
25 authorization determination on a claim for ben-

1 efits described in such subparagraph when a re-
2 quest for such an expedited determination is
3 made by a participant, beneficiary, or enrollee
4 (or authorized representative) at any time dur-
5 ing the process for making a determination and
6 a health care professional certifies, with the re-
7 quest, that a determination under the proce-
8 dures described in subparagraph (A) would seri-
9 ously jeopardize the life or health of the partici-
10 pant, beneficiary, or enrollee or the ability of
11 the participant, beneficiary, or enrollee to main-
12 tain or regain maximum function. Such deter-
13 mination shall be made in accordance with the
14 medical exigencies of the case and as soon as
15 possible, but in no case later than 72 hours
16 after the time the request is received by the
17 plan or issuer under this subparagraph.

18 (C) ONGOING CARE.—

19 (i) CONCURRENT REVIEW.—

20 (I) IN GENERAL.—Subject to
21 clause (ii), in the case of a concurrent
22 review of ongoing care (including hos-
23 pitalization), which results in a termi-
24 nation or reduction of such care, the
25 plan or issuer must provide by tele-

1 phone and in printed form notice of
2 the concurrent review determination
3 to the individual or the individual's
4 designee and the individual's health
5 care provider in accordance with the
6 medical exigencies of the case and as
7 soon as possible, with sufficient time
8 prior to the termination or reduction
9 to allow for an appeal under section
10 103(b)(3) to be completed before the
11 termination or reduction takes effect.

12 (II) CONTENTS OF NOTICE.—

13 Such notice shall include, with respect
14 to ongoing health care items and serv-
15 ices, the number of ongoing services
16 approved, the new total of approved
17 services, the date of onset of services,
18 and the next review date, if any, as
19 well as a statement of the individual's
20 rights to further appeal.

21 (ii) RULE OF CONSTRUCTION.—Clause
22 (i) shall not be construed as requiring
23 plans or issuers to provide coverage of care
24 that would exceed the coverage limitations
25 for such care.

1 (2) RETROSPECTIVE DETERMINATION.—A
2 group health plan, and a health insurance issuer of-
3 fering health insurance coverage, shall make a retro-
4 spective determination on a claim for benefits in ac-
5 cordance with the medical exigencies of the case and
6 as soon as possible, but not later than 30 days after
7 the date on which the plan or issuer receives infor-
8 mation that is reasonably necessary to enable the
9 plan or issuer to make a determination on the claim,
10 or, if earlier, 60 days after the date of receipt of the
11 claim for benefits.

12 (c) NOTICE OF A DENIAL OF A CLAIM FOR BENE-
13 FITS.—Written notice of a denial made under an initial
14 claim for benefits shall be issued to the participant, bene-
15 ficiary, or enrollee (or authorized representative) and the
16 treating health care professional in accordance with the
17 medical exigencies of the case and as soon as possible, but
18 in no case later than 2 days after the date of the deter-
19 mination (or, in the case described in subparagraph (B)
20 or (C) of subsection (b)(1), within the 72-hour or applica-
21 ble period referred to in such subparagraph).

22 (d) REQUIREMENTS OF NOTICE OF DETERMINA-
23 TIONS.—The written notice of a denial of a claim for bene-
24 fits determination under subsection (c) shall be provided
25 in printed form and written in a manner calculated to be

1 understood by the participant, beneficiary, or enrollee and
2 shall include—

3 (1) the specific reasons for the determination
4 (including a summary of the clinical or scientific evi-
5 dence used in making the determination);

6 (2) the procedures for obtaining additional in-
7 formation concerning the determination; and

8 (3) notification of the right to appeal the deter-
9 mination and instructions on how to initiate an ap-
10 peal in accordance with section 103.

11 (e) DEFINITIONS.—For purposes of this part:

12 (1) AUTHORIZED REPRESENTATIVE.—The term
13 “authorized representative” means, with respect to
14 an individual who is a participant, beneficiary, or en-
15 rollee, any health care professional or other person
16 acting on behalf of the individual with the individ-
17 ual’s consent or without such consent if the indi-
18 vidual is medically unable to provide such consent.

19 (2) CLAIM FOR BENEFITS.—The term “claim
20 for benefits” means any request for coverage (in-
21 cluding authorization of coverage), for eligibility, or
22 for payment in whole or in part, for an item or serv-
23 ice under a group health plan or health insurance
24 coverage.

1 (3) DENIAL OF CLAIM FOR BENEFITS.—The
2 term “denial” means, with respect to a claim for
3 benefits, a denial (in whole or in part) of, or a fail-
4 ure to act on a timely basis upon, the claim for ben-
5 efits and includes a failure to provide benefits (in-
6 cluding items and services) required to be provided
7 under this title.

8 (4) TREATING HEALTH CARE PROFESSIONAL.—
9 The term “treating health care professional” means,
10 with respect to services to be provided to a partici-
11 pant, beneficiary, or enrollee, a health care profes-
12 sional who is primarily responsible for delivering
13 those services to the participant, beneficiary, or en-
14 rollee.

15 **SEC. 103. INTERNAL APPEALS OF CLAIMS DENIALS.**

16 (a) RIGHT TO INTERNAL APPEAL.—

17 (1) IN GENERAL.—A participant, beneficiary, or
18 enrollee (or authorized representative) may appeal
19 any denial of a claim for benefits under section 102
20 under the procedures described in this section.

21 (2) TIME FOR APPEAL.—

22 (A) IN GENERAL.—A group health plan,
23 and a health insurance issuer offering health in-
24 surance coverage, shall ensure that a partici-
25 pant, beneficiary, or enrollee (or authorized rep-

1 representative) has a period of not less than 180
2 days beginning on the date of a denial of a
3 claim for benefits under section 102 in which to
4 appeal such denial under this section.

5 (B) DATE OF DENIAL.—For purposes of
6 subparagraph (A), the date of the denial shall
7 be deemed to be the date as of which the partic-
8 ipant, beneficiary, or enrollee knew of the denial
9 of the claim for benefits.

10 (3) FAILURE TO ACT.—The failure of a plan or
11 issuer to issue a determination on a claim for bene-
12 fits under section 102 within the applicable timeline
13 established for such a determination under such sec-
14 tion is a denial of a claim for benefits for purposes
15 this subtitle as of the date of the applicable deadline.

16 (4) PLAN WAIVER OF INTERNAL REVIEW.—A
17 group health plan, or health insurance issuer offer-
18 ing health insurance coverage, may waive the inter-
19 nal review process under this section. In such case
20 the plan or issuer shall provide notice to the partici-
21 pant, beneficiary, or enrollee (or authorized rep-
22 resentative) involved, the participant, beneficiary, or
23 enrollee (or authorized representative) involved shall
24 be relieved of any obligation to complete the internal
25 review involved, and may, at the option of such par-

1 participant, beneficiary, enrollee, or representative pro-
2 ceed directly to seek further appeal through external
3 review under section 104 or otherwise.

4 (b) TIMELINES FOR MAKING DETERMINATIONS.—

5 (1) ORAL REQUESTS.—In the case of an appeal
6 of a denial of a claim for benefits under this section
7 that involves an expedited or concurrent determina-
8 tion, a participant, beneficiary, or enrollee (or au-
9 thorized representative) may request such appeal
10 orally. A group health plan, or health insurance
11 issuer offering health insurance coverage, may re-
12 quire that the participant, beneficiary, or enrollee
13 (or authorized representative) provide written con-
14 firmation of such request in a timely manner on a
15 form provided by the plan or issuer. In the case of
16 such an oral request for an appeal of a denial, the
17 making of the request (and the timing of such re-
18 quest) shall be treated as the making at that time
19 of a request for an appeal without regard to whether
20 and when a written confirmation of such request is
21 made.

22 (2) ACCESS TO INFORMATION.—

23 (A) TIMELY PROVISION OF NECESSARY IN-
24 FORMATION.—With respect to an appeal of a
25 denial of a claim for benefits, the participant,

1 beneficiary, or enrollee (or authorized represent-
2 ative) and the treating health care professional
3 (if any) shall provide the plan or issuer with ac-
4 cess to information requested by the plan or
5 issuer that is necessary to make a determina-
6 tion relating to the appeal. Such access shall be
7 provided not later than 5 days after the date on
8 which the request for information is received,
9 or, in a case described in subparagraph (B) or
10 (C) of paragraph (3), by such earlier time as
11 may be necessary to comply with the applicable
12 timeline under such subparagraph.

13 (B) LIMITED EFFECT OF FAILURE ON
14 PLAN OR ISSUER'S OBLIGATIONS.—Failure of
15 the participant, beneficiary, or enrollee to com-
16 ply with the requirements of subparagraph (A)
17 shall not remove the obligation of the plan or
18 issuer to make a decision in accordance with
19 the medical exigencies of the case and as soon
20 as possible, based on the available information,
21 and failure to comply with the time limit estab-
22 lished by this paragraph shall not remove the
23 obligation of the plan or issuer to comply with
24 the requirements of this section.

1 (3) PRIOR AUTHORIZATION DETERMINA-
2 TIONS.—

3 (A) IN GENERAL.—Except as provided in
4 this paragraph or paragraph (4), a group
5 health plan, and a health insurance issuer offer-
6 ing health insurance coverage, shall make a de-
7 termination on an appeal of a denial of a claim
8 for benefits under this subsection in accordance
9 with the medical exigencies of the case and as
10 soon as possible, but in no case later than 14
11 days from the date on which the plan or issuer
12 receives information that is reasonably nec-
13 essary to enable the plan or issuer to make a
14 determination on the appeal and in no case
15 later than 28 days after the date the request
16 for the appeal is received.

17 (B) EXPEDITED DETERMINATION.—Not-
18 withstanding subparagraph (A), a group health
19 plan, and a health insurance issuer offering
20 health insurance coverage, shall expedite a prior
21 authorization determination on an appeal of a
22 denial of a claim for benefits described in sub-
23 paragraph (A), when a request for such an ex-
24 pedited determination is made by a participant,
25 beneficiary, or enrollee (or authorized represent-

1 ative) at any time during the process for mak-
2 ing a determination and a health care profes-
3 sional certifies, with the request, that a deter-
4 mination under the procedures described in sub-
5 paragraph (A) would seriously jeopardize the
6 life or health of the participant, beneficiary, or
7 enrollee or the ability of the participant, bene-
8 ficiary, or enrollee to maintain or regain max-
9 imum function. Such determination shall be
10 made in accordance with the medical exigencies
11 of the case and as soon as possible, but in no
12 case later than 72 hours after the time the re-
13 quest for such appeal is received by the plan or
14 issuer under this subparagraph.

15 (C) ONGOING CARE DETERMINATIONS.—

16 (i) IN GENERAL.—Subject to clause
17 (ii), in the case of a concurrent review de-
18 termination described in section
19 102(b)(1)(C)(i)(I), which results in a ter-
20 mination or reduction of such care, the
21 plan or issuer must provide notice of the
22 determination on the appeal under this
23 section by telephone and in printed form to
24 the individual or the individual’s designee
25 and the individual’s health care provider in

1 accordance with the medical exigencies of
2 the case and as soon as possible, with suf-
3 ficient time prior to the termination or re-
4 duction to allow for an external appeal
5 under section 104 to be completed before
6 the termination or reduction takes effect.

7 (ii) RULE OF CONSTRUCTION.—Clause

8 (i) shall not be construed as requiring
9 plans or issuers to provide coverage of care
10 that would exceed the coverage limitations
11 for such care.

12 (4) RETROSPECTIVE DETERMINATION.—A

13 group health plan, and a health insurance issuer of-
14 fering health insurance coverage, shall make a retro-
15 spective determination on an appeal of a denial of a
16 claim for benefits in no case later than 30 days after
17 the date on which the plan or issuer receives nec-
18 essary information that is reasonably necessary to
19 enable the plan or issuer to make a determination on
20 the appeal and in no case later than 60 days after
21 the date the request for the appeal is received.

22 (c) CONDUCT OF REVIEW.—

23 (1) IN GENERAL.—A review of a denial of a

24 claim for benefits under this section shall be con-

1 ducted by an individual with appropriate expertise
2 who was not involved in the initial determination.

3 (2) PEER REVIEW OF MEDICAL DECISIONS BY
4 HEALTH CARE PROFESSIONALS.—A review of an ap-
5 peal of a denial of a claim for benefits that is based
6 on a lack of medical necessity and appropriateness,
7 or based on an experimental or investigational treat-
8 ment, or requires an evaluation of medical facts—

9 (A) shall be made by a physician
10 (allopathic or osteopathic); or

11 (B) in a claim for benefits provided by a
12 non-physician health professional, shall be made
13 by a review panel including at least one prac-
14 ticing non-physician health professional of the
15 same or similar specialty;

16 with appropriate expertise (including, in the case of
17 a child, appropriate pediatric expertise) and acting
18 within the appropriate scope of practice within the
19 State in which the service is provided or rendered,
20 who was not involved in the initial determination.

21 (d) NOTICE OF DETERMINATION.—

22 (1) IN GENERAL.—Written notice of a deter-
23 mination made under an internal appeal of a denial
24 of a claim for benefits shall be issued to the partici-
25 pant, beneficiary, or enrollee (or authorized rep-

1 representative) and the treating health care professional
2 in accordance with the medical exigencies of the case
3 and as soon as possible, but in no case later than
4 2 days after the date of completion of the review (or,
5 in the case described in subparagraph (B) or (C) of
6 subsection (b)(3), within the 72-hour or applicable
7 period referred to in such subparagraph).

8 (2) FINAL DETERMINATION.—The decision by a
9 plan or issuer under this section shall be treated as
10 the final determination of the plan or issuer on a de-
11 nial of a claim for benefits. The failure of a plan or
12 issuer to issue a determination on an appeal of a de-
13 nial of a claim for benefits under this section within
14 the applicable timeline established for such a deter-
15 mination shall be treated as a final determination on
16 an appeal of a denial of a claim for benefits for pur-
17 poses of proceeding to external review under section
18 104.

19 (3) REQUIREMENTS OF NOTICE.—With respect
20 to a determination made under this section, the no-
21 tice described in paragraph (1) shall be provided in
22 printed form and written in a manner calculated to
23 be understood by the participant, beneficiary, or en-
24 rollee and shall include—

1 (A) the specific reasons for the determina-
2 tion (including a summary of the clinical or sci-
3 entific evidence used in making the determina-
4 tion);

5 (B) the procedures for obtaining additional
6 information concerning the determination; and

7 (C) notification of the right to an inde-
8 pendent external review under section 104 and
9 instructions on how to initiate such a review.

10 **SEC. 104. INDEPENDENT EXTERNAL APPEALS PROCE-**
11 **DURES.**

12 (a) **RIGHT TO EXTERNAL APPEAL.**—A group health
13 plan, and a health insurance issuer offering health insur-
14 ance coverage, shall provide in accordance with this sec-
15 tion participants, beneficiaries, and enrollees (or author-
16 ized representatives) with access to an independent exter-
17 nal review for any denial of a claim for benefits.

18 (b) **INITIATION OF THE INDEPENDENT EXTERNAL**
19 **REVIEW PROCESS.**—

20 (1) **TIME TO FILE.**—A request for an inde-
21 pendent external review under this section shall be
22 filed with the plan or issuer not later than 180 days
23 after the date on which the participant, beneficiary,
24 or enrollee receives notice of the denial under section
25 103(d) or notice of waiver of internal review under

1 section 103(a)(4) or the date on which the plan or
2 issuer has failed to make a timely decision under
3 section 103(d)(2) and notifies the participant or
4 beneficiary that it has failed to make a timely deci-
5 sion and that the beneficiary must file an appeal
6 with an external review entity within 180 days if the
7 participant or beneficiary desires to file such an ap-
8 peal.

9 (2) FILING OF REQUEST.—

10 (A) IN GENERAL.—Subject to the suc-
11 ceeding provisions of this subsection, a group
12 health plan, or health insurance issuer offering
13 health insurance coverage, may—

14 (i) except as provided in subparagraph

15 (B)(i), require that a request for review be
16 in writing;

17 (ii) limit the filing of such a request
18 to the participant, beneficiary, or enrollee
19 involved (or an authorized representative);

20 (iii) except if waived by the plan or
21 issuer under section 103(a)(4), condition
22 access to an independent external review
23 under this section upon a final determina-
24 tion of a denial of a claim for benefits

1 under the internal review procedure under
2 section 103;

3 (iv) except as provided in subpara-
4 graph (B)(ii), require payment of a filing
5 fee to the plan or issuer of a sum that does
6 not exceed \$25; and

7 (v) require that a request for review
8 include the consent of the participant, ben-
9 efiary, or enrollee (or authorized rep-
10 resentative) for the release of necessary
11 medical information or records of the par-
12 ticipant, beneficiary, or enrollee to the
13 qualified external review entity only for
14 purposes of conducting external review ac-
15 tivities.

16 (B) REQUIREMENTS AND EXCEPTION RE-
17 LATING TO GENERAL RULE.—

18 (i) ORAL REQUESTS PERMITTED IN
19 EXPEDITED OR CONCURRENT CASES.—In
20 the case of an expedited or concurrent ex-
21 ternal review as provided for under sub-
22 section (e), the request for such review
23 may be made orally. A group health plan,
24 or health insurance issuer offering health
25 insurance coverage, may require that the

1 participant, beneficiary, or enrollee (or au-
2 thorized representative) provide written
3 confirmation of such request in a timely
4 manner on a form provided by the plan or
5 issuer. Such written confirmation shall be
6 treated as a consent for purposes of sub-
7 paragraph (A)(v). In the case of such an
8 oral request for such a review, the making
9 of the request (and the timing of such re-
10 quest) shall be treated as the making at
11 that time of a request for such a review
12 without regard to whether and when a
13 written confirmation of such request is
14 made.

15 (ii) EXCEPTION TO FILING FEE RE-
16 QUIREMENT.—

17 (I) INDIGENCY.—Payment of a
18 filing fee shall not be required under
19 subparagraph (A)(iv) where there is a
20 certification (in a form and manner
21 specified in guidelines established by
22 the appropriate Secretary) that the
23 participant, beneficiary, or enrollee is
24 indigent (as defined in such guide-
25 lines).

1 (II) FEE NOT REQUIRED.—Pay-
2 ment of a filing fee shall not be re-
3 quired under subparagraph (A)(iv) if
4 the plan or issuer waives the internal
5 appeals process under section
6 103(a)(4).

7 (III) REFUNDING OF FEE.—The
8 filing fee paid under subparagraph
9 (A)(iv) shall be refunded if the deter-
10 mination under the independent exter-
11 nal review is to reverse the denial
12 which is the subject of the review.

13 (IV) COLLECTION OF FILING
14 FEE.—The failure to pay such a filing
15 fee shall not prevent the consideration
16 of a request for review but, subject to
17 the preceding provisions of this clause,
18 shall constitute a legal liability to pay.

19 (c) REFERRAL TO QUALIFIED EXTERNAL REVIEW
20 ENTITY UPON REQUEST.—

21 (1) IN GENERAL.—Upon the filing of a request
22 for independent external review with the group
23 health plan, or health insurance issuer offering
24 health insurance coverage, the plan or issuer shall
25 immediately refer such request, and forward the

1 plan or issuer's initial decision (including the infor-
2 mation described in section 103(d)(3)(A)), to a
3 qualified external review entity selected in accord-
4 ance with this section.

5 (2) ACCESS TO PLAN OR ISSUER AND HEALTH
6 PROFESSIONAL INFORMATION.—With respect to an
7 independent external review conducted under this
8 section, the participant, beneficiary, or enrollee (or
9 authorized representative), the plan or issuer, and
10 the treating health care professional (if any) shall
11 provide the external review entity with information
12 that is necessary to conduct a review under this sec-
13 tion, as determined and requested by the entity.
14 Such information shall be provided not later than 5
15 days after the date on which the request for infor-
16 mation is received, or, in a case described in clause
17 (ii) or (iii) of subsection (e)(1)(A), by such earlier
18 time as may be necessary to comply with the appli-
19 cable timeline under such clause.

20 (3) SCREENING OF REQUESTS BY QUALIFIED
21 EXTERNAL REVIEW ENTITIES.—

22 (A) IN GENERAL.—With respect to a re-
23 quest referred to a qualified external review en-
24 tity under paragraph (1) relating to a denial of
25 a claim for benefits, the entity shall refer such

1 request for the conduct of an independent med-
2 ical review unless the entity determines that—

3 (i) any of the conditions described in
4 clauses (ii) or (iii) of subsection (b)(2)(A)
5 have not been met;

6 (ii) the denial of the claim for benefits
7 does not involve a medically reviewable de-
8 cision under subsection (d)(2);

9 (iii) the denial of the claim for bene-
10 fits relates to a decision regarding whether
11 an individual is a participant, beneficiary,
12 or enrollee who is enrolled under the terms
13 and conditions of the plan or coverage (in-
14 cluding the applicability of any waiting pe-
15 riod under the plan or coverage); or

16 (iv) the denial of the claim for bene-
17 fits is a decision as to the application of
18 cost-sharing requirements or the applica-
19 tion of a specific exclusion or express limi-
20 tation on the amount, duration, or scope of
21 coverage of items or services under the
22 terms and conditions of the plan or cov-
23 erage unless the decision is a denial de-
24 scribed in subsection (d)(2).

1 Upon making a determination that any of
2 clauses (i) through (iv) applies with respect to
3 the request, the entity shall determine that the
4 denial of a claim for benefits involved is not eli-
5 gible for independent medical review under sub-
6 section (d), and shall provide notice in accord-
7 ance with subparagraph (C).

8 (B) PROCESS FOR MAKING DETERMINA-
9 TIONS.—

10 (i) NO DEFERENCE TO PRIOR DETER-
11 MINATIONS.—In making determinations
12 under subparagraph (A), there shall be no
13 deference given to determinations made by
14 the plan or issuer or the recommendation
15 of a treating health care professional (if
16 any).

17 (ii) USE OF APPROPRIATE PER-
18 SONNEL.—A qualified external review enti-
19 ty shall use appropriately qualified per-
20 sonnel to make determinations under this
21 section.

22 (C) NOTICES AND GENERAL TIMELINES
23 FOR DETERMINATION.—

24 (i) NOTICE IN CASE OF DENIAL OF
25 REFERRAL.—If the entity under this para-

1 graph does not make a referral to an inde-
2 pendent medical review panel, the entity
3 shall provide notice to the plan or issuer,
4 the participant, beneficiary, or enrollee (or
5 authorized representative) filing the re-
6 quest, and the treating health care profes-
7 sional (if any) that the denial is not sub-
8 ject to independent medical review. Such
9 notice—

10 (I) shall be written (and, in addi-
11 tion, may be provided orally) in a
12 manner calculated to be understood
13 by a participant or enrollee;

14 (II) shall include the reasons for
15 the determination;

16 (III) include any relevant terms
17 and conditions of the plan or cov-
18 erage; and

19 (IV) include a description of any
20 further recourse available to the indi-
21 vidual.

22 (ii) GENERAL TIMELINE FOR DETER-
23 MINATIONS.—Upon receipt of information
24 under paragraph (2), the qualified external
25 review entity, and if required the inde-

1 pendent medical review panel, shall make a
2 determination within the overall timeline
3 that is applicable to the case under review
4 as described in subsection (e), except that
5 if the entity determines that a referral to
6 an independent medical review panel is not
7 required, the entity shall provide notice of
8 such determination to the participant, ben-
9 eficiary, or enrollee (or authorized rep-
10 resentative) within such timeline and with-
11 in 2 days of the date of such determina-
12 tion.

13 (d) INDEPENDENT MEDICAL REVIEW.—

14 (1) IN GENERAL.—If a qualified external review
15 entity determines under subsection (c) that a denial
16 of a claim for benefits is eligible for independent
17 medical review, the entity shall refer the denial in-
18 volved to an independent medical reviewer for the
19 conduct of an independent medical review under this
20 subsection.

21 (2) MEDICALLY REVIEWABLE DECISIONS.—A
22 denial of a claim for benefits is eligible for inde-
23 pendent medical review if the benefit for the item or
24 service for which the claim is made would be a cov-
25 ered benefit under the terms and conditions of the

1 plan or coverage but for one (or more) of the fol-
2 lowing determinations:

3 (A) DENIALS BASED ON MEDICAL NECES-
4 SITY AND APPROPRIATENESS.—A determination
5 that the item or service is not covered because
6 it is not medically necessary and appropriate or
7 based on the application of substantially equiva-
8 lent terms.

9 (B) DENIALS BASED ON EXPERIMENTAL
10 OR INVESTIGATIONAL TREATMENT.—A deter-
11 mination that the item or service is not covered
12 because it is experimental or investigational or
13 based on the application of substantially equiva-
14 lent terms.

15 (C) DENIALS OTHERWISE BASED ON AN
16 EVALUATION OF MEDICAL FACTS.—A deter-
17 mination that the item or service or condition
18 is not covered based on grounds that require an
19 evaluation of the medical facts by a health care
20 professional in the specific case involved to de-
21 termine the coverage and extent of coverage of
22 the item or service or condition.

23 (3) INDEPENDENT MEDICAL REVIEW DETER-
24 MINATION.—

1 (A) IN GENERAL.—An independent med-
2 ical review panel under this section shall make
3 a new independent determination with respect
4 to whether or not the denial of a claim for a
5 benefit that is the subject of the review should
6 be upheld or reversed.

7 (B) STANDARD FOR DETERMINATION.—
8 The independent medical review panel’s deter-
9 mination relating to the medical necessity and
10 appropriateness, or the experimental or inves-
11 tigational nature, or the evaluation of the med-
12 ical facts, of the item, service, or condition in-
13 volved shall be based on the medical condition
14 of the participant, beneficiary, or enrollee (in-
15 cluding the medical records of the participant,
16 beneficiary, or enrollee) and valid, relevant sci-
17 entific evidence and clinical evidence, including
18 peer-reviewed medical literature or findings and
19 including expert opinion.

20 (C) NO COVERAGE FOR EXCLUDED BENE-
21 FITS.—Nothing in this subsection shall be con-
22 strued to permit an independent medical review
23 panel to require that a group health plan, or
24 health insurance issuer offering health insur-
25 ance coverage, provide coverage for items or

1 services for which benefits are specifically ex-
2 cluded or expressly limited under the plan or
3 coverage in the plain language of the plan docu-
4 ment (and which are disclosed under section
5 121(b)(1)(C)). Notwithstanding any other pro-
6 vision of this Act, any exclusion of an exact
7 medical procedure, any exact time limit on the
8 duration or frequency of coverage, and any
9 exact dollar limit on the amount of coverage
10 that is specifically enumerated and defined (in
11 the plain language of the plan or coverage docu-
12 ments) under the plan or coverage offered by a
13 group health plan or health insurance issuer of-
14 fering health insurance coverage and that is
15 disclosed under section 121(b)(1) shall be con-
16 sidered to govern the scope of the benefits that
17 may be required: *Provided*, That the terms and
18 conditions of the plan or coverage relating to
19 such an exclusion or limit are in compliance
20 with the requirements of law.

21 (D) EVIDENCE AND INFORMATION TO BE
22 USED IN MEDICAL REVIEWS.—In making a de-
23 termination under this subsection, the inde-
24 pendent medical review panel shall also consider

1 appropriate and available evidence and informa-
2 tion, including the following:

3 (i) The determination made by the
4 plan or issuer with respect to the claim
5 upon internal review and the evidence,
6 guidelines, or rationale used by the plan or
7 issuer in reaching such determination.

8 (ii) The recommendation of the treat-
9 ing health care professional and the evi-
10 dence, guidelines, and rationale used by
11 the treating health care professional in
12 reaching such recommendation.

13 (iii) Additional relevant evidence or
14 information obtained by the review panel
15 or submitted by the plan, issuer, partici-
16 pant, beneficiary, or enrollee (or an au-
17 thorized representative), or treating health
18 care professional.

19 (iv) The plan or coverage document.

20 (E) INDEPENDENT DETERMINATION.—In
21 making determinations under this section, a
22 qualified external review entity and an inde-
23 pendent medical review panel shall—

24 (i) consider the claim under review
25 without deference to the determinations

1 made by the plan or issuer or the rec-
2 ommendation of the treating health care
3 professional (if any); and

4 (ii) consider, but not be bound by, the
5 definition used by the plan or issuer of
6 “medically necessary and appropriate”, or
7 “experimental or investigational”, or other
8 substantially equivalent terms that are
9 used by the plan or issuer to describe med-
10 ical necessity and appropriateness or ex-
11 perimental or investigational nature of the
12 treatment.

13 (F) DETERMINATION OF INDEPENDENT
14 MEDICAL REVIEW PANEL.—An independent
15 medical review panel shall, in accordance with
16 the deadlines described in subsection (e), pre-
17 pare a written determination to uphold or re-
18 verse the denial under review. Such written de-
19 termination shall include—

20 (i) the determination of the review
21 panel;

22 (ii) the specific reasons of the review
23 panel for such determination, including a
24 summary of the clinical or scientific evi-

1 dence used in making the determination;
2 and

3 (iii) with respect to a determination to
4 reverse the denial under review, a time-
5 frame within which the plan or issuer must
6 comply with such determination.

7 (G) NONBINDING NATURE OF ADDITIONAL
8 RECOMMENDATIONS.—In addition to the deter-
9 mination under subparagraph (F), the review
10 panel may provide the plan or issuer and the
11 treating health care professional with additional
12 recommendations in connection with such a de-
13 termination, but any such recommendations
14 shall not affect (or be treated as part of) the
15 determination and shall not be binding on the
16 plan or issuer.

17 (e) TIMELINES AND NOTIFICATIONS.—

18 (1) TIMELINES FOR INDEPENDENT MEDICAL
19 REVIEW.—

20 (A) PRIOR AUTHORIZATION DETERMINA-
21 TION.—

22 (i) IN GENERAL.—The independent
23 medical review panel shall make a deter-
24 mination on a denial of a claim for benefits
25 that is referred to the review panel under

1 subsection (c)(3) in accordance with the
2 medical exigencies of the case and as soon
3 as possible, but in no case later than 14
4 days after the date of receipt of informa-
5 tion under subsection (c)(2) if the review
6 involves a prior authorization of items or
7 services and in no case later than 21 days
8 after the date the request for external re-
9 view is received.

10 (ii) EXPEDITED DETERMINATION.—

11 Notwithstanding clause (i) and subject to
12 clause (iii), the independent medical review
13 panel shall make an expedited determina-
14 tion on a denial of a claim for benefits de-
15 scribed in clause (i), when a request for
16 such an expedited determination is made
17 by a participant, beneficiary, or enrollee
18 (or authorized representative) at any time
19 during the process for making a deter-
20 mination, and a health care professional
21 certifies, with the request, that a deter-
22 mination under the timeline described in
23 clause (i) would seriously jeopardize the
24 life or health of the participant, bene-
25 ficiary, or enrollee or the ability of the par-

1 participant, beneficiary, or enrollee to main-
2 tain or regain maximum function. Such de-
3 termination shall be made in accordance
4 with the medical exigencies of the case and
5 as soon as possible, but in no case later
6 than 72 hours after the time the request
7 for external review is received by the quali-
8 fied external review entity.

9 (iii) ONGOING CARE DETERMINA-
10 TION.—Notwithstanding clause (i), in the
11 case of a review described in such clause
12 that involves a termination or reduction of
13 care, the notice of the determination shall
14 be completed not later than 24 hours after
15 the time the request for external review is
16 received by the qualified external review
17 entity and before the end of the approved
18 period of care.

19 (B) RETROSPECTIVE DETERMINATION.—
20 The independent medical review panel shall
21 complete a review in the case of a retrospective
22 determination on an appeal of a denial of a
23 claim for benefits that is referred to the review
24 panel under subsection (c)(3) in no case later
25 than 30 days after the date of receipt of infor-

1 mation under subsection (e)(2) and in no case
2 later than 60 days after the date the request
3 for external review is received by the qualified
4 external review entity.

5 (2) NOTIFICATION OF DETERMINATION.—The
6 external review entity shall ensure that the plan or
7 issuer, the participant, beneficiary, or enrollee (or
8 authorized representative) and the treating health
9 care professional (if any) receives a copy of the writ-
10 ten determination of the independent medical review
11 panel prepared under subsection (d)(3)(F). Nothing
12 in this paragraph shall be construed as preventing
13 an entity or review panel from providing an initial
14 oral notice of the review panel’s determination.

15 (3) FORM OF NOTICES.—Determinations and
16 notices under this subsection shall be written in a
17 manner calculated to be understood by a participant.

18 (f) COMPLIANCE.—

19 (1) APPLICATION OF DETERMINATIONS.—

20 (A) EXTERNAL REVIEW DETERMINATIONS
21 BINDING ON PLAN.—The determinations of an
22 external review entity and an independent med-
23 ical review panel under this section shall be
24 binding upon the plan or issuer involved.

1 (B) COMPLIANCE WITH DETERMINA-
2 TION.—If the determination of an independent
3 medical review panel is to reverse the denial,
4 the plan or issuer, upon the receipt of such de-
5 termination, shall authorize coverage to comply
6 with the medical reviewer’s determination in ac-
7 cordance with the timeframe established by the
8 medical review panel.

9 (2) FAILURE TO COMPLY.—

10 (A) IN GENERAL.—If a plan or issuer fails
11 to comply with the timeframe established under
12 paragraph (1)(B) with respect to a participant,
13 beneficiary, or enrollee, where such failure to
14 comply is caused by the plan or issuer, the par-
15 ticipant, beneficiary, or enrollee may obtain the
16 items or services involved (in a manner con-
17 sistent with the determination of the inde-
18 pendent external review panel) from any pro-
19 vider regardless of whether such provider is a
20 participating provider under the plan or cov-
21 erage.

22 (B) REIMBURSEMENT.—

23 (i) IN GENERAL.—Where a partici-
24 pant, beneficiary, or enrollee obtains items
25 or services in accordance with subpara-

1 graph (A), the plan or issuer involved shall
2 provide for reimbursement of the costs of
3 such items or services. Such reimburse-
4 ment shall be made to the treating health
5 care professional or to the participant, ben-
6 eficiary, or enrollee (in the case of a partic-
7 ipant, beneficiary, or enrollee who pays for
8 the costs of such items or services).

9 (ii) AMOUNT.—The plan or issuer
10 shall fully reimburse a professional, partici-
11 pant, beneficiary, or enrollee under clause
12 (i) for the total costs of the items or serv-
13 ices provided (regardless of any plan limi-
14 tations that may apply to the coverage of
15 such items or services) so long as the items
16 or services were provided in a manner con-
17 sistent with the determination of the inde-
18 pendent medical review panel.

19 (C) FAILURE TO REIMBURSE.—Where a
20 plan or issuer fails to provide reimbursement to
21 a professional, participant, beneficiary, or en-
22 rollee in accordance with this paragraph, the
23 professional, participant, beneficiary, or enrollee
24 may commence a civil action (or utilize other
25 remedies available under law) to recover only

1 the amount of any such reimbursement that is
2 owed by the plan or issuer and any necessary
3 legal costs or expenses (including attorney's
4 fees) incurred in recovering such reimburse-
5 ment.

6 (D) AVAILABLE REMEDIES.—The remedies
7 provided under this paragraph are in addition
8 to any other available remedies.

9 (3) PENALTIES AGAINST AUTHORIZED OFFI-
10 CIALS FOR REFUSING TO AUTHORIZE THE DETER-
11 MINATION OF AN EXTERNAL REVIEW ENTITY.—

12 (A) MONETARY PENALTIES.—

13 (i) IN GENERAL.—In any case in
14 which the determination of an external re-
15 view entity is not followed by a group
16 health plan, or by a health insurance issuer
17 offering health insurance coverage, any
18 person who, acting in the capacity of au-
19 thORIZING the benefit, causes such refusal
20 may, in the discretion of a court of com-
21 petent jurisdiction, be liable to an ag-
22 grieved participant, beneficiary, or enrollee
23 for a civil penalty in an amount of up to
24 \$1,000 a day from the date on which the
25 determination was transmitted to the plan

1 or issuer by the external review entity until
2 the date the refusal to provide the benefit
3 is corrected.

4 (ii) ADDITIONAL PENALTY FOR FAIL-
5 ING TO FOLLOW TIMELINE.—In any case
6 in which treatment was not commenced by
7 the plan in accordance with the determina-
8 tion of an independent external review
9 panel, the Secretary shall assess a civil
10 penalty of \$10,000 against the plan and
11 the plan shall pay such penalty to the par-
12 ticipant, beneficiary, or enrollee involved.

13 (B) CEASE AND DESIST ORDER AND
14 ORDER OF ATTORNEY'S FEES.—In any action
15 described in subparagraph (A) brought by a
16 participant, beneficiary, or enrollee with respect
17 to a group health plan, or a health insurance
18 issuer offering health insurance coverage, in
19 which a plaintiff alleges that a person referred
20 to in such subparagraph has taken an action re-
21 sulting in a refusal of a benefit determined by
22 an external appeal entity to be covered, or has
23 failed to take an action for which such person
24 is responsible under the terms and conditions of
25 the plan or coverage and which is necessary

1 under the plan or coverage for authorizing a
2 benefit, the court shall cause to be served on
3 the defendant an order requiring the defend-
4 ant—

5 (i) to cease and desist from the al-
6 leged action or failure to act; and

7 (ii) to pay to the plaintiff a reasonable
8 attorney's fee and other reasonable costs
9 relating to the prosecution of the action on
10 the charges on which the plaintiff prevails.

11 (C) ADDITIONAL CIVIL PENALTIES.—

12 (i) IN GENERAL.—In addition to any
13 penalty imposed under subparagraph (A)
14 or (B), the appropriate Secretary may as-
15 sess a civil penalty against a person acting
16 in the capacity of authorizing a benefit de-
17 termined by an external review entity for
18 one or more group health plans, or health
19 insurance issuers offering health insurance
20 coverage, for—

21 (I) any pattern or practice of re-
22 peated refusal to authorize a benefit
23 determined by an external appeal enti-
24 ty to be covered; or

1 (II) any pattern or practice of re-
2 peated violations of the requirements
3 of this section with respect to such
4 plan or coverage.

5 (ii) STANDARD OF PROOF AND
6 AMOUNT OF PENALTY.—Such penalty shall
7 be payable only upon proof by clear and
8 convincing evidence of such pattern or
9 practice and shall be in an amount not to
10 exceed the lesser of—

11 (I) 25 percent of the aggregate
12 value of benefits shown by the appro-
13 priate Secretary to have not been pro-
14 vided, or unlawfully delayed, in viola-
15 tion of this section under such pattern
16 or practice; or

17 (II) \$500,000.

18 (D) REMOVAL AND DISQUALIFICATION.—
19 Any person acting in the capacity of author-
20 izing benefits who has engaged in any such pat-
21 tern or practice described in subparagraph
22 (C)(i) with respect to a plan or coverage, upon
23 the petition of the appropriate Secretary, may
24 be removed by the court from such position,
25 and from any other involvement, with respect to

1 such a plan or coverage, and may be precluded
2 from returning to any such position or involve-
3 ment for a period determined by the court.

4 (4) PROTECTION OF LEGAL RIGHTS.—Nothing
5 in this subsection or subtitle shall be construed as
6 altering or eliminating any cause of action or legal
7 rights or remedies of participants, beneficiaries, en-
8 rollees, and others under State or Federal law (in-
9 cluding sections 502 and 503 of the Employee Re-
10 tirement Income Security Act of 1974), including
11 the right to file judicial actions to enforce rights.

12 (g) QUALIFICATIONS OF INDEPENDENT MEDICAL
13 REVIEWERS.—

14 (1) IN GENERAL.—In referring a denial to an
15 independent medical review panel to conduct inde-
16 pendent medical review under subsection (c), the
17 qualified external review entity shall ensure that—

18 (A) each independent medical reviewer
19 meets the qualifications described in paragraphs
20 (2) and (3);

21 (B) with respect to each review, the review
22 panel meets the requirements of paragraph (4)
23 and at least 1 reviewer on the panel meets the
24 requirements described in paragraph (5); and

1 (C) compensation provided by the entity to
2 each reviewer is consistent with paragraph (6).

3 (2) LICENSURE AND EXPERTISE.—Each inde-
4 pendent medical reviewer shall be a physician
5 (allopathic or osteopathic) or health care profes-
6 sional who—

7 (A) is appropriately credentialed or li-
8 censed in 1 or more States to deliver health
9 care services; and

10 (B) typically treats the condition, makes
11 the diagnosis, or provides the type of treatment
12 under review.

13 (3) INDEPENDENCE.—

14 (A) IN GENERAL.—Subject to subpara-
15 graph (B), each independent medical reviewer
16 in a case shall—

17 (i) not be a related party (as defined
18 in paragraph (7));

19 (ii) not have a material familial, fi-
20 nancial, or professional relationship with
21 such a party; and

22 (iii) not otherwise have a conflict of
23 interest with such a party (as determined
24 under regulations).

1 (B) EXCEPTION.—Nothing in subpara-
2 graph (A) shall be construed to—

3 (i) prohibit an individual, solely on the
4 basis of affiliation with the plan or issuer,
5 from serving as an independent medical re-
6 viewer if—

7 (I) a non-affiliated individual is
8 not reasonably available;

9 (II) the affiliated individual is
10 not involved in the provision of items
11 or services in the case under review;

12 (III) the fact of such an affili-
13 ation is disclosed to the plan or issuer
14 and the participant, beneficiary, or
15 enrollee (or authorized representative)
16 and neither party objects; and

17 (IV) the affiliated individual is
18 not an employee of the plan or issuer
19 and does not provide services exclu-
20 sively or primarily to or on behalf of
21 the plan or issuer;

22 (ii) prohibit an individual who has
23 staff privileges at the institution where the
24 treatment involved takes place from serv-
25 ing as an independent medical reviewer

1 merely on the basis of such affiliation if
2 the affiliation is disclosed to the plan or
3 issuer and the participant, beneficiary, or
4 enrollee (or authorized representative), and
5 neither party objects; or

6 (iii) prohibit receipt of compensation
7 by an independent medical reviewer from
8 an entity if the compensation is provided
9 consistent with paragraph (6).

10 (4) PRACTICING HEALTH CARE PROFESSIONAL
11 IN SAME FIELD.—

12 (A) IN GENERAL.—In a case involving
13 treatment, or the provision of items or serv-
14 ices—

15 (i) by a physician, a reviewer shall be
16 a practicing physician (allopathic or osteo-
17 pathic) of the same or similar specialty, as
18 a physician who, acting within the appro-
19 priate scope of practice within the State in
20 which the service is provided or rendered,
21 typically treats the condition, makes the
22 diagnosis, or provides the type of treat-
23 ment under review; or

24 (ii) by a non-physician health care
25 professional, the independent medical re-

1 view panel shall include at least one prac-
2 ticing non-physician health care profes-
3 sional of the same or similar specialty as
4 the non-physician health care professional
5 who, acting within the appropriate scope of
6 practice within the State in which the serv-
7 ice is provided or rendered, typically treats
8 the condition, makes the diagnosis, or pro-
9 vides the type of treatment under review.

10 (B) PRACTICING DEFINED.—For purposes
11 of this paragraph, the term “practicing” means,
12 with respect to an individual who is a physician
13 or other health care professional that the indi-
14 vidual provides health care services to individual
15 patients on average at least 2 days per week.

16 (5) PEDIATRIC EXPERTISE.—In the case of an
17 external review relating to a child, a reviewer shall
18 have expertise under paragraph (2) in pediatrics.

19 (6) LIMITATIONS ON REVIEWER COMPENSA-
20 TION.—Compensation provided by a qualified exter-
21 nal review entity to an independent medical reviewer
22 in connection with a review under this section
23 shall—

24 (A) not exceed a reasonable level; and

1 (B) not be contingent on the decision ren-
2 dered by the reviewer.

3 (7) RELATED PARTY DEFINED.—For purposes
4 of this section, the term “related party” means, with
5 respect to a denial of a claim under a plan or cov-
6 erage relating to a participant, beneficiary, or en-
7 rollee, any of the following:

8 (A) The plan, plan sponsor, or issuer in-
9 volved, or any fiduciary, officer, director, or em-
10 ployee of such plan, plan sponsor, or issuer.

11 (B) The participant, beneficiary, or en-
12 rollee (or authorized representative).

13 (C) The health care professional that pro-
14 vides the items or services involved in the de-
15 nial.

16 (D) The institution at which the items or
17 services (or treatment) involved in the denial
18 are provided.

19 (E) The manufacturer of any drug or
20 other item that is included in the items or serv-
21 ices involved in the denial.

22 (F) Any other party determined under any
23 regulations to have a substantial interest in the
24 denial involved.

25 (h) QUALIFIED EXTERNAL REVIEW ENTITIES.—

1 (1) SELECTION OF QUALIFIED EXTERNAL RE-
2 VIEW ENTITIES.—

3 (A) LIMITATION ON PLAN OR ISSUER SE-
4 LECTION.—The appropriate Secretary shall im-
5 plement procedures—

6 (i) to assure that the selection process
7 among qualified external review entities
8 will not create any incentives for external
9 review entities to make a decision in a bi-
10 ased manner; and

11 (ii) for auditing a sample of decisions
12 by such entities to assure that no such de-
13 cisions are made in a biased manner.

14 No such selection process under the procedures
15 implemented by the appropriate Secretary may
16 give either the patient or the plan or issuer any
17 ability to determine or influence the selection of
18 a qualified external review entity to review the
19 case of any participant, beneficiary, or enrollee.

20 (B) STATE AUTHORITY WITH RESPECT TO
21 QUALIFIED EXTERNAL REVIEW ENTITIES FOR
22 HEALTH INSURANCE ISSUERS.—With respect to
23 health insurance issuers offering health insur-
24 ance coverage in a State, the State may provide
25 for external review activities to be conducted by

1 a qualified external appeal entity that is des-
2 ignated by the State or that is selected by the
3 State in a manner determined by the State to
4 assure an unbiased determination.

5 (2) CONTRACT WITH QUALIFIED EXTERNAL RE-
6 VIEW ENTITY.—Except as provided in paragraph
7 (1)(B), the external review process of a plan or
8 issuer under this section shall be conducted under a
9 contract between the plan or issuer and 1 or more
10 qualified external review entities (as defined in para-
11 graph (4)(A)).

12 (3) TERMS AND CONDITIONS OF CONTRACT.—
13 The terms and conditions of a contract under para-
14 graph (2) shall—

15 (A) be consistent with the standards the
16 appropriate Secretary shall establish to assure
17 there is no real or apparent conflict of interest
18 in the conduct of external review activities; and

19 (B) provide that the costs of the external
20 review process shall be borne by the plan or
21 issuer.

22 Subparagraph (B) shall not be construed as apply-
23 ing to the imposition of a filing fee under subsection
24 (b)(2)(A)(iv) or costs incurred by the participant,
25 beneficiary, or enrollee (or authorized representative)

1 or treating health care professional (if any) in sup-
2 port of the review, including the provision of addi-
3 tional evidence or information.

4 (4) QUALIFICATIONS.—

5 (A) IN GENERAL.—In this section, the
6 term “qualified external review entity” means,
7 in relation to a plan or issuer, an entity that is
8 initially certified (and periodically recertified)
9 under subparagraph (C) as meeting the fol-
10 lowing requirements:

11 (i) The entity has (directly or through
12 contracts or other arrangements) sufficient
13 medical, legal, and other expertise and suf-
14 ficient staffing to carry out duties of a
15 qualified external review entity under this
16 section on a timely basis, including making
17 determinations under subsection (b)(2)(A)
18 and providing for independent medical re-
19 views under subsection (d).

20 (ii) The entity is not a plan or issuer
21 or an affiliate or a subsidiary of a plan or
22 issuer, and is not an affiliate or subsidiary
23 of a professional or trade association of
24 plans or issuers or of health care providers.

1 (iii) The entity has provided assur-
2 ances that it will conduct external review
3 activities consistent with the applicable re-
4 quirements of this section and standards
5 specified in subparagraph (C), including
6 that it will not conduct any external review
7 activities in a case unless the independence
8 requirements of subparagraph (B) are met
9 with respect to the case.

10 (iv) The entity has provided assur-
11 ances that it will provide information in a
12 timely manner under subparagraph (D).

13 (v) The entity meets such other re-
14 quirements as the appropriate Secretary
15 provides by regulation.

16 (B) INDEPENDENCE REQUIREMENTS.—

17 (i) IN GENERAL.—Subject to clause
18 (ii), an entity meets the independence re-
19 quirements of this subparagraph with re-
20 spect to any case if the entity—

21 (I) is not a related party (as de-
22 fined in subsection (g)(7));

23 (II) does not have a material fa-
24 milial, financial, or professional rela-
25 tionship with such a party; and

1 (III) does not otherwise have a
2 conflict of interest with such a party
3 (as determined under regulations).

4 (ii) EXCEPTION FOR REASONABLE
5 COMPENSATION.—Nothing in clause (i)
6 shall be construed to prohibit receipt by a
7 qualified external review entity of com-
8 pensation from a plan or issuer for the
9 conduct of external review activities under
10 this section if the compensation is provided
11 consistent with clause (iii).

12 (iii) LIMITATIONS ON ENTITY COM-
13 PENSATION.—Compensation provided by a
14 plan or issuer to a qualified external review
15 entity in connection with reviews under
16 this section shall—

17 (I) not exceed a reasonable level;

18 and

19 (II) not be contingent on any de-
20 cision rendered by the entity or by
21 any independent medical review panel.

22 (C) CERTIFICATION AND RECERTIFICATION
23 PROCESS.—

1 (i) IN GENERAL.—The initial certifi-
2 cation and recertification of a qualified ex-
3 ternal review entity shall be made—

4 (I) under a process that is recog-
5 nized or approved by the appropriate
6 Secretary; or

7 (II) by a qualified private stand-
8 ard-setting organization that is ap-
9 proved by the appropriate Secretary
10 under clause (iii).

11 In taking action under subclause (I), the
12 appropriate Secretary shall give deference
13 to entities that are under contract with the
14 Federal Government or with an applicable
15 State authority to perform functions of the
16 type performed by qualified external review
17 entities.

18 (ii) PROCESS.—The appropriate Sec-
19 retary shall not recognize or approve a
20 process under clause (i)(I) unless the proc-
21 ess applies standards (as promulgated in
22 regulations) that ensure that a qualified
23 external review entity—

24 (I) will carry out (and has car-
25 ried out, in the case of recertification)

1 the responsibilities of such an entity
2 in accordance with this section, in-
3 cluding meeting applicable deadlines;

4 (II) will meet (and has met, in
5 the case of recertification) appropriate
6 indicators of fiscal integrity;

7 (III) will maintain (and has
8 maintained, in the case of recertifi-
9 cation) appropriate confidentiality
10 with respect to individually identifi-
11 able health information obtained in
12 the course of conducting external re-
13 view activities; and

14 (IV) in the case of recertification,
15 shall review the matters described in
16 clause (iv).

17 (iii) APPROVAL OF QUALIFIED PRI-
18 VATE STANDARD-SETTING ORGANIZA-
19 TIONS.—For purposes of clause (i)(II), the
20 appropriate Secretary may approve a quali-
21 fied private standard-setting organization
22 if such Secretary finds that the organiza-
23 tion only certifies (or recertifies) external
24 review entities that meet at least the
25 standards required for the certification (or

1 recertification) of external review entities
2 under clause (ii).

3 (iv) CONSIDERATIONS IN RECERTIFI-
4 CATIONS.—In conducting recertifications of
5 a qualified external review entity under
6 this paragraph, the appropriate Secretary
7 or organization conducting the recertifi-
8 cation shall review compliance of the entity
9 with the requirements for conducting ex-
10 ternal review activities under this section,
11 including the following:

12 (I) Provision of information
13 under subparagraph (D).

14 (II) Adherence to applicable
15 deadlines (both by the entity and by
16 independent medical review panels it
17 refers cases to).

18 (III) Compliance with limitations
19 on compensation (with respect to both
20 the entity and independent medical re-
21 view panels it refers cases to).

22 (IV) Compliance with applicable
23 independence requirements.

24 (V) Compliance with the require-
25 ment of subsection (d)(1) that only

1 medically reviewable decisions shall be
2 the subject of independent medical re-
3 view and with the requirement of sub-
4 section (d)(3) that independent med-
5 ical review panels may not require
6 coverage for specifically excluded ben-
7 efits.

8 (v) PERIOD OF CERTIFICATION OR RE-
9 CERTIFICATION.—A certification or recer-
10 tification provided under this paragraph
11 shall extend for a period not to exceed 2
12 years.

13 (vi) REVOCATION.—A certification or
14 recertification under this paragraph may
15 be revoked by the appropriate Secretary or
16 by the organization providing such certifi-
17 cation upon a showing of cause. The Sec-
18 retary, or organization, shall revoke a cer-
19 tification or deny a recertification with re-
20 spect to an entity if there is a showing that
21 the entity has a pattern or practice of or-
22 dering coverage for benefits that are spe-
23 cifically excluded under the plan or cov-
24 erage.

1 (vii) PETITION FOR DENIAL OR WITH-
2 DRAWAL.—An individual may petition the
3 Secretary, or an organization providing the
4 certification involves, for a denial of recer-
5 tification or a withdrawal of a certification
6 with respect to an entity under this sub-
7 paragraph if there is a pattern or practice
8 of such entity failing to meet a require-
9 ment of this section.

10 (viii) SUFFICIENT NUMBER OF ENTI-
11 TIES.—The appropriate Secretary shall
12 certify and recertify a number of external
13 review entities which is sufficient to ensure
14 the timely and efficient provision of review
15 services.

16 (D) PROVISION OF INFORMATION.—

17 (i) IN GENERAL.—A qualified external
18 review entity shall provide to the appro-
19 priate Secretary, in such manner and at
20 such times as such Secretary may require,
21 such information (relating to the denials
22 which have been referred to the entity for
23 the conduct of external review under this
24 section) as such Secretary determines ap-
25 propriate to assure compliance with the

1 independence and other requirements of
2 this section to monitor and assess the qual-
3 ity of its external review activities and lack
4 of bias in making determinations. Such in-
5 formation shall include information de-
6 scribed in clause (ii) but shall not include
7 individually identifiable medical informa-
8 tion.

9 (ii) INFORMATION TO BE IN-
10 CLUDED.—The information described in
11 this subclause with respect to an entity is
12 as follows:

13 (I) The number and types of de-
14 nials for which a request for review
15 has been received by the entity.

16 (II) The disposition by the entity
17 of such denials, including the number
18 referred to an independent medical re-
19 view panel and the reasons for such
20 dispositions (including the application
21 of exclusions), on a plan or issuer-spe-
22 cific basis and on a health care spe-
23 cialty-specific basis.

1 (III) The length of time in mak-
2 ing determinations with respect to
3 such denials.

4 (IV) Updated information on the
5 information required to be submitted
6 as a condition of certification with re-
7 spect to the entity's performance of
8 external review activities.

9 (iii) INFORMATION TO BE PROVIDED
10 TO CERTIFYING ORGANIZATION.—

11 (I) IN GENERAL.—In the case of
12 a qualified external review entity
13 which is certified (or recertified)
14 under this subsection by a qualified
15 private standard-setting organization,
16 at the request of the organization, the
17 entity shall provide the organization
18 with the information provided to the
19 appropriate Secretary under clause
20 (i).

21 (II) ADDITIONAL INFORMA-
22 TION.—Nothing in this subparagraph
23 shall be construed as preventing such
24 an organization from requiring addi-
25 tional information as a condition of

1 certification or recertification of an
2 entity.

3 (iv) USE OF INFORMATION.—Informa-
4 tion provided under this subparagraph may
5 be used by the appropriate Secretary and
6 qualified private standard-setting organiza-
7 tions to conduct oversight of qualified ex-
8 ternal review entities, including recertifi-
9 cation of such entities, and shall be made
10 available to the public in an appropriate
11 manner.

12 (E) LIMITATION ON LIABILITY.—No quali-
13 fied external review entity having a contract
14 with a plan or issuer, and no person who is em-
15 ployed by any such entity or who furnishes pro-
16 fessional services to such entity (including as an
17 independent medical review panel), shall be held
18 by reason of the performance of any duty, func-
19 tion, or activity required or authorized pursuant
20 to this section, to be civilly liable under any law
21 of the United States or of any State (or polit-
22 ical subdivision thereof) if there was no actual
23 malice or gross misconduct in the performance
24 of such duty, function, or activity.

1 (5) REPORT.—Not later than 12 months after
2 the general effective date referred to in section 601,
3 the General Accounting Office shall prepare and
4 submit to the appropriate committees of Congress a
5 report concerning—

6 (A) the information that is provided under
7 paragraph (3)(D);

8 (B) the number of denials that have been
9 upheld by independent medical review panels
10 and the number of denials that have been re-
11 versed by such panels; and

12 (C) the extent to which independent med-
13 ical review panels are requiring coverage for
14 benefits that are specifically excluded under the
15 plan or coverage.

16 **SEC. 105. HEALTH CARE CONSUMER ASSISTANCE FUND.**

17 (a) GRANTS.—

18 (1) IN GENERAL.—The Secretary of Health and
19 Human Services (referred to in this section as the
20 “Secretary”) shall establish a fund, to be known as
21 the “Health Care Consumer Assistance Fund”, to be
22 used to award grants to eligible States to carry out
23 consumer assistance activities (including programs
24 established by States prior to the enactment of this

1 Act) designed to provide information, assistance, and
2 referrals to consumers of health insurance products.

3 (2) STATE ELIGIBILITY.—To be eligible to re-
4 ceive a grant under this subsection a State shall pre-
5 pare and submit to the Secretary an application at
6 such time, in such manner, and containing such in-
7 formation as the Secretary may require, including a
8 State plan that describes—

9 (A) the manner in which the State will en-
10 sure that the health care consumer assistance
11 office (established under paragraph (4)) will
12 educate and assist health care consumers in ac-
13 cessing needed care;

14 (B) the manner in which the State will co-
15 ordinate and distinguish the services provided
16 by the health care consumer assistance office
17 with the services provided by Federal, State and
18 local health-related ombudsman, information,
19 protection and advocacy, insurance, and fraud
20 and abuse programs;

21 (C) the manner in which the State will
22 provide information, outreach, and services to
23 underserved, minority populations with limited
24 English proficiency and populations residing in
25 rural areas;

1 (D) the manner in which the State will
2 oversee the health care consumer assistance of-
3 fice, its activities, product materials and evalu-
4 ate program effectiveness;

5 (E) the manner in which the State will en-
6 sure that funds made available under this sec-
7 tion will be used to supplement, and not sup-
8 plant, any other Federal, State, or local funds
9 expended to provide services for programs de-
10 scribed under this section and those described
11 in subparagraphs (C) and (D);

12 (F) the manner in which the State will en-
13 sure that health care consumer office personnel
14 have the professional background and training
15 to carry out the activities of the office; and

16 (G) the manner in which the State will en-
17 sure that consumers have direct access to con-
18 sumer assistance personnel during regular busi-
19 ness hours.

20 (3) AMOUNT OF GRANT.—

21 (A) IN GENERAL.—From amounts appro-
22 priated under subsection (b) for a fiscal year,
23 the Secretary shall award a grant to a State in
24 an amount that bears the same ratio to such
25 amounts as the number of individuals within

1 the State covered under a group health plan or
2 under health insurance coverage offered by a
3 health insurance issuer bears to the total num-
4 ber of individuals so covered in all States (as
5 determined by the Secretary). Any amounts
6 provided to a State under this subsection that
7 are not used by the State shall be remitted to
8 the Secretary and reallocated in accordance
9 with this subparagraph.

10 (B) MINIMUM AMOUNT.—In no case shall
11 the amount provided to a State under a grant
12 under this subsection for a fiscal year be less
13 than an amount equal to 0.5 percent of the
14 amount appropriated for such fiscal year to
15 carry out this section.

16 (C) NON-FEDERAL CONTRIBUTIONS.—A
17 State will provide for the collection of non-Fed-
18 eral contributions for the operation of the office
19 in an amount that is not less than 25 percent
20 of the amount of Federal funds provided to the
21 State under this section.

22 (4) PROVISION OF FUNDS FOR ESTABLISHMENT
23 OF OFFICE.—

24 (A) IN GENERAL.—From amounts pro-
25 vided under a grant under this subsection, a

1 State shall, directly or through a contract with
2 an independent, nonprofit entity with dem-
3 onstrated experience in serving the needs of
4 health care consumers, provide for the estab-
5 lishment and operation of a State health care
6 consumer assistance office.

7 (B) ELIGIBILITY OF ENTITY.—To be eligi-
8 ble to enter into a contract under subparagraph
9 (A), an entity shall demonstrate that it has the
10 technical, organizational, and professional ca-
11 pacity to deliver the services described in sub-
12 section (b) to all public and private health in-
13 surance participants, beneficiaries, enrollees, or
14 prospective enrollees.

15 (C) EXISTING STATE ENTITY.—Nothing in
16 this section shall prevent the funding of an ex-
17 isting health care consumer assistance program
18 that otherwise meets the requirements of this
19 section.

20 (b) USE OF FUNDS.—

21 (1) BY STATE.—A State shall use amounts pro-
22 vided under a grant awarded under this section to
23 carry out consumer assistance activities directly or
24 by contract with an independent, non-profit organi-
25 zation. An eligible entity may use some reasonable

1 amount of such grant to ensure the adequate train-
2 ing of personnel carrying out such activities. To re-
3 ceive amounts under this subsection, an eligible enti-
4 ty shall provide consumer assistance services, includ-
5 ing—

6 (A) the operation of a toll-free telephone
7 hotline to respond to consumer requests;

8 (B) the dissemination of appropriate edu-
9 cational materials on available health insurance
10 products and on how best to access health care
11 and the rights and responsibilities of health
12 care consumers;

13 (C) the provision of education on effective
14 methods to promptly and efficiently resolve
15 questions, problems, and grievances;

16 (D) the coordination of educational and
17 outreach efforts with health plans, health care
18 providers, payers, and governmental agencies;

19 (E) referrals to appropriate private and
20 public entities to resolve questions, problems
21 and grievances; and

22 (F) the provision of information and as-
23 sistance, including acting as an authorized rep-
24 resentative, regarding internal, external, or ad-
25 ministrative grievances or appeals procedures in

1 nonlitigative settings to appeal the denial, ter-
2 mination, or reduction of health care services,
3 or the refusal to pay for such services, under a
4 group health plan or health insurance coverage
5 offered by a health insurance issuer.

6 (2) CONFIDENTIALITY AND ACCESS TO INFOR-
7 MATION.—

8 (A) STATE ENTITY.—With respect to a
9 State that directly establishes a health care con-
10 sumer assistance office, such office shall estab-
11 lish and implement procedures and protocols in
12 accordance with applicable Federal and State
13 laws.

14 (B) CONTRACT ENTITY.—With respect to a
15 State that, through contract, establishes a
16 health care consumer assistance office, such of-
17 fice shall establish and implement procedures
18 and protocols, consistent with applicable Fed-
19 eral and State laws, to ensure the confiden-
20 tiality of all information shared by a partici-
21 pant, beneficiary, enrollee, or their personal
22 representative and their health care providers,
23 group health plans, or health insurance insurers
24 with the office and to ensure that no such infor-
25 mation is used by the office, or released or dis-

1 closed to State agencies or outside persons or
2 entities without the prior written authorization
3 (in accordance with section 164.508 of title 45,
4 Code of Federal Regulations) of the individual
5 or personal representative. The office may, con-
6 sistent with applicable Federal and State con-
7 fidentiality laws, collect, use or disclose aggre-
8 gate information that is not individually identi-
9 fiable (as defined in section 164.501 of title 45,
10 Code of Federal Regulations). The office shall
11 provide a written description of the policies and
12 procedures of the office with respect to the
13 manner in which health information may be
14 used or disclosed to carry out consumer assist-
15 ance activities. The office shall provide health
16 care providers, group health plans, or health in-
17 surance issuers with a written authorization (in
18 accordance with section 164.508 of title 45,
19 Code of Federal Regulations) to allow the office
20 to obtain medical information relevant to the
21 matter before the office.

22 (3) AVAILABILITY OF SERVICES.—The health
23 care consumer assistance office of a State shall not
24 discriminate in the provision of information, refer-
25 rals, and services regardless of the source of the in-

1 dividual’s health insurance coverage or prospective
2 coverage, including individuals covered under a
3 group health plan or health insurance coverage of-
4 fered by a health insurance issuer, the medicare or
5 medicaid programs under title XVIII or XIX of the
6 Social Security Act (42 U.S.C. 1395 and 1396 et
7 seq.), or under any other Federal or State health
8 care program.

9 (4) DESIGNATION OF RESPONSIBILITIES.—

10 (A) WITHIN EXISTING STATE ENTITY.—If
11 the health care consumer assistance office of a
12 State is located within an existing State regu-
13 latory agency or office of an elected State offi-
14 cial, the State shall ensure that—

15 (i) there is a separate delineation of
16 the funding, activities, and responsibilities
17 of the office as compared to the other
18 funding, activities, and responsibilities of
19 the agency; and

20 (ii) the office establishes and imple-
21 ments procedures and protocols to ensure
22 the confidentiality of all information
23 shared by a participant, beneficiary, or en-
24 rollee or their personal representative and
25 their health care providers, group health

1 plans, or health insurance issuers with the
2 office and to ensure that no information is
3 disclosed to the State agency or office
4 without the written authorization of the in-
5 dividual or their personal representative in
6 accordance with paragraph (2).

7 (B) CONTRACT ENTITY.—In the case of an
8 entity that enters into a contract with a State
9 under subsection (a)(3), the entity shall provide
10 assurances that the entity has no conflict of in-
11 terest in carrying out the activities of the office
12 and that the entity is independent of group
13 health plans, health insurance issuers, pro-
14 viders, payers, and regulators of health care.

15 (5) SUBCONTRACTS.—The health care con-
16 sumer assistance office of a State may carry out ac-
17 tivities and provide services through contracts en-
18 tered into with 1 or more nonprofit entities so long
19 as the office can demonstrate that all of the require-
20 ments of this section are complied with by the office.

21 (6) TERM.—A contract entered into under this
22 subsection shall be for a term of 3 years.

23 (c) REPORT.—Not later than 1 year after the Sec-
24 retary first awards grants under this section, and annually
25 thereafter, the Secretary shall prepare and submit to the

1 appropriate committees of Congress a report concerning
2 the activities funded under this section and the effective-
3 ness of such activities in resolving health care-related
4 problems and grievances.

5 (d) AUTHORIZATION OF APPROPRIATIONS.—There
6 are authorized to be appropriated such sums as may be
7 necessary to carry out this section.

8 **Subtitle B—Access to Care**

9 **SEC. 111. CONSUMER CHOICE OPTION.**

10 (a) IN GENERAL.—If—

11 (1) a health insurance issuer providing health
12 insurance coverage in connection with a group health
13 plan offers to enrollees health insurance coverage
14 which provides for coverage of services (including
15 physician pathology services) only if such services
16 are furnished through health care professionals and
17 providers who are members of a network of health
18 care professionals and providers who have entered
19 into a contract with the issuer to provide such serv-
20 ices, or

21 (2) a group health plan offers to participants or
22 beneficiaries health benefits which provide for cov-
23 erage of services only if such services are furnished
24 through health care professionals and providers who
25 are members of a network of health care profes-

1 sionals and providers who have entered into a con-
2 tract with the plan to provide such services,
3 then the issuer or plan shall also offer or arrange to be
4 offered to such enrollees, participants, or beneficiaries (at
5 the time of enrollment and during an annual open season
6 as provided under subsection (c)) the option of health in-
7 surance coverage or health benefits which provide for cov-
8 erage of such services which are not furnished through
9 health care professionals and providers who are members
10 of such a network unless such enrollees, participants, or
11 beneficiaries are offered such non-network coverage
12 through another group health plan or through another
13 health insurance issuer in the group market.

14 (b) ADDITIONAL COSTS.—The amount of any addi-
15 tional premium charged by the health insurance issuer or
16 group health plan for the additional cost of the creation
17 and maintenance of the option described in subsection (a)
18 and the amount of any additional cost sharing imposed
19 under such option shall be borne by the enrollee, partici-
20 pant, or beneficiary unless it is paid by the health plan
21 sponsor or group health plan through agreement with the
22 health insurance issuer.

23 (c) OPEN SEASON.—An enrollee, participant, or ben-
24 eficiary, may change to the offering provided under this
25 section only during a time period determined by the health

1 insurance issuer or group health plan. Such time period
2 shall occur at least annually.

3 **SEC. 112. CHOICE OF HEALTH CARE PROFESSIONAL.**

4 (a) PRIMARY CARE.—If a group health plan, or a
5 health insurance issuer that offers health insurance cov-
6 erage, requires or provides for designation by a partici-
7 pant, beneficiary, or enrollee of a participating primary
8 care provider, then the plan or issuer shall permit each
9 participant, beneficiary, and enrollee to designate any par-
10 ticipating primary care provider who is available to accept
11 such individual.

12 (b) SPECIALISTS.—

13 (1) IN GENERAL.—Subject to paragraph (2), a
14 group health plan and a health insurance issuer that
15 offers health insurance coverage shall permit each
16 participant, beneficiary, or enrollee to receive medi-
17 cally necessary and appropriate specialty care, pur-
18 suant to appropriate referral procedures, from any
19 qualified participating health care professional who
20 is available to accept such individual for such care.

21 (2) LIMITATION.—Paragraph (1) shall not
22 apply to specialty care if the plan or issuer clearly
23 informs participants, beneficiaries, and enrollees of
24 the limitations on choice of participating health care
25 professionals with respect to such care.

1 (3) CONSTRUCTION.—Nothing in this sub-
2 section shall be construed as affecting the applica-
3 tion of section 114 (relating to access to specialists).

4 **SEC. 113. 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 or covers any benefits with re-
9 spect to services in an emergency department of a
10 hospital, the plan or issuer shall cover emergency
11 services (as defined in paragraph (2)(B))—

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

14 (B) whether the health care provider fur-
15 nishing such services is a participating provider
16 with respect to such services;

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

20 (i) by a nonparticipating health care
21 provider with or without prior authoriza-
22 tion, or

23 (ii) by a participating health care pro-
24 vider without prior authorization,

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

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

15 (2) DEFINITIONS.—In this section:

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

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

3 (B) EMERGENCY SERVICES.—The term
4 “emergency services” means, with respect to an
5 emergency medical condition—

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

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

19 (C) STABILIZE.—The term “to stabilize”,
20 with respect to an emergency medical condition
21 (as defined in subparagraph (A)), has the
22 meaning given in section 1867(e)(3) of the So-
23 cial Security Act (42 U.S.C. 1395dd(e)(3)).

24 (b) REIMBURSEMENT FOR MAINTENANCE CARE AND
25 POST-STABILIZATION CARE.—A group health plan, and

1 health insurance coverage offered by a health insurance
2 issuer, must provide reimbursement for maintenance care
3 and post-stabilization care in accordance with the require-
4 ments of section 1852(d)(2) of the Social Security Act (42
5 U.S.C. 1395w-22(d)(2)). Such reimbursement shall be
6 provided in a manner consistent with subsection (a)(1)(C).

7 (c) COVERAGE OF EMERGENCY AMBULANCE SERV-
8 ICES.—

9 (1) IN GENERAL.—If a group health plan, or
10 health insurance coverage provided by a health in-
11 surance issuer, provides any benefits with respect to
12 ambulance services and emergency services, the plan
13 or issuer shall cover emergency ambulance services
14 (as defined in paragraph (2)) furnished under the
15 plan or coverage under the same terms and condi-
16 tions under subparagraphs (A) through (D) of sub-
17 section (a)(1) under which coverage is provided for
18 emergency services.

19 (2) EMERGENCY AMBULANCE SERVICES.—For
20 purposes of this subsection, the term “emergency
21 ambulance services” means ambulance services (as
22 defined for purposes of section 1861(s)(7) of the So-
23 cial Security Act) furnished to transport an indi-
24 vidual who has an emergency medical condition (as
25 defined in subsection (a)(2)(A)) to a hospital for the

1 receipt of emergency services (as defined in sub-
2 section (a)(2)(B)) in a case in which the emergency
3 services are covered under the plan or coverage pur-
4 suant to subsection (a)(1) and a prudent layperson,
5 with an average knowledge of health and medicine,
6 could reasonably expect that the absence of such
7 transport would result in placing the health of the
8 individual in serious jeopardy, serious impairment of
9 bodily function, or serious dysfunction of any bodily
10 organ or part.

11 **SEC. 114. TIMELY ACCESS TO SPECIALISTS.**

12 (a) **TIMELY ACCESS.**—

13 (1) **IN GENERAL.**—A group health plan and a
14 health insurance issuer offering health insurance
15 coverage shall ensure that participants, beneficiaries,
16 and enrollees receive timely access to specialists who
17 are appropriate to the condition of, and accessible
18 to, the participant, beneficiary, or enrollee, when
19 such specialty care is a covered benefit under the
20 plan or coverage.

21 (2) **RULE OF CONSTRUCTION.**—Nothing in
22 paragraph (1) shall be construed—

23 (A) to require the coverage under a group
24 health plan or health insurance coverage of ben-
25 efits or services;

1 (B) to prohibit a plan or issuer from in-
2 cluding providers in the network only to the ex-
3 tent necessary to meet the needs of the plan's
4 or issuer's participants, beneficiaries, or enroll-
5 ees; or

6 (C) to override any State licensure or
7 scope-of-practice law.

8 (3) ACCESS TO CERTAIN PROVIDERS.—

9 (A) IN GENERAL.—With respect to spe-
10 cialty care under this section, if a participating
11 specialist is not available and qualified to pro-
12 vide such care to the participant, beneficiary, or
13 enrollee, the plan or issuer shall provide for cov-
14 erage of such care by a nonparticipating spe-
15 cialist.

16 (B) TREATMENT OF NONPARTICIPATING
17 PROVIDERS.—If a participant, beneficiary, or
18 enrollee receives care from a nonparticipating
19 specialist pursuant to subparagraph (A), such
20 specialty care shall be provided at no additional
21 cost to the participant, beneficiary, or enrollee
22 beyond what the participant, beneficiary, or en-
23 rollee would otherwise pay for such specialty
24 care if provided by a participating specialist.

25 (b) REFERRALS.—

1 (1) AUTHORIZATION.—Subject to subsection
2 (a)(1), a group health plan or health insurance
3 issuer may require an authorization in order to ob-
4 tain coverage for specialty services under this sec-
5 tion. Any such authorization—

6 (A) shall be for an appropriate duration of
7 time or number of referrals, including an au-
8 thorization for a standing referral where appro-
9 priate; and

10 (B) may not be refused solely because the
11 authorization involves services of a nonpartici-
12 pating specialist (described in subsection
13 (a)(3)).

14 (2) REFERRALS FOR ONGOING SPECIAL CONDI-
15 TIONS.—

16 (A) IN GENERAL.—Subject to subsection
17 (a)(1), a group health plan and a health insur-
18 ance issuer shall permit a participant, bene-
19 ficiary, or enrollee who has an ongoing special
20 condition (as defined in subparagraph (B)) to
21 receive a referral to a specialist for the treat-
22 ment of such condition and such specialist may
23 authorize such referrals, procedures, tests, and
24 other medical services with respect to such con-
25 dition, or coordinate the care for such condi-

1 tion, subject to the terms of a treatment plan
2 (if any) referred to in subsection (c) with re-
3 spect to the condition.

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

8 (i) is life-threatening, degenerative,
9 potentially disabling, or congenital; and

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

12 (c) TREATMENT PLANS.—

13 (1) IN GENERAL.—A group health plan or
14 health insurance issuer may require that the spe-
15 cialty care be provided—

16 (A) pursuant to a treatment plan, but only
17 if the treatment plan—

18 (i) is developed by the specialist, in
19 consultation with the case manager or pri-
20 mary care provider, and the participant,
21 beneficiary, or enrollee, and

22 (ii) is approved by the plan or issuer
23 in a timely manner, if the plan or issuer
24 requires such approval; and

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

4 (2) NOTIFICATION.—Nothing in paragraph (1)
5 shall be construed as prohibiting a plan or issuer
6 from requiring the specialist to provide the plan or
7 issuer with regular updates on the specialty care
8 provided, as well as all other reasonably necessary
9 medical information.

10 (d) SPECIALIST DEFINED.—For purposes of this sec-
11 tion, the term “specialist” means, with respect to the con-
12 dition of the participant, beneficiary, or enrollee, a health
13 care professional, facility, or center that has adequate ex-
14 pertise through appropriate training and experience (in-
15 cluding, in the case of a child, appropriate pediatric exper-
16 tise) to provide high quality care in treating the condition.

17 **SEC. 115. PATIENT ACCESS TO OBSTETRICAL AND GYNECO-**
18 **LOGICAL CARE.**

19 (a) GENERAL RIGHTS.—

20 (1) DIRECT ACCESS.—A group health plan, and
21 a health insurance issuer offering health insurance
22 coverage, described in subsection (b) may not re-
23 quire authorization or referral by the plan, issuer, or
24 any person (including a primary care provider de-
25 scribed in subsection (b)(2)) in the case of a female

1 participant, beneficiary, or enrollee who seeks cov-
2 erage for obstetrical or gynecological care provided
3 by a participating health care professional who spe-
4 cializes in obstetrics or gynecology.

5 (2) OBSTETRICAL AND GYNECOLOGICAL
6 CARE.—A group health plan and a health insurance
7 issuer described in subsection (b) shall treat the pro-
8 vision of obstetrical and gynecological care, and the
9 ordering of related obstetrical and gynecological
10 items and services, pursuant to the direct access de-
11 scribed under paragraph (1), by a participating
12 health care professional who specializes in obstetrics
13 or gynecology as the authorization of the primary
14 care provider.

15 (b) APPLICATION OF SECTION.—A group health plan,
16 or health insurance issuer offering health insurance cov-
17 erage, described in this subsection is a group health plan
18 or coverage that—

19 (1) provides coverage for obstetric or
20 gynecologic care; and

21 (2) requires the designation by a participant,
22 beneficiary, or enrollee of a participating primary
23 care provider.

24 (c) CONSTRUCTION.—Nothing in subsection (a) shall
25 be construed to—

1 (1) waive any exclusions of coverage under the
2 terms and conditions of the plan or health insurance
3 coverage with respect to coverage of obstetrical or
4 gynecological care; or

5 (2) preclude the group health plan or health in-
6 surance issuer involved from requiring that the ob-
7 stetrical or gynecological provider notify the primary
8 care health care professional or the plan or issuer of
9 treatment decisions.

10 **SEC. 116. ACCESS TO PEDIATRIC CARE.**

11 (a) PEDIATRIC CARE.—In the case of a person who
12 has a child who is a participant, beneficiary, or enrollee
13 under a group health plan, or health insurance coverage
14 offered by a health insurance issuer, if the plan or issuer
15 requires or provides for the designation of a participating
16 primary care provider for the child, the plan or issuer shall
17 permit such person to designate a physician (allopathic or
18 osteopathic) who specializes in pediatrics as the child's pri-
19 mary care provider if such provider participates in the net-
20 work of the plan or issuer.

21 (b) CONSTRUCTION.—Nothing in subsection (a) shall
22 be construed to waive any exclusions of coverage under
23 the terms and conditions of the plan or health insurance
24 coverage with respect to coverage of pediatric care.

1 **SEC. 117. CONTINUITY OF CARE.**

2 (a) **TERMINATION OF PROVIDER.—**

3 (1) **IN GENERAL.—If—**

4 (A) a contract between a group health
5 plan, or a health insurance issuer offering
6 health insurance coverage, and a treating health
7 care provider is terminated (as defined in para-
8 graph (e)(4)), or

9 (B) benefits or coverage provided by a
10 health care provider are terminated because of
11 a change in the terms of provider participation
12 in such plan or coverage,

13 the plan or issuer shall meet the requirements of
14 paragraph (3) with respect to each continuing care
15 patient.

16 (2) **TREATMENT OF TERMINATION OF CON-**
17 **TRACT WITH HEALTH INSURANCE ISSUER.—If a**
18 **contract for the provision of health insurance cov-**
19 **erage between a group health plan and a health in-**
20 **surance issuer is terminated and, as a result of such**
21 **termination, coverage of services of a health care**
22 **provider is terminated with respect to an individual,**
23 **the provisions of paragraph (1) (and the succeeding**
24 **provisions of this section) shall apply under the plan**
25 **in the same manner as if there had been a contract**
26 **between the plan and the provider that had been ter-**

1 minated, but only with respect to benefits that are
2 covered under the plan after the contract termi-
3 nation.

4 (3) REQUIREMENTS.—The requirements of this
5 paragraph are that the plan or issuer—

6 (A) notify the continuing care patient in-
7 volved, or arrange to have the patient notified
8 pursuant to subsection (d)(2), on a timely basis
9 of the termination described in paragraph (1)
10 (or paragraph (2), if applicable) and the right
11 to elect continued transitional care from the
12 provider under this section;

13 (B) provide the patient with an oppor-
14 tunity to notify the plan or issuer of the pa-
15 tient’s need for transitional care; and

16 (C) subject to subsection (c), permit the
17 patient to elect to continue to be covered with
18 respect to the course of treatment by such pro-
19 vider with the provider’s consent during a tran-
20 sitional period (as provided for under subsection
21 (b)).

22 (4) CONTINUING CARE PATIENT.—For purposes
23 of this section, the term “continuing care patient”
24 means a participant, beneficiary, or enrollee who—

1 (A) is undergoing a course of treatment
2 for a serious and complex condition from the
3 provider at the time the plan or issuer receives
4 or provides notice of provider, benefit, or cov-
5 erage termination described in paragraph (1)
6 (or paragraph (2), if applicable);

7 (B) is undergoing a course of institutional
8 or inpatient care from the provider at the time
9 of such notice;

10 (C) is scheduled to undergo non-elective
11 surgery from the provider at the time of such
12 notice;

13 (D) is pregnant and undergoing a course
14 of treatment for the pregnancy from the pro-
15 vider at the time of such notice; or

16 (E) is or was determined to be terminally
17 ill (as determined under section 1861(dd)(3)(A)
18 of the Social Security Act) at the time of such
19 notice, but only with respect to a provider that
20 was treating the terminal illness before the date
21 of such notice.

22 (b) TRANSITIONAL PERIODS.—

23 (1) SERIOUS AND COMPLEX CONDITIONS.—The
24 transitional period under this subsection with re-
25 spect to a continuing care patient described in sub-

1 section (a)(4)(A) shall extend for up to 90 days (as
2 determined by the treating health care professional)
3 from the date of the notice described in subsection
4 (a)(3)(A).

5 (2) INSTITUTIONAL OR INPATIENT CARE.—The
6 transitional period under this subsection for a con-
7 tinuing care patient described in subsection
8 (a)(4)(B) shall extend until the earlier of—

9 (A) the expiration of the 90-day period be-
10 ginning on the date on which the notice under
11 subsection (a)(3)(A) is provided; or

12 (B) the date of discharge of the patient
13 from such care or the termination of the period
14 of institutionalization, or, if later, the date of
15 completion of reasonable follow-up care.

16 (3) SCHEDULED NON-ELECTIVE SURGERY.—
17 The transitional period under this subsection for a
18 continuing care patient described in subsection
19 (a)(4)(C) shall extend until the completion of the
20 surgery involved and post-surgical follow-up care re-
21 lating to the surgery and occurring within 90 days
22 after the date of the surgery.

23 (4) PREGNANCY.—The transitional period
24 under this subsection for a continuing care patient
25 described in subsection (a)(4)(D) shall extend

1 through the provision of post-partum care directly
2 related to the delivery.

3 (5) **TERMINAL ILLNESS.**—The transitional pe-
4 riod under this subsection for a continuing care pa-
5 tient described in subsection (a)(4)(E) shall extend
6 for the remainder of the patient’s life for care that
7 is directly related to the treatment of the terminal
8 illness or its medical manifestations.

9 (c) **PERMISSIBLE TERMS AND CONDITIONS.**—A
10 group health plan or health insurance issuer may condi-
11 tion coverage of continued treatment by a provider under
12 this section upon the provider agreeing to the following
13 terms and conditions:

14 (1) The treating health care provider agrees to
15 accept reimbursement from the plan or issuer and
16 continuing care patient involved (with respect to
17 cost-sharing) at the rates applicable prior to the
18 start of the transitional period as payment in full
19 (or, in the case described in subsection (a)(2), at the
20 rates applicable under the replacement plan or cov-
21 erage after the date of the termination of the con-
22 tract with the group health plan or health insurance
23 issuer) and not to impose cost-sharing with respect
24 to the patient in an amount that would exceed the
25 cost-sharing that could have been imposed if the

1 contract referred to in subsection (a)(1) had not
2 been terminated.

3 (2) The treating health care provider agrees to
4 adhere to the quality assurance standards of the
5 plan or issuer responsible for payment under para-
6 graph (1) and to provide to such plan or issuer nec-
7 essary medical information related to the care pro-
8 vided.

9 (3) The treating health care provider agrees
10 otherwise to adhere to such plan's or issuer's policies
11 and procedures, including procedures regarding re-
12 ferrals and obtaining prior authorization and pro-
13 viding services pursuant to a treatment plan (if any)
14 approved by the plan or issuer.

15 (d) RULES OF CONSTRUCTION.—Nothing in this sec-
16 tion shall be construed—

17 (1) to require the coverage of benefits which
18 would not have been covered if the provider involved
19 remained a participating provider; or

20 (2) with respect to the termination of a con-
21 tract under subsection (a) to prevent a group health
22 plan or health insurance issuer from requiring that
23 the health care provider—

24 (A) notify participants, beneficiaries, or en-
25 rollees of their rights under this section; or

1 (B) provide the plan or issuer with the
2 name of each participant, beneficiary, or en-
3 rollee who the provider believes is a continuing
4 care patient.

5 (e) DEFINITIONS.—In this section:

6 (1) CONTRACT.—The term “contract” includes,
7 with respect to a plan or issuer and a treating
8 health care provider, a contract between such plan
9 or issuer and an organized network of providers that
10 includes the treating health care provider, and (in
11 the case of such a contract) the contract between the
12 treating health care provider and the organized net-
13 work.

14 (2) HEALTH CARE PROVIDER.—The term
15 “health care provider” or “provider” means—

16 (A) any individual who is engaged in the
17 delivery of health care services in a State and
18 who is required by State law or regulation to be
19 licensed or certified by the State to engage in
20 the delivery of such services in the State; and

21 (B) any entity that is engaged in the deliv-
22 ery of health care services in a State and that,
23 if it is required by State law or regulation to be
24 licensed or certified by the State to engage in

1 the delivery of such services in the State, is so
2 licensed.

3 (3) **SERIOUS AND COMPLEX CONDITION.**—The
4 term “serious and complex condition” means, with
5 respect to a participant, beneficiary, or enrollee
6 under the plan or coverage—

7 (A) in the case of an acute illness, a condi-
8 tion that is serious enough to require special-
9 ized medical treatment to avoid the reasonable
10 possibility of death or permanent harm; or

11 (B) in the case of a chronic illness or con-
12 dition, is an ongoing special condition (as de-
13 fined in section 114(b)(2)(B)).

14 (4) **TERMINATED.**—The term “terminated” in-
15 cludes, with respect to a contract, the expiration or
16 nonrenewal of the contract, but does not include a
17 termination of the contract for failure to meet appli-
18 cable quality standards or for fraud.

19 **SEC. 118. ACCESS TO NEEDED PRESCRIPTION DRUGS.**

20 (a) **IN GENERAL.**—To the extent that a group health
21 plan, or health insurance coverage offered by a health in-
22 surance issuer, provides coverage for benefits with respect
23 to prescription drugs, and limits such coverage to drugs
24 included in a formulary, the plan or issuer shall—

1 (1) ensure the participation of physicians and
2 pharmacists in developing and reviewing such for-
3 mulary;

4 (2) provide for disclosure of the formulary to
5 providers; and

6 (3) in accordance with the applicable quality as-
7 surance and utilization review standards of the plan
8 or issuer, provide for exceptions from the formulary
9 limitation when a non-formulary alternative is medi-
10 cally necessary and appropriate and, in the case of
11 such an exception, apply the same cost-sharing re-
12 quirements that would have applied in the case of a
13 drug covered under the formulary.

14 (b) COVERAGE OF APPROVED DRUGS AND MEDICAL
15 DEVICES.—

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

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

23 (i) is included in the labeling author-
24 ized by the application in effect for the
25 drug pursuant to subsection (b) or (j) of

1 section 505 of the Federal Food, Drug,
2 and Cosmetic Act, without regard to any
3 postmarketing requirements that may
4 apply under such Act; or

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

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

19 (2) CONSTRUCTION.—Nothing in this sub-
20 section shall be construed as requiring a group
21 health plan (or health insurance coverage offered in
22 connection with such a plan) to provide any coverage
23 of prescription drugs or medical devices.

1 **SEC. 119. COVERAGE FOR INDIVIDUALS PARTICIPATING IN**
2 **APPROVED CLINICAL TRIALS.**

3 (a) **COVERAGE.**—

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

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

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

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

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

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

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

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

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

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

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

22 (2) Either—

23 (A) the referring physician is a partici-
24 pating health care professional and has con-
25 cluded that the individual’s participation in

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

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

10 (c) PAYMENT.—

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

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

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

23 (B) a nonparticipating provider, the pay-
24 ment rate shall be at the rate the plan or issuer

1 would normally pay for comparable services
2 under subparagraph (A).

3 (d) APPROVED CLINICAL TRIAL DEFINED.—

4 (1) IN GENERAL.—In this section, the term
5 “approved clinical trial” means a clinical research
6 study or clinical investigation—

7 (A) approved and funded (which may in-
8 clude funding through in-kind contributions) by
9 one or more of the following:

10 (i) the National Institutes of Health;

11 (ii) a cooperative group or center of
12 the National Institutes of Health, includ-
13 ing a qualified nongovernmental research
14 entity to which the National Cancer Insti-
15 tute has awarded a center support grant;

16 (iii) either of the following if the con-
17 ditions described in paragraph (2) are
18 met—

19 (I) the Department of Veterans
20 Affairs;

21 (II) the Department of Defense;

22 or

23 (B) approved by the Food and Drug Ad-
24 ministration.

1 (2) CONDITIONS FOR DEPARTMENTS.—The
2 conditions described in this paragraph, for a study
3 or investigation conducted by a Department, are
4 that the study or investigation has been reviewed
5 and approved through a system of peer review that
6 the appropriate Secretary determines—

7 (A) to be comparable to the system of peer
8 review of studies and investigations used by the
9 National Institutes of Health; and

10 (B) assures unbiased review of the highest
11 ethical standards by qualified individuals who
12 have no interest in the outcome of the review.

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

16 **SEC. 120. REQUIRED COVERAGE FOR MINIMUM HOSPITAL**
17 **STAY FOR MASTECTOMIES AND LYMPH NODE**
18 **DISSECTIONS FOR THE TREATMENT OF**
19 **BREAST CANCER AND COVERAGE FOR SEC-**
20 **ONDARY CONSULTATIONS.**

21 (a) INPATIENT CARE.—

22 (1) IN GENERAL.—A group health plan, and a
23 health insurance issuer providing health insurance
24 coverage, that provides medical and surgical benefits
25 shall ensure that inpatient coverage with respect to

1 the treatment of breast cancer is provided for a pe-
2 riod of time as is determined by the attending physi-
3 cian, in consultation with the patient, to be medi-
4 cally necessary and appropriate following—

5 (A) a mastectomy;

6 (B) a lumpectomy; or

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

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

14 (b) PROHIBITION ON CERTAIN MODIFICATIONS.—In
15 implementing the requirements of this section, a group
16 health plan, and a health insurance issuer providing health
17 insurance coverage, may not modify the terms and condi-
18 tions of coverage based on the determination by a partici-
19 pant, beneficiary, or enrollee to request less than the min-
20 imum coverage required under subsection (a).

21 (c) SECONDARY CONSULTATIONS.—

22 (1) IN GENERAL.—A group health plan, and a
23 health insurance issuer providing health insurance
24 coverage, that provides coverage with respect to
25 medical and surgical services provided in relation to

1 the diagnosis and treatment of cancer shall ensure
2 that full coverage is provided for secondary consulta-
3 tions by specialists in the appropriate medical fields
4 (including pathology, radiology, and oncology) to
5 confirm or refute such diagnosis. Such plan or issuer
6 shall ensure that full coverage is provided for such
7 secondary consultation whether such consultation is
8 based on a positive or negative initial diagnosis. In
9 any case in which the attending physician certifies in
10 writing that services necessary for such a secondary
11 consultation are not sufficiently available from spe-
12 cialists operating under the plan or coverage with re-
13 spect to whose services coverage is otherwise pro-
14 vided under such plan or by such issuer, such plan
15 or issuer shall ensure that coverage is provided with
16 respect to the services necessary for the secondary
17 consultation with any other specialist selected by the
18 attending physician for such purpose at no addi-
19 tional cost to the individual beyond that which the
20 individual would have paid if the specialist was par-
21 ticipating in the network of the plan or issuer.

22 (2) EXCEPTION.—Nothing in paragraph (1)
23 shall be construed as requiring the provision of sec-
24 ondary consultations where the patient determines
25 not to seek such a consultation.

1 (d) PROHIBITION ON PENALTIES OR INCENTIVES.—
2 A group health plan, and a health insurance issuer pro-
3 viding health insurance coverage, may not—

4 (1) penalize or otherwise reduce or limit the re-
5 imbursement of a provider or specialist because the
6 provider or specialist provided care to a participant,
7 beneficiary, or enrollee in accordance with this sec-
8 tion;

9 (2) provide financial or other incentives to a
10 physician or specialist to induce the physician or
11 specialist to keep the length of inpatient stays of pa-
12 tients following a mastectomy, lumpectomy, or a
13 lymph node dissection for the treatment of breast
14 cancer below certain limits or to limit referrals for
15 secondary consultations; or

16 (3) provide financial or other incentives to a
17 physician or specialist to induce the physician or
18 specialist to refrain from referring a participant,
19 beneficiary, or enrollee for a secondary consultation
20 that would otherwise be covered by the plan or cov-
21 erage involved under subsection (c).

22 **Subtitle C—Access to Information**

23 **SEC. 121. PATIENT ACCESS TO INFORMATION.**

24 (a) REQUIREMENT.—

25 (1) DISCLOSURE.—

1 (A) IN GENERAL.—A group health plan,
2 and a health insurance issuer that provides cov-
3 erage in connection with health insurance cov-
4 erage, shall provide for the disclosure to partici-
5 pants, beneficiaries, and enrollees—

6 (i) of the information described in
7 subsection (b) at the time of the initial en-
8 rollment of the participant, beneficiary, or
9 enrollee under the plan or coverage;

10 (ii) of such information on an annual
11 basis—

12 (I) in conjunction with the elec-
13 tion period of the plan or coverage if
14 the plan or coverage has such an elec-
15 tion period; or

16 (II) in the case of a plan or cov-
17 erage that does not have an election
18 period, in conjunction with the begin-
19 ning of the plan or coverage year; and

20 (iii) of information relating to any
21 material reduction to the benefits or infor-
22 mation described in such subsection or
23 subsection (c), in the form of a notice pro-
24 vided not later than 30 days before the
25 date on which the reduction takes effect.

1 (B) PARTICIPANTS, BENEFICIARIES, AND
2 ENROLLEES.—The disclosure required under
3 subparagraph (A) shall be provided—

4 (i) jointly to each participant, bene-
5 ficiary, and enrollee who reside at the same
6 address; or

7 (ii) in the case of a beneficiary or en-
8 rollee who does not reside at the same ad-
9 dress as the participant or another en-
10 rollee, separately to the participant or
11 other enrollees and such beneficiary or en-
12 rollee.

13 (2) PROVISION OF INFORMATION.—Information
14 shall be provided to participants, beneficiaries, and
15 enrollees under this section at the last known ad-
16 dress maintained by the plan or issuer with respect
17 to such participants, beneficiaries, or enrollees, to
18 the extent that such information is provided to par-
19 ticipants, beneficiaries, or enrollees via the United
20 States Postal Service or other private delivery serv-
21 ice.

22 (b) REQUIRED INFORMATION.—The informational
23 materials to be distributed under this section shall include
24 for each option available under the group health plan or
25 health insurance coverage the following:

1 (1) BENEFITS.—A description of the covered
2 benefits, including—

3 (A) any in- and out-of-network benefits;

4 (B) specific preventive services covered
5 under the plan or coverage if such services are
6 covered;

7 (C) any specific exclusions or express limi-
8 tations of benefits described in section
9 104(d)(3)(C);

10 (D) any other benefit limitations, including
11 any annual or lifetime benefit limits and any
12 monetary limits or limits on the number of vis-
13 its, days, or services, and any specific coverage
14 exclusions; and

15 (E) any definition of medical necessity
16 used in making coverage determinations by the
17 plan, issuer, or claims administrator.

18 (2) COST SHARING.—A description of any cost-
19 sharing requirements, including—

20 (A) any premiums, deductibles, coinsur-
21 ance, copayment amounts, and liability for bal-
22 ance billing, for which the participant, bene-
23 ficiary, or enrollee will be responsible under
24 each option available under the plan;

1 (B) any maximum out-of-pocket expense
2 for which the participant, beneficiary, or en-
3 rollee may be liable;

4 (C) any cost-sharing requirements for out-
5 of-network benefits or services received from
6 nonparticipating providers; and

7 (D) any additional cost-sharing or charges
8 for benefits and services that are furnished
9 without meeting applicable plan or coverage re-
10 quirements, such as prior authorization or
11 precertification.

12 (3) DISENROLLMENT.—Information relating to
13 the disenrollment of a participant, beneficiary, or en-
14 rollee.

15 (4) SERVICE AREA.—A description of the plan
16 or issuer's service area, including the provision of
17 any out-of-area coverage.

18 (5) PARTICIPATING PROVIDERS.—A directory of
19 participating providers (to the extent a plan or
20 issuer provides coverage through a network of pro-
21 viders) that includes, at a minimum, the name, ad-
22 dress, and telephone number of each participating
23 provider, and information about how to inquire
24 whether a participating provider is currently accept-
25 ing new patients.

1 (6) CHOICE OF PRIMARY CARE PROVIDER.—A
2 description of any requirements and procedures to
3 be used by participants, beneficiaries, and enrollees
4 in selecting, accessing, or changing their primary
5 care provider, including providers both within and
6 outside of the network (if the plan or issuer permits
7 out-of-network services), and the right to select a pe-
8 diatrician as a primary care provider under section
9 116 for a participant, beneficiary, or enrollee who is
10 a child if such section applies.

11 (7) PREAUTHORIZATION REQUIREMENTS.—A
12 description of the requirements and procedures to be
13 used to obtain preauthorization for health services,
14 if such preauthorization is required.

15 (8) EXPERIMENTAL AND INVESTIGATIONAL
16 TREATMENTS.—A description of the process for de-
17 termining whether a particular item, service, or
18 treatment is considered experimental or investiga-
19 tional, and the circumstances under which such
20 treatments are covered by the plan or issuer.

21 (9) SPECIALTY CARE.—A description of the re-
22 quirements and procedures to be used by partici-
23 pants, beneficiaries, and enrollees in accessing spe-
24 cialty care and obtaining referrals to participating
25 and nonparticipating specialists, including any limi-

1 tations on choice of health care professionals re-
2 ferred to in section 112(b)(2) and the right to timely
3 access to specialists care under section 114 if such
4 section applies.

5 (10) CLINICAL TRIALS.—A description of the
6 circumstances and conditions under which participa-
7 tion in clinical trials is covered under the terms and
8 conditions of the plan or coverage, and the right to
9 obtain coverage for approved clinical trials under
10 section 119 if such section applies.

11 (11) PRESCRIPTION DRUGS.—To the extent the
12 plan or issuer provides coverage for prescription
13 drugs, a statement of whether such coverage is lim-
14 ited to drugs included in a formulary, a description
15 of any provisions and cost-sharing required for ob-
16 taining on- and off-formulary medications, and a de-
17 scription of the rights of participants, beneficiaries,
18 and enrollees in obtaining access to prescription
19 drugs under section 118 if such section applies.

20 (12) EMERGENCY SERVICES.—A summary of
21 the rules and procedures for accessing emergency
22 services, including the right of a participant, bene-
23 ficiary, or enrollee to obtain emergency services
24 under the prudent layperson standard under section
25 113, if such section applies, and any educational in-

1 information that the plan or issuer may provide re-
2 garding the appropriate use of emergency services.

3 (13) CLAIMS AND APPEALS.—A description of
4 the plan or issuer’s rules and procedures pertaining
5 to claims and appeals, a description of the rights
6 (including deadlines for exercising rights) of partici-
7 pants, beneficiaries, and enrollees under subtitle A
8 in obtaining covered benefits, filing a claim for bene-
9 fits, and appealing coverage decisions internally and
10 externally (including telephone numbers and mailing
11 addresses of the appropriate authority), and a de-
12 scription of any additional legal rights and remedies
13 available under section 502 of the Employee Retirement
14 Income Security Act of 1974 and applicable
15 State law.

16 (14) ADVANCE DIRECTIVES AND ORGAN DONA-
17 TION.—A description of procedures for advance di-
18 rectives and organ donation decisions if the plan or
19 issuer maintains such procedures.

20 (15) INFORMATION ON PLANS AND ISSUERS.—
21 The name, mailing address, and telephone number
22 or numbers of the plan administrator and the issuer
23 to be used by participants, beneficiaries, and enroll-
24 ees seeking information about plan or coverage bene-
25 fits and services, payment of a claim, or authoriza-

1 tion for services and treatment. Notice of whether
2 the benefits under the plan or coverage are provided
3 under a contract or policy of insurance issued by an
4 issuer, or whether benefits are provided directly by
5 the plan sponsor who bears the insurance risk.

6 (16) TRANSLATION SERVICES.—A summary de-
7 scription of any translation or interpretation services
8 (including the availability of printed information in
9 languages other than English, audio tapes, or infor-
10 mation in Braille) that are available for non-English
11 speakers and participants, beneficiaries, and enroll-
12 ees with communication disabilities and a description
13 of how to access these items or services.

14 (17) ACCREDITATION INFORMATION.—Any in-
15 formation that is made public by accrediting organi-
16 zations in the process of accreditation if the plan or
17 issuer is accredited, or any additional quality indica-
18 tors (such as the results of enrollee satisfaction sur-
19 veys) that the plan or issuer makes public or makes
20 available to participants, beneficiaries, and enrollees.

21 (18) NOTICE OF REQUIREMENTS.—A descrip-
22 tion of any rights of participants, beneficiaries, and
23 enrollees that are established by the provisions of
24 this Act (excluding those described in paragraphs
25 (1) through (17)) if such provisions apply. The de-

1 scription required under this paragraph may be com-
2 bined with the notices of the type described in sec-
3 tions 711(d), 713(b), or 606(a)(1) of the Employee
4 Retirement Income Security Act of 1974 and with
5 any other notice provision that the appropriate Sec-
6 retary determines may be combined, so long as such
7 combination does not result in any reduction in the
8 information that would otherwise be provided to the
9 recipient.

10 (19) AVAILABILITY OF ADDITIONAL INFORMA-
11 TION.—A statement that the information described
12 in subsection (c), and instructions on obtaining such
13 information (including telephone numbers and, if
14 available, Internet websites), shall be made available
15 upon request.

16 (20) DESIGNATED DECISIONMAKERS.—A de-
17 scription of the participants and beneficiaries with
18 respect to whom each designated decisionmaker
19 under the plan has assumed liability under section
20 502(o) of the Employee Retirement Income Security
21 Act of 1974 and the name and address of each such
22 decisionmaker.

23 (c) ADDITIONAL INFORMATION.—The informational
24 materials to be provided upon the request of a participant,
25 beneficiary, or enrollee shall include for each option avail-

1 able under a group health plan or health insurance cov-
2 erage the following:

3 (1) STATUS OF PROVIDERS.—The State licen-
4 sure status of the plan or issuer’s participating
5 health care professionals and participating health
6 care facilities, and, if available, the education, train-
7 ing, specialty qualifications or certifications of such
8 professionals.

9 (2) COMPENSATION METHODS.—A summary
10 description by category of the applicable methods
11 (such as capitation, fee-for-service, salary, bundled
12 payments, per diem, or a combination thereof) used
13 for compensating prospective or treating health care
14 professionals (including primary care providers and
15 specialists) and facilities in connection with the pro-
16 vision of health care under the plan or coverage.

17 (3) PRESCRIPTION DRUGS.—Information about
18 whether a specific prescription medication is in-
19 cluded in the formulary of the plan or issuer, if the
20 plan or issuer uses a defined formulary.

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

1 sections 101 and 102, including any drug formulary
2 program under section 118.

3 (5) EXTERNAL APPEALS INFORMATION.—Ag-
4 gregate information on the number and outcomes of
5 external medical reviews, relative to the sample size
6 (such as the number of covered lives) under the plan
7 or under the coverage of the issuer.

8 (d) MANNER OF DISCLOSURE.—The information de-
9 scribed in this section shall be disclosed in an accessible
10 medium and format that is calculated to be understood
11 by a participant or enrollee.

12 (e) RULES OF CONSTRUCTION.—Nothing in this sec-
13 tion shall be construed to prohibit a group health plan,
14 or a health insurance issuer in connection with health in-
15 surance coverage, from—

16 (1) distributing any other additional informa-
17 tion determined by the plan or issuer to be impor-
18 tant or necessary in assisting participants, bene-
19 ficiaries, and enrollees in the selection of a health
20 plan or health insurance coverage; and

21 (2) complying with the provisions of this section
22 by providing information in brochures, through the
23 Internet or other electronic media, or through other
24 similar means, so long as—

1 (A) the disclosure of such information in
2 such form is in accordance with requirements
3 as the appropriate Secretary may impose, and

4 (B) in connection with any such disclosure
5 of information through the Internet or other
6 electronic media—

7 (i) the recipient has affirmatively con-
8 sented to the disclosure of such informa-
9 tion in such form,

10 (ii) the recipient is capable of access-
11 ing the information so disclosed on the re-
12 cipient's individual workstation or at the
13 recipient's home,

14 (iii) the recipient retains an ongoing
15 right to receive paper disclosure of such in-
16 formation and receives, in advance of any
17 attempt at disclosure of such information
18 to him or her through the Internet or
19 other electronic media, notice in printed
20 form of such ongoing right and of the
21 proper software required to view informa-
22 tion so disclosed, and

23 (iv) the plan administrator appro-
24 priately ensures that the intended recipient
25 is receiving the information so disclosed

1 and provides the information in printed
2 form if the information is not received.

3 **Subtitle D—Protecting the Doctor-**
4 **patient Relationship**

5 **SEC. 131. PROHIBITION OF INTERFERENCE WITH CERTAIN**
6 **MEDICAL COMMUNICATIONS.**

7 (a) GENERAL RULE.—The provisions of any contract
8 or agreement, or the operation of any contract or agree-
9 ment, between a group health plan or health insurance
10 issuer in relation to health insurance coverage (including
11 any partnership, association, or other organization that
12 enters into or administers such a contract or agreement)
13 and a health care provider (or group of health care pro-
14 viders) shall not prohibit or otherwise restrict a health
15 care professional from advising such a participant, bene-
16 ficiary, or enrollee who is a patient of the professional
17 about the health status of the individual or medical care
18 or treatment for the individual's condition or disease, re-
19 gardless of whether benefits for such care or treatment
20 are provided under the plan or coverage, if the professional
21 is acting within the lawful scope of practice.

22 (b) NULLIFICATION.—Any contract provision or
23 agreement that restricts or prohibits medical communica-
24 tions in violation of subsection (a) shall be null and void.

1 **SEC. 132. PROHIBITION OF DISCRIMINATION AGAINST PRO-**
2 **VIDERS BASED ON LICENSURE.**

3 (a) IN GENERAL.—A group health plan, and a health
4 insurance issuer with respect to health insurance coverage,
5 shall not discriminate with respect to participation or in-
6 demnification as to any provider who is acting within the
7 scope of the provider’s license or certification under appli-
8 cable State law, solely on the basis of such license or cer-
9 tification.

10 (b) CONSTRUCTION.—Subsection (a) shall not be con-
11 strued—

12 (1) as requiring the coverage under a group
13 health plan or health insurance coverage of a par-
14 ticular benefit or service or to prohibit a plan or
15 issuer from including providers only to the extent
16 necessary to meet the needs of the plan’s or issuer’s
17 participants, beneficiaries, or enrollees or from es-
18 tablishing any measure designed to maintain quality
19 and control costs consistent with the responsibilities
20 of the plan or issuer;

21 (2) to override any State licensure or scope-of-
22 practice law; or

23 (3) as requiring a plan or issuer that offers net-
24 work coverage to include for participation every will-
25 ing provider who meets the terms and conditions of
26 the plan or issuer.

1 **SEC. 133. PROHIBITION AGAINST IMPROPER INCENTIVE**
2 **ARRANGEMENTS.**

3 (a) IN GENERAL.—A group health plan and a health
4 insurance issuer offering health insurance coverage may
5 not operate any physician incentive plan (as defined in
6 subparagraph (B) of section 1852(j)(4) of the Social Secu-
7 rity Act) unless the requirements described in clauses (i),
8 (ii)(I), and (iii) of subparagraph (A) of such section are
9 met with respect to such a plan.

10 (b) APPLICATION.—For purposes of carrying out
11 paragraph (1), any reference in section 1852(j)(4) of the
12 Social Security Act to the Secretary, a Medicare+Choice
13 or MedicareAdvantage organization, or an individual en-
14 rolled with such an organization shall be treated as a ref-
15 erence to the applicable authority, a group health plan or
16 health insurance issuer, respectively, and a participant,
17 beneficiary, or enrollee with the plan or organization, re-
18 spectively.

19 (c) CONSTRUCTION.—Nothing in this section shall be
20 construed as prohibiting all capitation and similar ar-
21 rangements or all provider discount arrangements.

22 **SEC. 134. PAYMENT OF CLAIMS.**

23 A group health plan, and a health insurance issuer
24 offering health insurance coverage, shall provide for
25 prompt payment of claims submitted for health care serv-
26 ices or supplies furnished to a participant, beneficiary, or

1 enrollee with respect to benefits covered by the plan or
2 issuer, in a manner that is no less protective than the pro-
3 visions of section 1842(c)(2) of the Social Security Act
4 (42 U.S.C. 1395u(c)(2)).

5 **SEC. 135. PROTECTION FOR PATIENT ADVOCACY.**

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

16 (b) PROTECTION FOR QUALITY ADVOCACY BY
17 HEALTH CARE PROFESSIONALS.—

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

22 (A) discloses information relating to the
23 care, services, or conditions affecting one or
24 more participants, beneficiaries, or enrollees of
25 the plan or issuer to an appropriate public reg-

1 ulatory agency, an appropriate private accredi-
2 tation body, or appropriate management per-
3 sonnel of the plan or issuer; or

4 (B) initiates, cooperates, or otherwise par-
5 ticipates in an investigation or proceeding by
6 such an agency with respect to such care, serv-
7 ices, or conditions.

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

21 (2) GOOD FAITH ACTION.—For purposes of
22 paragraph (1), a protected health care professional
23 is considered to be acting in good faith with respect
24 to disclosure of information or participation if, with

1 respect to the information disclosed as part of the
2 action—

3 (A) the disclosure is made on the basis of
4 personal knowledge and is consistent with that
5 degree of learning and skill ordinarily possessed
6 by health care professionals with the same li-
7 censure or certification and the same experi-
8 ence;

9 (B) the professional reasonably believes the
10 information to be true;

11 (C) the information evidences either a vio-
12 lation of a law, rule, or regulation, of an appli-
13 cable accreditation standard, or of a generally
14 recognized professional or clinical standard or
15 that a patient is in imminent hazard of loss of
16 life or serious injury; and

17 (D) subject to subparagraphs (B) and (C)
18 of paragraph (3), the professional has followed
19 reasonable internal procedures of the plan,
20 issuer, or institutional health care provider es-
21 tablished for the purpose of addressing quality
22 concerns before making the disclosure.

23 (3) EXCEPTION AND SPECIAL RULE.—

24 (A) GENERAL EXCEPTION.—Paragraph (1)
25 does not protect disclosures that would violate

1 Federal or State law or diminish or impair the
2 rights of any person to the continued protection
3 of confidentiality of communications provided
4 by such law.

5 (B) NOTICE OF INTERNAL PROCEDURES.—
6 Subparagraph (D) of paragraph (2) shall not
7 apply unless the internal procedures involved
8 are reasonably expected to be known to the
9 health care professional involved. For purposes
10 of this subparagraph, a health care professional
11 is reasonably expected to know of internal pro-
12 cedures if those procedures have been made
13 available to the professional through distribu-
14 tion or posting.

15 (C) INTERNAL PROCEDURE EXCEPTION.—
16 Subparagraph (D) of paragraph (2) also shall
17 not apply if—

18 (i) the disclosure relates to an immi-
19 nent hazard of loss of life or serious injury
20 to a patient;

21 (ii) the disclosure is made to an ap-
22 propriate private accreditation body pursu-
23 ant to disclosure procedures established by
24 the body; or

1 (iii) the disclosure is in response to an
2 inquiry made in an investigation or pro-
3 ceeding of an appropriate public regulatory
4 agency and the information disclosed is
5 limited to the scope of the investigation or
6 proceeding.

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

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

22 (6) CONSTRUCTIONS.—

23 (A) DETERMINATIONS OF COVERAGE.—
24 Nothing in this subsection shall be construed to
25 prohibit a plan or issuer from making a deter-

1 mination not to pay for a particular medical
2 treatment or service or the services of a type of
3 health care professional.

4 (B) ENFORCEMENT OF PEER REVIEW PRO-
5 TOCOLS AND INTERNAL PROCEDURES.—Noth-
6 ing in this subsection shall be construed to pro-
7 hibit a plan, issuer, or provider from estab-
8 lishing and enforcing reasonable peer review or
9 utilization review protocols or determining
10 whether a protected health care professional has
11 complied with those protocols or from estab-
12 lishing and enforcing internal procedures for
13 the purpose of addressing quality concerns.

14 (C) RELATION TO OTHER RIGHTS.—Noth-
15 ing in this subsection shall be construed to
16 abridge rights of participants, beneficiaries, en-
17 rollees, and protected health care professionals
18 under other applicable Federal or State laws.

19 (7) PROTECTED HEALTH CARE PROFESSIONAL
20 DEFINED.—For purposes of this subsection, the
21 term “protected health care professional” means an
22 individual who is a licensed or certified health care
23 professional and who—

24 (A) with respect to a group health plan or
25 health insurance issuer, is an employee of the

1 plan or issuer or has a contract with the plan
2 or issuer for provision of services for which ben-
3 efits are available under the plan or issuer; or

4 (B) with respect to an institutional health
5 care provider, is an employee of the provider or
6 has a contract or other arrangement with the
7 provider respecting the provision of health care
8 services.

9 **Subtitle E—Definitions**

10 **SEC. 151. DEFINITIONS.**

11 (a) INCORPORATION OF GENERAL DEFINITIONS.—
12 Except as otherwise provided, the provisions of section
13 2791 of the Public Health Service Act shall apply for pur-
14 poses of this title in the same manner as they apply for
15 purposes of title XXVII of such Act.

16 (b) SECRETARY.—Except as otherwise provided, the
17 term “Secretary” means the Secretary of Health and
18 Human Services, in consultation with the Secretary of
19 Labor and the term “appropriate Secretary” means the
20 Secretary of Health and Human Services in relation to
21 carrying out this title under sections 2706 and 2751 of
22 the Public Health Service Act and the Secretary of Labor
23 in relation to carrying out this title under section 714 of
24 the Employee Retirement Income Security Act of 1974.

1 (c) ADDITIONAL DEFINITIONS.—For purposes of this
2 title:

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

5 (A) in the case of a group health plan, the
6 Secretary of Health and Human Services and
7 the Secretary of Labor; and

8 (B) in the case of a health insurance issuer
9 with respect to a specific provision of this title,
10 the applicable State authority (as defined in
11 section 2791(d) of the Public Health Service
12 Act), or the Secretary of Health and Human
13 Services, if such Secretary is enforcing such
14 provision under section 2722(a)(2) or
15 2761(a)(2) of the Public Health Service Act.

16 (2) ENROLLEE.—The term “enrollee” means,
17 with respect to health insurance coverage offered by
18 a health insurance issuer, an individual enrolled with
19 the issuer to receive such coverage.

20 (3) GROUP HEALTH PLAN.—The term “group
21 health plan” has the meaning given such term in
22 section 733(a) of the Employee Retirement Income
23 Security Act of 1974, except that such term includes
24 an employee welfare benefit plan treated as a group
25 health plan under section 732(d) of such Act or de-

1 fined as such a plan under section 607(1) of such
2 Act.

3 (4) HEALTH CARE PROFESSIONAL.—The term
4 “health care professional” means an individual who
5 is licensed, accredited, or certified under State law
6 to provide specified health care services and who is
7 operating within the scope of such licensure, accredi-
8 tation, or certification.

9 (5) HEALTH CARE PROVIDER.—The term
10 “health care provider” includes a physician or other
11 health care professional, as well as an institutional
12 or other facility or agency that provides health care
13 services and that is licensed, accredited, or certified
14 to provide health care items and services under ap-
15 plicable State law.

16 (6) NETWORK.—The term “network” means,
17 with respect to a group health plan or health insur-
18 ance issuer offering health insurance coverage, the
19 participating health care professionals and providers
20 through whom the plan or issuer provides health
21 care items and services to participants, beneficiaries,
22 or enrollees.

23 (7) NONPARTICIPATING.—The term “non-
24 participating” means, with respect to a health care
25 provider that provides health care items and services

1 to a participant, beneficiary, or enrollee under group
2 health plan or health insurance coverage, a health
3 care provider that is not a participating health care
4 provider with respect to such items and services.

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

13 (9) PRIOR AUTHORIZATION.—The term “prior
14 authorization” means the process of obtaining prior
15 approval from a health insurance issuer or group
16 health plan for the provision or coverage of medical
17 services.

18 (10) TERMS AND CONDITIONS.—The term
19 “terms and conditions” includes, with respect to a
20 group health plan or health insurance coverage, re-
21 quirements imposed under this title with respect to
22 the plan or coverage.

1 **SEC. 152. PREEMPTION; STATE FLEXIBILITY; CONSTRUC-**
2 **TION.**

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

5 (1) IN GENERAL.—Subject to paragraph (2),
6 this title shall not be construed to supersede any
7 provision of State law which establishes, implements,
8 or continues in effect any standard or requirement
9 solely relating to health insurance issuers (in connec-
10 tion with group health insurance coverage or other-
11 wise) except to the extent that such standard or re-
12 quirement prevents the application of a requirement
13 of this title.

14 (2) CONTINUED PREEMPTION WITH RESPECT
15 TO GROUP HEALTH PLANS.—Nothing in this title
16 shall be construed to affect or modify the provisions
17 of section 514 of the Employee Retirement Income
18 Security Act of 1974 with respect to group health
19 plans.

20 (3) CONSTRUCTION.—In applying this section,
21 a State law that provides for equal access to, and
22 availability of, all categories of licensed health care
23 providers and services shall not be treated as pre-
24 venting the application of any requirement of this
25 title.

1 (b) APPLICATION OF SUBSTANTIALLY COMPLIANT
2 STATE LAWS.—

3 (1) IN GENERAL.—In the case of a State law
4 that imposes, with respect to health insurance cov-
5 erage offered by a health insurance issuer and with
6 respect to a group health plan that is a non-Federal
7 governmental plan, a requirement that substantially
8 complies (within the meaning of subsection (e)) with
9 a patient protection requirement (as defined in para-
10 graph (3)) and does not prevent the application of
11 other requirements under this Act (except in the
12 case of other substantially compliant requirements),
13 in applying the requirements of this title under sec-
14 tion 2707 and 2753 (as applicable) of the Public
15 Health Service Act (as added by title II), subject to
16 subsection (a)(2)—

17 (A) the State law shall not be treated as
18 being superseded under subsection (a); and

19 (B) the State law shall apply instead of the
20 patient protection requirement otherwise appli-
21 cable with respect to health insurance coverage
22 and non-Federal governmental plans.

23 (2) LIMITATION.—In the case of a group health
24 plan covered under title I of the Employee Retire-
25 ment Income Security Act of 1974, paragraph (1)

1 shall be construed to apply only with respect to the
2 health insurance coverage (if any) offered in connec-
3 tion with the plan.

4 (3) DEFINITIONS.—In this section:

5 (A) PATIENT PROTECTION REQUIRE-
6 MENT.—The term “patient protection require-
7 ment” means a requirement under this title,
8 and includes (as a single requirement) a group
9 or related set of requirements under a section
10 or similar unit under this title.

11 (B) SUBSTANTIALLY COMPLIANT.—The
12 terms “substantially compliant”, “substantially
13 complies”, or “substantial compliance” with re-
14 spect to a State law, mean that the State law
15 has the same or similar features as the patient
16 protection requirements and has a similar ef-
17 fect.

18 (c) DETERMINATIONS OF SUBSTANTIAL COMPLI-
19 ANCE.—

20 (1) CERTIFICATION BY STATES.—A State may
21 submit to the Secretary a certification that a State
22 law provides for patient protections that are at least
23 substantially compliant with one or more patient
24 protection requirements. Such certification shall be
25 accompanied by such information as may be re-

1 quired to permit the Secretary to make the deter-
2 mination described in paragraph (2)(A).

3 (2) REVIEW.—

4 (A) IN GENERAL.—The Secretary shall
5 promptly review a certification submitted under
6 paragraph (1) with respect to a State law to de-
7 termine if the State law substantially complies
8 with the patient protection requirement (or re-
9 quirements) to which the law relates.

10 (B) APPROVAL DEADLINES.—

11 (i) INITIAL REVIEW.—Such a certifi-
12 cation is considered approved unless the
13 Secretary notifies the State in writing,
14 within 90 days after the date of receipt of
15 the certification, that the certification is
16 disapproved (and the reasons for dis-
17 approval) or that specified additional infor-
18 mation is needed to make the determina-
19 tion described in subparagraph (A).

20 (ii) ADDITIONAL INFORMATION.—

21 With respect to a State that has been noti-
22 fied by the Secretary under clause (i) that
23 specified additional information is needed
24 to make the determination described in
25 subparagraph (A), the Secretary shall

1 make the determination within 60 days
2 after the date on which such specified ad-
3 ditional information is received by the Sec-
4 retary.

5 (3) APPROVAL.—

6 (A) IN GENERAL.—The Secretary shall ap-
7 prove a certification under paragraph (1) un-
8 less—

9 (i) the State fails to provide sufficient
10 information to enable the Secretary to
11 make a determination under paragraph
12 (2)(A); or

13 (ii) the Secretary determines that the
14 State law involved does not provide for pa-
15 tient protections that substantially comply
16 with the patient protection requirement (or
17 requirements) to which the law relates.

18 (B) STATE CHALLENGE.—A State that has
19 a certification disapproved by the Secretary
20 under subparagraph (A) may challenge such
21 disapproval in the appropriate United States
22 district court.

23 (C) DEFERENCE TO STATES.—With re-
24 spect to a certification submitted under para-
25 graph (1), the Secretary shall give deference to

1 the State's interpretation of the State law in-
2 volved with respect to the patient protection in-
3 volved.

4 (D) PUBLIC NOTIFICATION.—The Sec-
5 retary shall—

6 (i) provide a State with a notice of the
7 determination to approve or disapprove a
8 certification under this paragraph;

9 (ii) promptly publish in the Federal
10 Register a notice that a State has sub-
11 mitted a certification under paragraph (1);

12 (iii) promptly publish in the Federal
13 Register the notice described in clause (i)
14 with respect to the State; and

15 (iv) annually publish the status of all
16 States with respect to certifications.

17 (4) CONSTRUCTION.—Nothing in this sub-
18 section shall be construed as preventing the certifi-
19 cation (and approval of certification) of a State law
20 under this subsection solely because it provides for
21 greater protections for patients than those protec-
22 tions otherwise required to establish substantial
23 compliance.

24 (5) PETITIONS.—

1 (A) PETITION PROCESS.—Effective on the
2 date on which the provisions of this Act become
3 effective, as provided for in section 601, a
4 group health plan, health insurance issuer, par-
5 ticipant, beneficiary, or enrollee may submit a
6 petition to the Secretary for an advisory opinion
7 as to whether or not a standard or requirement
8 under a State law applicable to the plan, issuer,
9 participant, beneficiary, or enrollee that is not
10 the subject of a certification under this sub-
11 section, is superseded under subsection (a)(1)
12 because such standard or requirement prevents
13 the application of a requirement of this title.

14 (B) OPINION.—The Secretary shall issue
15 an advisory opinion with respect to a petition
16 submitted under subparagraph (A) within the
17 60-day period beginning on the date on which
18 such petition is submitted.

19 (d) DEFINITIONS.—For purposes of this section:

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

1 (2) STATE.—The term “State” includes a
2 State, the District of Columbia, Puerto Rico, the
3 Virgin Islands, Guam, American Samoa, the North-
4 ern Mariana Islands, any political subdivisions of
5 such, or any agency or instrumentality of such.

6 **SEC. 153. EXCLUSIONS.**

7 (a) NO BENEFIT REQUIREMENTS.—Nothing in this
8 title shall be construed to require a group health plan or
9 a health insurance issuer offering health insurance cov-
10 erage to include specific items and services under the
11 terms of such a plan or coverage, other than those pro-
12 vided under the terms and conditions of such plan or cov-
13 erage.

14 (b) EXCLUSION FROM ACCESS TO CARE MANAGED
15 CARE PROVISIONS FOR FEE-FOR-SERVICE COVERAGE.—

16 (1) IN GENERAL.—The provisions of sections
17 111 through 117 shall not apply to a group health
18 plan or health insurance coverage if the only cov-
19 erage offered under the plan or coverage is fee-for-
20 service coverage (as defined in paragraph (2)).

21 (2) FEE-FOR-SERVICE COVERAGE DEFINED.—
22 For purposes of this subsection, the term “fee-for-
23 service coverage” means coverage under a group
24 health plan or health insurance coverage that—

1 (A) reimburses hospitals, health profes-
2 sionals, and other providers on a fee-for-service
3 basis without placing the provider at financial
4 risk;

5 (B) does not vary reimbursement for such
6 a provider based on an agreement to contract
7 terms and conditions or the utilization of health
8 care items or services relating to such provider;

9 (C) allows access to any provider that is
10 lawfully authorized to provide the covered serv-
11 ices and that agrees to accept the terms and
12 conditions of payment established under the
13 plan or by the issuer; and

14 (D) for which the plan or issuer does not
15 require prior authorization before providing for
16 any health care services.

17 **SEC. 154. TREATMENT OF EXCEPTED BENEFITS.**

18 (a) IN GENERAL.—The requirements of this title
19 shall not apply to excepted benefits (as defined in section
20 733(c) of such Act), other than benefits described in sec-
21 tion 733(c)(2)(A) of such Act, in the same manner as the
22 provisions of part 7 of subtitle B of title I of such Act
23 do not apply to such benefits under subsections (b) and
24 (c) of section 732 of such Act.

1 (b) COVERAGE OF CERTAIN LIMITED SCOPE
2 PLANS.—Only for purposes of applying the requirements
3 of this title under sections 2707 and 2753 of the Public
4 Health Service Act, section 714 of the Employee Retirement
5 Income Security Act of 1974, and section 9813 of
6 the Internal Revenue Code of 1986, the following sections
7 shall be deemed not to apply:

8 (1) Section 2791(c)(2)(A) of the Public Health
9 Service Act.

10 (2) Section 733(c)(2)(A) of the Employee Retirement
11 Income Security Act of 1974.

12 (3) Section 9832(c)(2)(A) of the Internal Revenue
13 Code of 1986.

14 **SEC. 155. REGULATIONS.**

15 The Secretaries of Health and Human Services,
16 Labor, and the Treasury shall issue such regulations as
17 may be necessary or appropriate to carry out this title.
18 Such regulations shall be issued consistent with section
19 104 of Health Insurance Portability and Accountability
20 Act of 1996. Such Secretaries may promulgate any interim
21 final rules as the Secretaries determine are appropriate
22 to carry out this title.

1 **SEC. 156. INCORPORATION INTO PLAN OR COVERAGE DOC-**
2 **UMENTS.**

3 The requirements of this title with respect to a group
4 health plan or health insurance coverage are, subject to
5 section 154, deemed to be incorporated into, and made
6 a part of, such plan or the policy, certificate, or contract
7 providing such coverage and are enforceable under law as
8 if directly included in the documentation of such plan or
9 such policy, certificate, or contract.

10 **SEC. 157. PRESERVATION OF PROTECTIONS.**

11 (a) **IN GENERAL.**—The rights under this Act (includ-
12 ing the right to maintain a civil action and any other
13 rights under the amendments made by this Act) may not
14 be waived, deferred, or lost pursuant to any agreement
15 not authorized under this Act.

16 (b) **EXCEPTION.**—Subsection (a) shall not apply to
17 an agreement providing for arbitration or participation in
18 any other nonjudicial procedure to resolve a dispute if the
19 agreement is entered into knowingly and voluntarily by the
20 parties involved after the dispute has arisen or is pursuant
21 to the terms of a collective bargaining agreement. Nothing
22 in this subsection shall be construed to permit the waiver
23 of the requirements of sections 103 and 104 (relating to
24 internal and external review).

1 **TITLE II—APPLICATION OF**
2 **QUALITY CARE STANDARDS**
3 **TO GROUP HEALTH PLANS**
4 **AND HEALTH INSURANCE**
5 **COVERAGE UNDER THE PUB-**
6 **LIC HEALTH SERVICE ACT**

7 **SEC. 201. APPLICATION TO GROUP HEALTH PLANS AND**
8 **GROUP HEALTH INSURANCE COVERAGE.**

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

12 **“SEC. 2707. PATIENT PROTECTION STANDARDS.**

13 “Each group health plan shall comply with patient
14 protection requirements under title I of the Patient Pro-
15 tection Act of 2005, and each health insurance issuer shall
16 comply with patient protection requirements under such
17 title with respect to group health insurance coverage it of-
18 fers, and such requirements shall be deemed to be incor-
19 porated into this subsection.”.

20 (b) CONFORMING AMENDMENT.—Section
21 2721(b)(2)(A) of such Act (42 U.S.C. 300gg–21(b)(2)(A))
22 is amended by inserting “(other than section 2707)” after
23 “requirements of such subparts”.

1 **SEC. 202. APPLICATION TO INDIVIDUAL HEALTH INSUR-**
2 **ANCE COVERAGE.**

3 Part B of title XXVII of the Public Health Service
4 Act is amended by inserting after section 2752 the fol-
5 lowing new section:

6 **“SEC. 2753. PATIENT PROTECTION STANDARDS.**

7 “Each health insurance issuer shall comply with pa-
8 tient protection requirements under title I of the Patient
9 Protection Act of 2005 with respect to individual health
10 insurance coverage it offers, and such requirements shall
11 be deemed to be incorporated into this subsection.”.

12 **SEC. 203. COOPERATION BETWEEN FEDERAL AND STATE**
13 **AUTHORITIES.**

14 Part C of title XXVII of the Public Health Service
15 Act (42 U.S.C. 300gg–91 et seq.) is amended by adding
16 at the end the following:

17 **“SEC. 2793. COOPERATION BETWEEN FEDERAL AND STATE**
18 **AUTHORITIES.**

19 “(a) AGREEMENT WITH STATES.—A State may
20 enter into an agreement with the Secretary for the delega-
21 tion to the State of some or all of the Secretary’s authority
22 under this title to enforce the requirements applicable
23 under title I of the Patient Protection Act of 2005 with
24 respect to health insurance coverage offered by a health
25 insurance issuer and with respect to a group health plan
26 that is a non-Federal governmental plan.

1 “(b) DELEGATIONS.—Any department, agency, or in-
2 strumentality of a State to which authority is delegated
3 pursuant to an agreement entered into under this section
4 may, if authorized under State law and to the extent con-
5 sistent with such agreement, exercise the powers of the
6 Secretary under this title which relate to such authority.”.

7 **TITLE III—APPLICATION OF PA-**
8 **TIENT PROTECTION STAND-**
9 **ARDS TO FEDERAL HEALTH**
10 **INSURANCE PROGRAMS**

11 **SEC. 301. APPLICATION OF PATIENT PROTECTION STAND-**
12 **ARDS TO FEDERAL HEALTH INSURANCE PRO-**
13 **GRAMS.**

14 (a) SENSE OF CONGRESS.—It is the sense of Con-
15 gress that enrollees in Federal health insurance programs
16 should have the same rights and privileges as those af-
17 farded under title I and under the amendments made by
18 title IV to participants and beneficiaries under group
19 health plans.

20 (b) CONFORMING FEDERAL HEALTH INSURANCE
21 PROGRAMS.—It is the sense of Congress that the Presi-
22 dent should require, by executive order, the Federal offi-
23 cial with authority over each Federal health insurance pro-
24 gram, to the extent feasible, to take such steps as are nec-

1 essary to implement the rights and privileges described in
2 subsection (a) with respect to such program.

3 (c) GAO REPORT ON ADDITIONAL STEPS RE-
4 QUIRED.—Not later than 1 year after the date of the en-
5 actment of this Act, the Comptroller General of the United
6 States shall submit to Congress a report on statutory
7 changes that are required to implement such rights and
8 privileges in a manner that is consistent with the missions
9 of the Federal health insurance programs and that avoids
10 unnecessary duplication or disruption of such programs.

11 (d) FEDERAL HEALTH INSURANCE PROGRAM.—In
12 this section, the term “Federal health insurance program”
13 means a Federal program that provides creditable cov-
14 erage (as defined in section 2701(c)(1) of the Public
15 Health Service Act) and includes a health program of the
16 Department of Veterans Affairs.

1 **TITLE IV—AMENDMENTS TO THE**
 2 **EMPLOYEE RETIREMENT IN-**
 3 **COME SECURITY ACT OF 1974**

4 **SEC. 401. APPLICATION OF PATIENT PROTECTION STAND-**
 5 **ARDS TO GROUP HEALTH PLANS AND GROUP**
 6 **HEALTH INSURANCE COVERAGE UNDER THE**
 7 **EMPLOYEE RETIREMENT INCOME SECURITY**
 8 **ACT OF 1974.**

9 Subpart B of part 7 of subtitle B of title I of the
 10 Employee Retirement Income Security Act of 1974 is
 11 amended by adding at the end the following new section:

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

13 “(a) IN GENERAL.—Subject to subsection (b), a
 14 group health plan (and a health insurance issuer offering
 15 group health insurance coverage in connection with such
 16 a plan) shall comply with the requirements of title I of
 17 the Patient Protection Act of 2005 (as in effect as of the
 18 date of the enactment of such Act), and such requirements
 19 shall be deemed to be incorporated into this subsection.

20 “(b) PLAN SATISFACTION OF CERTAIN REQUIRE-
 21 MENTS.—

22 “(1) SATISFACTION OF CERTAIN REQUIRE-
 23 MENTS THROUGH INSURANCE.—For purposes of
 24 subsection (a), insofar as a group health plan pro-
 25 vides benefits in the form of health insurance cov-

1 erage through a health insurance issuer, the plan
2 shall be treated as meeting the following require-
3 ments of title I of the Patient Protection Act of
4 2005 with respect to such benefits and not be con-
5 sidered as failing to meet such requirements because
6 of a failure of the issuer to meet such requirements
7 so long as the plan sponsor or its representatives did
8 not cause such failure by the issuer:

9 “(A) Section 111 (relating to consumer
10 choice option).

11 “(B) Section 112 (relating to choice of
12 health care professional).

13 “(C) Section 113 (relating to access to
14 emergency care).

15 “(D) Section 114 (relating to timely access
16 to specialists).

17 “(E) Section 115 (relating to patient ac-
18 cess to obstetrical and gynecological care).

19 “(F) Section 116 (relating to access to pe-
20 diatric care).

21 “(G) Section 117 (relating to continuity of
22 care), but only insofar as a replacement issuer
23 assumes the obligation for continuity of care.

24 “(H) Section 118 (relating to access to
25 needed prescription drugs).

1 “(I) Section 119 (relating to coverage for
2 individuals participating in approved clinical
3 trials).

4 “(J) Section 120 (relating to required cov-
5 erage for minimum hospital stay for
6 mastectomies and lymph node dissections for
7 the treatment of breast cancer and coverage for
8 secondary consultations).

9 “(K) Section 134 (relating to payment of
10 claims).

11 “(2) INFORMATION.—With respect to informa-
12 tion required to be provided or made available under
13 section 121 of the Patient Protection Act of 2005,
14 in the case of a group health plan that provides ben-
15 efits in the form of health insurance coverage
16 through a health insurance issuer, the Secretary
17 shall determine the circumstances under which the
18 plan is not required to provide or make available the
19 information (and is not liable for the issuer’s failure
20 to provide or make available the information), if the
21 issuer is obligated to provide and make available (or
22 provides and makes available) such information.

23 “(3) INTERNAL APPEALS.—With respect to the
24 internal appeals process required to be established
25 under section 103 of such Act, in the case of a

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

9 “(4) EXTERNAL APPEALS.—Pursuant to rules
10 of the Secretary, insofar as a group health plan en-
11 ters into a contract with a qualified external appeal
12 entity for the conduct of external appeal activities in
13 accordance with section 104 of such Act, the plan
14 shall be treated as meeting the requirement of such
15 section and is not liable for the entity’s failure to
16 meet any requirements under such section.

17 “(5) APPLICATION TO PROHIBITIONS.—Pursu-
18 ant to rules of the Secretary, if a health insurance
19 issuer offers health insurance coverage in connection
20 with a group health plan and takes an action in vio-
21 lation of any of the following sections of the Patient
22 Protection Act of 2005, the group health plan shall
23 not be liable for such violation unless the plan
24 caused such violation:

1 “(A) Section 131 (relating to prohibition of
2 interference with certain medical communica-
3 tions).

4 “(B) Section 132 (relating to prohibition
5 of discrimination against providers based on li-
6 censure).

7 “(C) Section 133 (relating to prohibition
8 against improper incentive arrangements).

9 “(D) Section 135 (relating to protection
10 for patient advocacy).

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

15 “(7) TREATMENT OF SUBSTANTIALLY COMPLI-
16 ANT STATE LAWS.—For purposes of applying this
17 subsection in connection with health insurance cov-
18 erage, any reference in this subsection to a require-
19 ment in a section or other provision in the Patient
20 Protection Act of 2005 with respect to a health in-
21 surance issuer is deemed to include a reference to a
22 requirement under a State law that substantially
23 complies (as determined under section 152(c) of
24 such Act) with the requirement in such section or
25 other provisions.

1 “(8) APPLICATION TO CERTAIN PROHIBITIONS
2 AGAINST RETALIATION.—With respect to compliance
3 with the requirements of section 135(b)(1) of the
4 Patient Protection Act of 2005, for purposes of this
5 subtitle the term ‘group health plan’ is deemed to in-
6 clude a reference to an institutional health care pro-
7 vider.

8 “(c) ENFORCEMENT OF CERTAIN REQUIREMENTS.—

9 “(1) COMPLAINTS.—Any protected health care
10 professional who believes that the professional has
11 been retaliated or discriminated against in violation
12 of section 135(b)(1) of the Patient Protection Act of
13 2005 may file with the Secretary a complaint within
14 180 days of the date of the alleged retaliation or dis-
15 crimination.

16 “(2) INVESTIGATION.—The Secretary shall in-
17 vestigate such complaints and shall determine if a
18 violation of such section has occurred and, if so,
19 shall issue an order to ensure that the protected
20 health care professional does not suffer any loss of
21 position, pay, or benefits in relation to the plan,
22 issuer, or provider involved, as a result of the viola-
23 tion found by the Secretary.

24 “(d) CONFORMING REGULATIONS.—The Secretary
25 shall issue regulations to coordinate the requirements on

1 group health plans and health insurance issuers under this
2 section with the requirements imposed under the other
3 provisions of this title. In order to reduce duplication and
4 clarify the rights of participants and beneficiaries with re-
5 spect to information that is required to be provided, such
6 regulations shall coordinate the information disclosure re-
7 quirements under section 121 of the Patient Protection
8 Act of 2005 with the reporting and disclosure require-
9 ments imposed under part 1, so long as such coordination
10 does not result in any reduction in the information that
11 would otherwise be provided to participants and bene-
12 ficiaries.”.

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

17 “(b) In the case of a group health plan (as defined
18 in section 733), compliance with the requirements of sub-
19 title A of title I of the Patient Protection Act of 2005,
20 and compliance with regulations promulgated by the Sec-
21 retary, in the case of a claims denial, shall be deemed com-
22 pliance with subsection (a) with respect to such claims de-
23 nial.”.

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 714”.

4 (2) The table of contents in section 1 of such Act
5 is amended by inserting after the item relating to section
6 713 the following new item:

“714. 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
9 135(b))” after “part 7”.

10 **SEC. 402. COOPERATION BETWEEN FEDERAL AND STATE**
11 **AUTHORITIES.**

12 Subpart C of part 7 of subtitle B of title I of the
13 Employee Retirement Income Security Act of 1974 (29
14 U.S.C. 1191 et seq.) is amended by adding at the end
15 the following new section:

16 **“SEC. 735. COOPERATION BETWEEN FEDERAL AND STATE**
17 **AUTHORITIES.**

18 “(a) AGREEMENT WITH STATES.—A State may
19 enter into an agreement with the Secretary for the delega-
20 tion to the State of some or all of the Secretary’s authority
21 under this title to enforce the requirements applicable
22 under title I of the Patient Protection Act of 2005 with
23 respect to health insurance coverage offered by a health
24 insurance issuer.

1 and

2 (2) by inserting after section 9812 the fol-
3 lowing:

4 **“SEC. 9813. STANDARD RELATING TO PATIENTS’ BILL OF**
5 **RIGHTS.**

6 “A group health plan shall comply with the require-
7 ments of title I of the Patient Protection Act of 2005 (as
8 in effect as of the date of the enactment of such Act),
9 and such requirements shall be deemed to be incorporated
10 into this section.”.

11 **SEC. 502. CONFORMING ENFORCEMENT FOR WOMEN’S**
12 **HEALTH AND CANCER RIGHTS.**

13 Subchapter B of chapter 100 of the Internal Revenue
14 Code of 1986, as amended by section 501, is further
15 amended—

16 (1) in the table of sections, by inserting after
17 the item relating to section 9813 the following new
18 item:

“9814. Standard relating to women’s health and cancer rights.”;

19 and

20 (2) by inserting after section 9813 the fol-
21 lowing:

22 **“SEC. 9814. STANDARD RELATING TO WOMEN’S HEALTH**
23 **AND CANCER RIGHTS.**

24 “The provisions of section 713 of the Employee Re-
25 tirement Income Security Act of 1974 (as in effect as of

1 the date of the enactment of this section) shall apply to
2 group health plans as if included in this subchapter.”.

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

6 **SEC. 601. EFFECTIVE DATES.**

7 (a) GROUP HEALTH COVERAGE.—

8 (1) IN GENERAL.—Subject to paragraph (2)
9 and subsection (d), the amendments made by sec-
10 tions 201(a), 401, 501, and 502 (and title I insofar
11 as it relates to such sections) shall apply with re-
12 spect to group health plans, and health insurance
13 coverage offered in connection with group health
14 plans, for plan years beginning on or after October
15 1, 2005 (in this section referred to as the “general
16 effective date”).

17 (2) TREATMENT OF COLLECTIVE BARGAINING
18 AGREEMENTS.—In the case of a group health plan
19 maintained pursuant to one or more collective bar-
20 gaining agreements between employee representa-
21 tives and one or more employers ratified before the
22 date of the enactment of this Act, the amendments
23 made by sections 201(a), 401, 501, and 502 (and
24 title I insofar as it relates to such sections) shall not
25 apply to plan 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 (excluding any extension thereof agreed
4 to after the date of the enactment of this Act);
5 or

6 (B) the general effective date;
7 but shall apply not later than 1 year after the gen-
8 eral effective date. For purposes of subparagraph
9 (A), any plan amendment made pursuant to a collec-
10 tive bargaining agreement relating to the plan which
11 amends the plan solely to conform to any require-
12 ment added by this Act shall not be treated as a ter-
13 mination of such collective bargaining agreement.

14 (b) INDIVIDUAL HEALTH INSURANCE COVERAGE.—
15 Subject to subsection (d), the amendments made by sec-
16 tion 202 shall apply with respect to individual health in-
17 surance coverage offered, sold, issued, renewed, in effect,
18 or operated in the individual market on or after the gen-
19 eral effective date.

20 (c) TREATMENT OF RELIGIOUS NONMEDICAL PRO-
21 VIDERS.—

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

24 (A) restrict or limit the right of group
25 health plans, and of health insurance issuers of-

1 fering health insurance coverage, to include as
2 providers religious nonmedical providers;

3 (B) require such plans or issuers to—

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

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

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

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

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

1 (2) RELIGIOUS NONMEDICAL PROVIDER.—For
2 purposes of this subsection, the term “religious non-
3 medical provider” means a provider who provides no
4 medical care but who provides only religious non-
5 medical treatment or religious nonmedical nursing
6 care.

7 (d) TRANSITION FOR NOTICE REQUIREMENT.—The
8 disclosure of information required under section 121 of
9 this Act shall first be provided pursuant to—

10 (1) subsection (a) with respect to a group
11 health plan that is maintained as of the general ef-
12 fective date, not later than 30 days before the begin-
13 ning of the first plan year to which title I applies
14 in connection with the plan under such subsection;
15 or

16 (2) subsection (b) with respect to an individual
17 health insurance coverage that is in effect as of the
18 general effective date, not later than 30 days before
19 the first date as of which title I applies to the cov-
20 erage under such subsection.

21 **SEC. 602. COORDINATION IN IMPLEMENTATION.**

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

1 (1) regulations, rulings, and interpretations
2 issued by such Secretaries relating to the same mat-
3 ter over which such Secretaries have responsibility
4 under the provisions of this Act (and the amend-
5 ments made thereby) are administered so as to have
6 the same effect at all times; and

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

12 **SEC. 603. SEVERABILITY.**

13 If any provision of this Act, an amendment made by
14 this Act, or the application of such provision or amend-
15 ment to any person or circumstance is held to be unconsti-
16 tutional, the remainder of this Act, the amendments made
17 by this Act, and the application of the provisions of such
18 to any person or circumstance shall not be affected there-
19 by.

20 **TITLE VII—MISCELLANEOUS**
21 **PROVISIONS**

22 **SEC. 701. NO IMPACT ON SOCIAL SECURITY TRUST FUND.**

23 (a) IN GENERAL.—Nothing in this Act (or an amend-
24 ment made by this Act) shall be construed to alter or

1 amend the Social Security Act (or any regulation promul-
2 gated under that Act).

3 (b) TRANSFERS.—

4 (1) ESTIMATE OF SECRETARY.—The Secretary
5 of the Treasury shall annually estimate the impact
6 that the enactment of this Act has on the income
7 and balances of the trust funds established under
8 section 201 of the Social Security Act (42 U.S.C.
9 401).

10 (2) TRANSFER OF FUNDS.—If, under para-
11 graph (1), the Secretary of the Treasury estimates
12 that the enactment of this Act has a negative impact
13 on the income and balances of the trust funds estab-
14 lished under section 201 of the Social Security Act
15 (42 U.S.C. 401), the Secretary shall transfer, not
16 less frequently than quarterly, from the general reve-
17 nues of the Federal Government an amount suffi-
18 cient so as to ensure that the income and balances
19 of such trust funds are not reduced as a result of
20 the enactment of such Act.

21 **SEC. 702. SENSE OF CONGRESS WITH RESPECT TO PARTICI-
22 PATION IN CLINICAL TRIALS AND ACCESS TO
23 SPECIALTY CARE.**

24 (a) FINDINGS.—The Congress finds the following:

1 (1) Breast cancer is the most common form of
2 cancer among women, excluding skin cancers.

3 (2) During 2005, 211,240 new cases of female
4 breast cancer are projected to be diagnosed, and an
5 estimated 40,410 women are projected to die from
6 the disease.

7 (3) During 2005, 1,690 male breast cancer
8 cases are projected to be diagnosed, and 460 men
9 are projected to die from the disease.

10 (4) Breast cancer is the second leading cause of
11 cancer death among all women and a leading cause
12 of cancer death among women between ages 40 and
13 55.

14 (5) During 2004, 9,200 children were projected
15 to be diagnosed with cancer.

16 (6) During 2004, 1,510 children were projected
17 to die from cancer.

18 (7) There are approximately 400,000 people di-
19 agnosed with multiple sclerosis in the United States
20 and approximately 250 new cases are diagnosed
21 each week.

22 (8) Parkinson's disease is a chronic and pro-
23 gressive disorder of the central nervous system, af-
24 fecting as many as 1,500,000 people in the United
25 States.

1 (9) During 2005, 232,090 men are projected to
2 be diagnosed with prostate cancer.

3 (10) During 2005, 30,350 men are projected to
4 die from prostate cancer. It is the second leading
5 cause of cancer death in men.

6 (11) Information obtained from clinical trials is
7 essential to improve the way diseases are prevented,
8 screened for, diagnosed, and treated. While there are
9 already measures in place, clinical trials are not
10 without risk. Future efforts should be taken in addi-
11 tion to those already undertaken to protect the
12 health and safety of adults and children who enroll
13 in clinical trials. Some of these include the use of in-
14 stitutional review boards, informed consent, and
15 data safety monitoring boards.

16 (12) While employers and health plans should
17 be responsible for covering the routine costs associ-
18 ated with Federally approved or funded clinical
19 trials, such employers and health plans should not
20 be held legally responsible for the design, implemen-
21 tation, or outcome of such clinical trials, consistent
22 with any applicable State or Federal liability stat-
23 utes.

24 (13) By passing legislation or instituting special
25 agreements, 21 states now require that insurance

1 companies cover the routine costs of medical care for
2 patients who enroll on a clinical trial. There is little
3 information available regarding the effect these laws
4 and agreements have had on clinical trial participa-
5 tion.

6 (14) When evaluating clinical trial participa-
7 tion, it is vital to review the issues of quantity and
8 quality. Identifying as many patients as possible who
9 meet the eligibility criteria to participate in a clinical
10 trial, and providing all of those eligible patients with
11 the opportunity to decide whether or not to enroll,
12 are together one important aspect. Having quality
13 clinical trials available which utilize sound scientific
14 and ethical guidelines to answer imminent questions
15 related to particular diseases is also quite important.

16 (b) SENSE OF THE CONGRESS.—It is the sense of
17 the Congress that—

18 (1) men and women battling life-threatening,
19 deadly diseases, including advanced breast or ovar-
20 ian cancer, should have the opportunity to partici-
21 pate in a Federally approved or funded clinical trial
22 recommended by their physician;

23 (2) an individual should have the opportunity to
24 participate in a Federally approved or funded clin-
25 ical trial recommended by their physician if—

1 (A) that individual—

2 (i) has a life-threatening or serious ill-
3 ness for which no standard treatment is ef-
4 fective; or

5 (ii) is eligible to participate in a Fed-
6 erally approved or funded clinical trial ac-
7 cording to the trial protocol with respect to
8 treatment of the illness;

9 (B) that individual's participation in the
10 trial offers meaningful potential for significant
11 clinical benefit for the individual; and

12 (C) either—

13 (i) the referring physician is a partici-
14 pating health care professional and has
15 concluded that the individual's participa-
16 tion in the trial would be appropriate,
17 based upon the individual meeting the con-
18 ditions described in subparagraph (A); or

19 (ii) the participant, beneficiary, or en-
20 rollee provides medical and scientific infor-
21 mation establishing that the individual's
22 participation in the trial would be appro-
23 priate, based upon the individual meeting
24 the conditions described in subparagraph
25 (A);

1 (3) a child with a life-threatening illness, in-
2 cluding cancer, should be allowed to participate in a
3 Federally approved or funded clinical trial if that
4 participation meets the requirements of paragraph
5 (2);

6 (4) a child with a rare cancer should be allowed
7 to go to a cancer center capable of providing high
8 quality care for that disease; and

9 (5) a health maintenance organization's deci-
10 sion that an in-network physician without the nec-
11 essary expertise can provide care for a seriously ill
12 patient, including a woman battling cancer, should
13 be appealable to an independent, impartial body, and
14 that this same right should be available to all Ameri-
15 cans in need of access to high quality specialty care.

16 **SEC. 703. SENSE OF THE CONGRESS REGARDING FAIR RE-**
17 **VIEW PROCESS.**

18 (a) FINDINGS.—The Congress finds the following:

19 (1) A fair, timely, impartial independent exter-
20 nal appeals process is essential to any meaningful
21 program of patient protection.

22 (2) The independence and objectivity of the re-
23 view organization and review process must be en-
24 sured.

1 (3) It is incompatible with a fair and inde-
2 pendent appeals process to allow a health mainte-
3 nance organization to select the review organization
4 that is entrusted with providing a neutral and unbi-
5 ased medical review.

6 (4) The American Arbitration Association and
7 arbitration standards adopted under chapter 44 of
8 title 28, United States Code (28 U.S.C. 651 et seq.)
9 both prohibit, as inherently unfair, the right of one
10 party to a dispute to choose the judge in that dis-
11 pute.

12 (b) SENSE OF THE CONGRESS.—It is the sense of
13 the Congress that—

14 (1) every patient who is denied care by a health
15 maintenance organization or other health insurance
16 company should be entitled to a fair, speedy, impar-
17 tial appeal to a review organization that has not
18 been selected by the health plan;

19 (2) the States should be empowered to maintain
20 and develop the appropriate process for selection of
21 the independent external review entity;

22 (3) a child battling a rare cancer whose health
23 maintenance organization has denied a covered
24 treatment recommended by its physician should be
25 entitled to a fair and impartial external appeal to a

1 review organization that has not been chosen by the
2 organization or plan that has denied the care; and
3 (4) patient protection legislation should not pre-
4 empt existing State laws in States where there al-
5 ready are strong laws in place regarding the selec-
6 tion of independent review organizations.

7 **SEC. 704. ANNUAL REVIEW.**

8 (a) IN GENERAL.—Not later than 24 months after
9 the general effective date referred to in section 601(a)(1),
10 and annually thereafter for each of the succeeding 4 cal-
11 endar years (or until a repeal is effective under subsection
12 (b)), the Secretary of Health and Human Services shall
13 request that the Institute of Medicine of the National
14 Academy of Sciences prepare and submit to the appro-
15 priate committees of Congress a report concerning the im-
16 pact of this Act, and the amendments made by this Act,
17 on the number of individuals in the United States with
18 health insurance coverage.

19 (b) FUNDING.—From funds appropriated to the De-
20 partment of Health and Human Services for fiscal years
21 2006 and 2007, the Secretary of Health and Human Serv-
22 ices shall provide for such funding as the Secretary deter-
23 mines necessary for the conduct of the study of the Na-
24 tional Academy of Sciences under this section.

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