

108TH CONGRESS
2D SESSION

S. 2083

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

IN THE SENATE OF THE UNITED STATES

FEBRUARY 12, 2004

Mrs. BOXER introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

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

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Bipartisan Patient Protection Act of 2004”.

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

Sec. 1. Short title; table of contents.

TITLE I—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.
- Sec. 122. Genetic 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. Coverage of limited scope plans.
- Sec. 155. Regulations.
- Sec. 156. Incorporation into plan or coverage documents.

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.
- Sec. 204. Elimination of option of non-Federal governmental plans to be excepted from requirements concerning genetic information.

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

Sec. 301. Application of patient protection standards to Federal health care 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. Availability of civil remedies.

Sec. 403. Limitation on certain class action litigation.

Sec. 404. Limitations on actions.

Sec. 405. Cooperation between Federal and State authorities.

Sec. 406. Sense of the senate concerning the importance of certain unpaid services.

TITLE V—EFFECTIVE DATES; COORDINATION IN IMPLEMENTATION

Sec. 501. Effective dates.

Sec. 502. Coordination in implementation.

Sec. 503. Severability.

TITLE VI—MISCELLANEOUS PROVISIONS

Sec. 601. No impact on Social Security Trust Fund.

Sec. 602. Customs user fees.

Sec. 603. Fiscal year 2005 medicare payments.

Sec. 604. Sense of Senate with respect to participation in clinical trials and access to specialty care.

Sec. 605. Sense of the Senate regarding fair review process.

Sec. 606. 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

1 under such plan or coverage only in accordance with
2 a utilization review program that meets the require-
3 ments of this section and section 102.

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

12 (3) UTILIZATION REVIEW DEFINED.—For pur-
13 poses of this section, the terms “utilization review”
14 and “utilization review activities” mean procedures
15 used to monitor or evaluate the use or coverage,
16 clinical necessity, appropriateness, efficacy, or effi-
17 ciency of health care services, procedures or settings,
18 and includes prospective review, concurrent review,
19 second opinions, case management, discharge plan-
20 ning, or retrospective review.

21 (b) WRITTEN POLICIES AND CRITERIA.—

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

(2) USE OF WRITTEN CRITERIA.—

(A) IN GENERAL.—Such a program shall utilize written clinical review criteria developed with input from a range of appropriate actively practicing health care professionals, as determined by the plan, pursuant to the program. Such criteria shall include written clinical review criteria that are based on valid clinical evidence where available and that are directed specifically at meeting the needs of at-risk populations and covered individuals with chronic conditions or severe illnesses, including gender-specific criteria and pediatric-specific criteria where available and appropriate.

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

1 (C) REVIEW OF SAMPLE OF CLAIMS DENI-
2 ALS.—Such a program shall provide for a peri-
3 odic evaluation of the clinical appropriateness of
4 at least a sample of denials of claims for bene-
5 fits.

6 (c) CONDUCT OF PROGRAM ACTIVITIES.—

7 (1) ADMINISTRATION BY HEALTH CARE PRO-
8 FESSIONALS.—A utilization review program shall be
9 administered by qualified health care professionals
10 who shall oversee review decisions.

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

13 (A) IN GENERAL.—A utilization review
14 program shall provide for the conduct of utiliza-
15 tion review activities only through personnel
16 who are qualified and have received appropriate
17 training in the conduct of such activities under
18 the program.

19 (B) PROHIBITION OF CONTINGENT COM-
20 PENSATION ARRANGEMENTS.—Such a program
21 shall not, with respect to utilization review ac-
22 tivities, permit or provide compensation or any-
23 thing of value to its employees, agents, or con-
24 tractors in a manner that encourages denials of
25 claims for benefits.

1 (C) PROHIBITION OF CONFLICTS.—Such a
2 program shall not permit a health care profes-
3 sional who is providing health care services to
4 an individual to perform utilization review ac-
5 tivities in connection with the health care serv-
6 ices being provided to the individual.

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

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

1 **SEC. 102. PROCEDURES FOR INITIAL CLAIMS FOR BENE-**
 2 **FITS AND PRIOR AUTHORIZATION DETER-**
 3 **MINATIONS.**

4 (a) PROCEDURES OF INITIAL CLAIMS FOR BENE-
 5 FITS.—

6 (1) IN GENERAL.—A group health plan, or
 7 health insurance issuer offering health insurance
 8 coverage, shall—

9 (A) make a determination on an initial
 10 claim for benefits by a participant, beneficiary,
 11 or enrollee (or authorized representative) re-
 12 garding payment or coverage for items or serv-
 13 ices under the terms and conditions of the plan
 14 or coverage involved, including any cost-sharing
 15 amount that the participant, beneficiary, or en-
 16 rollee is required to pay with respect to such
 17 claim for benefits; and

18 (B) notify a participant, beneficiary, or en-
 19 rollee (or authorized representative) and the
 20 treating health care professional involved re-
 21 garding a determination on an initial claim for
 22 benefits made under the terms and conditions
 23 of the plan or coverage, including any cost-shar-
 24 ing amounts that the participant, beneficiary,
 25 or enrollee may be required to make with re-
 26 spect to such claim for benefits, and of the

1 right of the participant, beneficiary, or enrollee
2 to an internal appeal under section 103.

3 (2) ACCESS TO INFORMATION.—

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

19 (B) LIMITED EFFECT OF FAILURE ON
20 PLAN OR ISSUER'S OBLIGATIONS.—Failure of
21 the participant, beneficiary, or enrollee to com-
22 ply with the requirements of subparagraph (A)
23 shall not remove the obligation of the plan or
24 issuer to make a decision in accordance with
25 the medical exigencies of the case and as soon

as possible, based on the available information,
and failure to comply with the time limit estab-
lished by this paragraph shall not remove the
obligation of the plan or issuer to comply with
the requirements of this section.

(3) ORAL REQUESTS.—In the case of a claim
for benefits involving an expedited or concurrent de-
termination, a participant, beneficiary, or enrollee
(or authorized representative) may make an initial
claim for benefits orally, but a group health plan, or
health insurance issuer offering health insurance
coverage, may require that the participant, bene-
ficiary, or enrollee (or authorized representative)
provide written confirmation of such request in a
timely manner on a form provided by the plan or
issuer. In the case of such an oral request for bene-
fits, the making of the request (and the timing of
such request) shall be treated as the making at that
time of a claims for such benefits without regard to
whether and when a written confirmation of such re-
quest is made.

(b) TIMELINE FOR MAKING DETERMINATIONS.—

(1) PRIOR AUTHORIZATION DETERMINATION.—

(A) IN GENERAL.—A group health plan, or
health insurance issuer offering health insur-

1 ance coverage, shall make a prior authorization
2 determination on a claim for benefits (whether
3 oral or written) in accordance with the medical
4 exigencies of the case and as soon as possible,
5 but in no case later than 14 days from the date
6 on which the plan or issuer receives information
7 that is reasonably necessary to enable the plan
8 or issuer to make a determination on the re-
9 quest for prior authorization and in no case
10 later than 28 days after the date of the claim
11 for benefits is received.

12 (B) EXPEDITED DETERMINATION.—Not-
13 withstanding subparagraph (A), a group health
14 plan, or health insurance issuer offering health
15 insurance coverage, shall expedite a prior au-
16 thorization determination on a claim for bene-
17 fits described in such subparagraph when a re-
18 quest for such an expedited determination is
19 made by a participant, beneficiary, or enrollee
20 (or authorized representative) at any time dur-
21 ing the process for making a determination and
22 a health care professional certifies, with the re-
23 quest, that a determination under the proce-
24 dures described in subparagraph (A) would seri-
25 ously jeopardize the life or health of the partici-

1 pant, beneficiary, or enrollee or the ability of
 2 the participant, beneficiary, or enrollee to main-
 3 tain or regain maximum function. Such deter-
 4 mination shall be made in accordance with the
 5 medical exigencies of the case and as soon as
 6 possible, but in no case later than 72 hours
 7 after the time the request is received by the
 8 plan or issuer under this subparagraph.

9 (C) ONGOING CARE.—

10 (i) CONCURRENT REVIEW.—

11 (I) IN GENERAL.—Subject to
 12 clause (ii), in the case of a concurrent
 13 review of ongoing care (including hos-
 14 pitalization), which results in a termi-
 15 nation or reduction of such care, the
 16 plan or issuer must provide by tele-
 17 phone and in printed form notice of
 18 the concurrent review determination
 19 to the individual or the individual's
 20 designee and the individual's health
 21 care provider in accordance with the
 22 medical exigencies of the case and as
 23 soon as possible, with sufficient time
 24 prior to the termination or reduction
 25 to allow for an appeal under section

1 103(b)(3) to be completed before the
2 termination or reduction takes effect.

3 (II) CONTENTS OF NOTICE.—

4 Such notice shall include, with respect
5 to ongoing health care items and serv-
6 ices, the number of ongoing services
7 approved, the new total of approved
8 services, the date of onset of services,
9 and the next review date, if any, as
10 well as a statement of the individual's
11 rights to further appeal.

12 (ii) RULE OF CONSTRUCTION.—Clause

13 (i) shall not be construed as requiring
14 plans or issuers to provide coverage of care
15 that would exceed the coverage limitations
16 for such care.

17 (2) RETROSPECTIVE DETERMINATION.—A

18 group health plan, or health insurance issuer offer-
19 ing health insurance coverage, shall make a retro-
20 spective determination on a claim for benefits in ac-
21 cordance with the medical exigencies of the case and
22 as soon as possible, but not later than 30 days after
23 the date on which the plan or issuer receives infor-
24 mation that is reasonably necessary to enable the
25 plan or issuer to make a determination on the claim,

1 or, if earlier, 60 days after the date of receipt of the
2 claim for benefits.

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

13 (d) REQUIREMENTS OF NOTICE OF DETERMINA-
14 TIONS.—The written notice of a denial of a claim for bene-
15 fits determination under subsection (c) shall be provided
16 in printed form and written in a manner calculated to be
17 understood by the participant, beneficiary, or enrollee and
18 shall include—

19 (1) the specific reasons for the determination
20 (including a summary of the clinical or scientific evi-
21 dence used in making the determination);

22 (2) the procedures for obtaining additional in-
23 formation concerning the determination; and

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

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

5 (1) AUTHORIZED REPRESENTATIVE.—The term
 6 “authorized representative” means, with respect to
 7 an individual who is a participant, beneficiary, or en-
 8 rollee, any health care professional or other person
 9 acting on behalf of the individual with the individ-
 10 ual’s consent or without such consent if the indi-
 11 vidual is medically unable to provide such consent.

12 (2) CLAIM FOR BENEFITS.—The term “claim
 13 for benefits” means any request for coverage (in-
 14 cluding authorization of coverage), for eligibility, or
 15 for payment in whole or in part, for an item or serv-
 16 ice under a group health plan or health insurance
 17 coverage.

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

1 (4) TREATING HEALTH CARE PROFESSIONAL.—

2 The term “treating health care professional” means,
 3 with respect to services to be provided to a partici-
 4 pant, beneficiary, or enrollee, a health care profes-
 5 sional who is primarily responsible for delivering
 6 those services to the participant, beneficiary, or en-
 7 rollee.

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

9 (a) RIGHT TO INTERNAL APPEAL.—

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

14 (2) TIME FOR APPEAL.—

15 (A) IN GENERAL.—A group health plan, or
 16 health insurance issuer offering health insur-
 17 ance coverage, shall ensure that a participant,
 18 beneficiary, or enrollee (or authorized represent-
 19 ative) has a period of not less than 180 days
 20 beginning on the date of a denial of a claim for
 21 benefits under section 102 in which to appeal
 22 such denial under this section.

23 (B) DATE OF DENIAL.—For purposes of
 24 subparagraph (A), the date of the denial shall
 25 be deemed to be the date as of which the partic-

1 ipant, beneficiary, or enrollee knew of the denial
2 of the claim for benefits.

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

9 (4) PLAN WAIVER OF INTERNAL REVIEW.—A
10 group health plan, or health insurance issuer offer-
11 ing health insurance coverage, may waive the inter-
12 nal review process under this section. In such case
13 the plan or issuer shall provide notice to the partici-
14 pant, beneficiary, or enrollee (or authorized rep-
15 resentative) involved, the participant, beneficiary, or
16 enrollee (or authorized representative) involved shall
17 be relieved of any obligation to complete the internal
18 review involved, and may, at the option of such par-
19 ticipant, beneficiary, enrollee, or representative pro-
20 ceed directly to seek further appeal through external
21 review under section 104 or otherwise.

22 (b) TIMELINES FOR MAKING DETERMINATIONS.—

23 (1) ORAL REQUESTS.—In the case of an appeal
24 of a denial of a claim for benefits under this section
25 that involves an expedited or concurrent determina-

1 tion, a participant, beneficiary, or enrollee (or au-
 2 thorized representative) may request such appeal
 3 orally. A group health plan, or health insurance
 4 issuer offering health insurance coverage, may re-
 5 quire that the participant, beneficiary, or enrollee
 6 (or authorized representative) provide written con-
 7 firmation of such request in a timely manner on a
 8 form provided by the plan or issuer. In the case of
 9 such an oral request for an appeal of a denial, the
 10 making of the request (and the timing of such re-
 11 quest) shall be treated as the making at that time
 12 of a request for an appeal without regard to whether
 13 and when a written confirmation of such request is
 14 made.

15 (2) ACCESS TO INFORMATION.—

16 (A) TIMELY PROVISION OF NECESSARY IN-
 17 FORMATION.—With respect to an appeal of a
 18 denial of a claim for benefits, the participant,
 19 beneficiary, or enrollee (or authorized represent-
 20 ative) and the treating health care professional
 21 (if any) shall provide the plan or issuer with ac-
 22 cess to information requested by the plan or
 23 issuer that is necessary to make a determina-
 24 tion relating to the appeal. Such access shall be
 25 provided not later than 5 days after the date on

1 which the request for information is received,
 2 or, in a case described in subparagraph (B) or
 3 (C) of paragraph (3), by such earlier time as
 4 may be necessary to comply with the applicable
 5 timeline under such subparagraph.

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

18 (3) PRIOR AUTHORIZATION DETERMINA-
 19 TIONS.—

20 (A) IN GENERAL.—A group health plan, or
 21 health insurance issuer offering health insur-
 22 ance coverage, shall make a determination on
 23 an appeal of a denial of a claim for benefits
 24 under this subsection in accordance with the
 25 medical exigencies of the case and as soon as

possible, but in no case later than 14 days from the date on which the plan or issuer receives information that is reasonably necessary to enable the plan or issuer to make a determination on the appeal and in no case later than 28 days after the date the request for the appeal is received.

(B) EXPEDITED DETERMINATION.—Notwithstanding subparagraph (A), a group health plan, or health insurance issuer offering health insurance coverage, shall expedite a prior authorization determination on an appeal of a denial of a claim for benefits described in subparagraph (A), when a request for such an expedited determination is made by a participant, beneficiary, or enrollee (or authorized representative) at any time during the process for making a determination and a health care professional certifies, with the request, that a determination under the procedures described in subparagraph (A) would seriously jeopardize the life or health of the participant, beneficiary, or enrollee or the ability of the participant, beneficiary, or enrollee to maintain or regain maximum function. Such determination shall be

1 made in accordance with the medical exigencies
2 of the case and as soon as possible, but in no
3 case later than 72 hours after the time the re-
4 quest for such appeal is received by the plan or
5 issuer under this subparagraph.

6 (C) ONGOING CARE DETERMINATIONS.—

7 (i) IN GENERAL.—Subject to clause
8 (ii), in the case of a concurrent review de-
9 termination described in section
10 102(b)(1)(C)(i)(I), which results in a ter-
11 mination or reduction of such care, the
12 plan or issuer must provide notice of the
13 determination on the appeal under this
14 section by telephone and in printed form to
15 the individual or the individual's designee
16 and the individual's health care provider in
17 accordance with the medical exigencies of
18 the case and as soon as possible, with suf-
19 ficient time prior to the termination or re-
20 duction to allow for an external appeal
21 under section 104 to be completed before
22 the termination or reduction takes effect.

23 (ii) RULE OF CONSTRUCTION.—Clause
24 (i) shall not be construed as requiring
25 plans or issuers to provide coverage of care

1 that would exceed the coverage limitations
2 for such care.

3 (4) RETROSPECTIVE DETERMINATION.—A
4 group health plan, or health insurance issuer offer-
5 ing health insurance coverage, shall make a retro-
6 spective determination on an appeal of a claim for
7 benefits in no case later than 30 days after the date
8 on which the plan or issuer receives necessary infor-
9 mation that is reasonably necessary to enable the
10 plan or issuer to make a determination on the ap-
11 peal and in no case later than 60 days after the date
12 the request for the appeal is received.

13 (c) CONDUCT OF REVIEW.—

14 (1) IN GENERAL.—A review of a denial of a
15 claim for benefits under this section shall be con-
16 ducted by an individual with appropriate expertise
17 who was not involved in the initial determination.

18 (2) PEER REVIEW OF MEDICAL DECISIONS BY
19 HEALTH CARE PROFESSIONALS.—A review of an ap-
20 peal of a denial of a claim for benefits that is based
21 on a lack of medical necessity and appropriateness,
22 or based on an experimental or investigational treat-
23 ment, or requires an evaluation of medical facts—

24 (A) shall be made by a physician
25 (allopathic or osteopathic); or

1 (B) in a claim for benefits provided by a
 2 non-physician health professional, shall be made
 3 by reviewer (or reviewers) including at least one
 4 practicing non-physician health professional of
 5 the same or similar specialty;
 6 with appropriate expertise (including, in the case of
 7 a child, appropriate pediatric expertise) and acting
 8 within the appropriate scope of practice within the
 9 State in which the service is provided or rendered,
 10 who was not involved in the initial determination.

11 (d) NOTICE OF DETERMINATION.—

12 (1) IN GENERAL.—Written notice of a deter-
 13 mination made under an internal appeal of a denial
 14 of a claim for benefits shall be issued to the partici-
 15 pant, beneficiary, or enrollee (or authorized rep-
 16 resentative) and the treating health care professional
 17 in accordance with the medical exigencies of the case
 18 and as soon as possible, but in no case later than
 19 2 days after the date of completion of the review (or,
 20 in the case described in subparagraph (B) or (C) of
 21 subsection (b)(3), within the 72-hour or applicable
 22 period referred to in such subparagraph).

23 (2) FINAL DETERMINATION.—The decision by a
 24 plan or issuer under this section shall be treated as
 25 the final determination of the plan or issuer on a de-

1 nial of a claim for benefits. The failure of a plan or
2 issuer to issue a determination on an appeal of a de-
3 nial of a claim for benefits under this section within
4 the applicable timeline established for such a deter-
5 mination shall be treated as a final determination on
6 an appeal of a denial of a claim for benefits for pur-
7 poses of proceeding to external review under section
8 104.

9 (3) REQUIREMENTS OF NOTICE.—With respect
10 to a determination made under this section, the no-
11 tice described in paragraph (1) shall be provided in
12 printed form and written in a manner calculated to
13 be understood by the participant, beneficiary, or en-
14 rollee and shall include—

15 (A) the specific reasons for the determina-
16 tion (including a summary of the clinical or sci-
17 entific evidence used in making the determina-
18 tion);

19 (B) the procedures for obtaining additional
20 information concerning the determination; and

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

1 **SEC. 104. INDEPENDENT EXTERNAL APPEALS PROCE-**
2 **DURES.**

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

9 (b) **INITIATION OF THE INDEPENDENT EXTERNAL**
10 **REVIEW PROCESS.**—

11 (1) **TIME TO FILE.**—A request for an inde-
12 pendent external review under this section shall be
13 filed with the plan or issuer not later than 180 days
14 after the date on which the participant, beneficiary,
15 or enrollee receives notice of the denial under section
16 103(d) or notice of waiver of internal review under
17 section 103(a)(4) or the date on which the plan or
18 issuer has failed to make a timely decision under
19 section 103(d)(2) and notifies the participant or
20 beneficiary that it has failed to make a timely deci-
21 sion and that the beneficiary must file an appeal
22 with an external review entity within 180 days if the
23 participant or beneficiary desires to file such an ap-
24 peal.

25 (2) **FILING OF REQUEST.**—

1 (A) IN GENERAL.—Subject to the suc-
2 ceeding provisions of this subsection, a group
3 health plan, and a health insurance issuer offer-
4 ing health insurance coverage, may—

5 (i) except as provided in subparagraph

6 (B)(i), require that a request for review be
7 in writing;

8 (ii) limit the filing of such a request
9 to the participant, beneficiary, or enrollee
10 involved (or an authorized representative);

11 (iii) except if waived by the plan or
12 issuer under section 103(a)(4), condition
13 access to an independent external review
14 under this section upon a final determina-
15 tion of a denial of a claim for benefits
16 under the internal review procedure under
17 section 103;

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

22 (v) require that a request for review
23 include the consent of the participant, ben-
24 eficiary, or enrollee (or authorized rep-
25 resentative) for the release of necessary

1 medical information or records of the par-
2 ticipant, beneficiary, or enrollee to the
3 qualified external review entity only for
4 purposes of conducting external review ac-
5 tivities.

6 (B) REQUIREMENTS AND EXCEPTION RE-
7 LATING TO GENERAL RULE.—

8 (i) ORAL REQUESTS PERMITTED IN
9 EXPEDITED OR CONCURRENT CASES.—In
10 the case of an expedited or concurrent ex-
11 ternal review as provided for under sub-
12 section (e), the request may be made oral-
13 ly. A group health plan, or health insur-
14 ance issuer offering health insurance cov-
15 erage, may require that the participant,
16 beneficiary, or enrollee (or authorized rep-
17 resentative) provide written confirmation
18 of such request in a timely manner on a
19 form provided by the plan or issuer. Such
20 written confirmation shall be treated as a
21 consent for purposes of subparagraph
22 (A)(v). In the case of such an oral request
23 for such a review, the making of the re-
24 quest (and the timing of such request)
25 shall be treated as the making at that time

1 of a request for such an external review
 2 without regard to whether and when a
 3 written confirmation of such request is
 4 made.

5 (ii) EXCEPTION TO FILING FEE RE-
 6 QUIREMENT.—

7 (I) INDIGENCY.—Payment of a
 8 filing fee shall not be required under
 9 subparagraph (A)(iv) where there is a
 10 certification (in a form and manner
 11 specified in guidelines established by
 12 the appropriate Secretary) that the
 13 participant, beneficiary, or enrollee is
 14 indigent (as defined in such guide-
 15 lines).

16 (II) FEE NOT REQUIRED.—Pay-
 17 ment of a filing fee shall not be re-
 18 quired under subparagraph (A)(iv) if
 19 the plan or issuer waives the internal
 20 appeals process under section
 21 103(a)(4).

22 (III) REFUNDING OF FEE.—The
 23 filing fee paid under subparagraph
 24 (A)(iv) shall be refunded if the deter-
 25 mination under the independent exter-

1 nal review is to reverse or modify the
2 denial which is the subject of the re-
3 view.

4 (IV) COLLECTION OF FILING
5 FEE.—The failure to pay such a filing
6 fee shall not prevent the consideration
7 of a request for review but, subject to
8 the preceding provisions of this clause,
9 shall constitute a legal liability to pay.

10 (c) REFERRAL TO QUALIFIED EXTERNAL REVIEW
11 ENTITY UPON REQUEST.—

12 (1) IN GENERAL.—Upon the filing of a request
13 for independent external review with the group
14 health plan, or health insurance issuer offering
15 health insurance coverage, the plan or issuer shall
16 immediately refer such request, and forward the
17 plan or issuer's initial decision (including the infor-
18 mation described in section 103(d)(3)(A)), to a
19 qualified external review entity selected in accord-
20 ance with this section.

21 (2) ACCESS TO PLAN OR ISSUER AND HEALTH
22 PROFESSIONAL INFORMATION.—With respect to an
23 independent external review conducted under this
24 section, the participant, beneficiary, or enrollee (or
25 authorized representative), the plan or issuer, and

1 the treating health care professional (if any) shall
 2 provide the external review entity with information
 3 that is necessary to conduct a review under this sec-
 4 tion, as determined and requested by the entity.
 5 Such information shall be provided not later than
 6 5 days after the date on which the request for infor-
 7 mation is received, or, in a case described in clause
 8 (ii) or (iii) of subsection (e)(1)(A), by such earlier
 9 time as may be necessary to comply with the appli-
 10 cable timeline under such clause.

11 (3) SCREENING OF REQUESTS BY QUALIFIED
 12 EXTERNAL REVIEW ENTITIES.—

13 (A) IN GENERAL.—With respect to a re-
 14 quest referred to a qualified external review en-
 15 tity under paragraph (1) relating to a denial of
 16 a claim for benefits, the entity shall refer such
 17 request for the conduct of an independent med-
 18 ical review unless the entity determines that—

19 (i) any of the conditions described in
 20 clauses (ii) or (iii) of subsection (b)(2)(A)
 21 have not been met;

22 (ii) the denial of the claim for benefits
 23 does not involve a medically reviewable de-
 24 cision under subsection (d)(2);

(iii) the denial of the claim for benefits relates to a decision regarding whether an individual is a participant, beneficiary, or enrollee who is enrolled under the terms and conditions of the plan or coverage (including the applicability of any waiting period under the plan or coverage); or

(iv) the denial of the claim for benefits is a decision as to the application of cost-sharing requirements or the application of a specific exclusion or express limitation on the amount, duration, or scope of coverage of items or services under the terms and conditions of the plan or coverage unless the decision is a denial described in subsection (d)(2).

Upon making a determination that any of clauses (i) through (iv) applies with respect to the request, the entity shall determine that the denial of a claim for benefits involved is not eligible for independent medical review under subsection (d), and shall provide notice in accordance with subparagraph (C).

(B) PROCESS FOR MAKING DETERMINATIONS.—

(i) NO DEFERENCE TO PRIOR DETERMINATIONS.—In making determinations under subparagraph (A), there shall be no deference given to determinations made by the plan or issuer or the recommendation of a treating health care professional (if any).

(ii) USE OF APPROPRIATE PERSONNEL.—A qualified external review entity shall use appropriately qualified personnel to make determinations under this section.

(C) NOTICES AND GENERAL TIMELINES FOR DETERMINATION.—

(i) NOTICE IN CASE OF DENIAL OF REFERRAL.—If the entity under this paragraph does not make a referral to an independent medical reviewer, the entity shall provide notice to the plan or issuer, the participant, beneficiary, or enrollee (or authorized representative) filing the request, and the treating health care professional (if any) that the denial is not subject to independent medical review. Such notice—

1 (I) shall be written (and, in addi-
 2 tion, may be provided orally) in a
 3 manner calculated to be understood
 4 by a participant or enrollee;

5 (II) shall include the reasons for
 6 the determination;

7 (III) include any relevant terms
 8 and conditions of the plan or cov-
 9 erage; and

10 (IV) include a description of any
 11 further recourse available to the indi-
 12 vidual.

13 (ii) GENERAL TIMELINE FOR DETER-
 14 MINATIONS.—Upon receipt of information
 15 under paragraph (2), the qualified external
 16 review entity, and if required the inde-
 17 pendent medical reviewer, shall make a de-
 18 termination within the overall timeline that
 19 is applicable to the case under review as
 20 described in subsection (e), except that if
 21 the entity determines that a referral to an
 22 independent medical reviewer is not re-
 23 quired, the entity shall provide notice of
 24 such determination to the participant, ben-
 25 eficiary, or enrollee (or authorized rep-

1 representative) within such timeline and with-
2 in 2 days of the date of such determina-
3 tion.

4 (d) INDEPENDENT MEDICAL REVIEW.—

5 (1) IN GENERAL.—If a qualified external review
6 entity determines under subsection (c) that a denial
7 of a claim for benefits is eligible for independent
8 medical review, the entity shall refer the denial in-
9 volved to an independent medical reviewer for the
10 conduct of an independent medical review under this
11 subsection.

12 (2) MEDICALLY REVIEWABLE DECISIONS.—A
13 denial of a claim for benefits is eligible for inde-
14 pendent medical review if the benefit for the item or
15 service for which the claim is made would be a cov-
16 ered benefit under the terms and conditions of the
17 plan or coverage but for one (or more) of the fol-
18 lowing determinations:

19 (A) DENIALS BASED ON MEDICAL NECES-
20 SITY AND APPROPRIATENESS.—A determination
21 that the item or service is not covered because
22 it is not medically necessary and appropriate or
23 based on the application of substantially equiva-
24 lent terms.

1 (B) DENIALS BASED ON EXPERIMENTAL
 2 OR INVESTIGATIONAL TREATMENT.—A deter-
 3 mination that the item or service is not covered
 4 because it is experimental or investigational or
 5 based on the application of substantially equiva-
 6 lent terms.

7 (C) DENIALS OTHERWISE BASED ON AN
 8 EVALUATION OF MEDICAL FACTS.—A deter-
 9 mination that the item or service or condition
 10 is not covered based on grounds that require an
 11 evaluation of the medical facts by a health care
 12 professional in the specific case involved to de-
 13 termine the coverage and extent of coverage of
 14 the item or service or condition.

15 (3) INDEPENDENT MEDICAL REVIEW DETER-
 16 MINATION.—

17 (A) IN GENERAL.—An independent med-
 18 ical reviewer under this section shall make a
 19 new independent determination with respect to
 20 whether or not the denial of a claim for a ben-
 21 efit that is the subject of the review should be
 22 upheld, reversed, or modified.

23 (B) STANDARD FOR DETERMINATION.—
 24 The independent medical reviewer's determina-
 25 tion relating to the medical necessity and ap-

1 appropriateness, or the experimental or investiga-
2 tion nature, or the evaluation of the medical
3 facts of the item, service, or condition shall be
4 based on the medical condition of the partici-
5 pant, beneficiary, or enrollee (including the
6 medical records of the participant, beneficiary,
7 or enrollee) and valid, relevant scientific evi-
8 dence and clinical evidence, including peer-re-
9 viewed medical literature or findings and in-
10 cluding expert opinion.

11 (C) NO COVERAGE FOR EXCLUDED BENE-
12 FITS.—Nothing in this subsection shall be con-
13 strued to permit an independent medical re-
14 viewer to require that a group health plan, or
15 health insurance issuer offering health insur-
16 ance coverage, provide coverage for items or
17 services for which benefits are specifically ex-
18 cluded or expressly limited under the plan or
19 coverage in the plain language of the plan docu-
20 ment (and which are disclosed under section
21 121(b)(1)(C)). Notwithstanding any other pro-
22 vision of this Act, any exclusion of an exact
23 medical procedure, any exact time limit on the
24 duration or frequency of coverage, and any
25 exact dollar limit on the amount of coverage

that is specifically enumerated and defined (in the plain language of the plan or coverage documents) under the plan or coverage offered by a group health plan or health insurance issuer offering health insurance coverage and that is disclosed under section 121(b)(1) shall be considered to govern the scope of the benefits that may be required: *Provided*, That the terms and conditions of the plan or coverage relating to such an exclusion or limit are in compliance with the requirements of law.

(D) EVIDENCE AND INFORMATION TO BE USED IN MEDICAL REVIEWS.—In making a determination under this subsection, the independent medical reviewer shall also consider appropriate and available evidence and information, including the following:

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

(ii) The recommendation of the treating health care professional and the evidence, guidelines, and rationale used by

the treating health care professional in reaching such recommendation.

(iii) Additional relevant evidence or information obtained by the reviewer or submitted by the plan, issuer, participant, beneficiary, or enrollee (or an authorized representative), or treating health care professional.

(iv) The plan or coverage document.

(E) INDEPENDENT DETERMINATION.—In making determinations under this subtitle, a qualified external review entity and an independent medical reviewer shall—

(i) consider the claim under review without deference to the determinations made by the plan or issuer or the recommendation of the treating health care professional (if any); and

(ii) consider, but not be bound by the definition used by the plan or issuer of “medically necessary and appropriate”, or “experimental or investigational”, or other substantially equivalent terms that are used by the plan or issuer to describe medical necessity and appropriateness or ex-

1 perimental or investigational nature of the
2 treatment.

3 (F) DETERMINATION OF INDEPENDENT
4 MEDICAL REVIEWER.—An independent medical
5 reviewer shall, in accordance with the deadlines
6 described in subsection (e), prepare a written
7 determination to uphold, reverse, or modify the
8 denial under review. Such written determination
9 shall include—

10 (i) the determination of the reviewer;
11 (ii) the specific reasons of the re-
12 viewer for such determination, including a
13 summary of the clinical or scientific evi-
14 dence used in making the determination;
15 and

16 (iii) with respect to a determination to
17 reverse or modify the denial under review,
18 a timeframe within which the plan or
19 issuer must comply with such determina-
20 tion.

21 (G) NONBINDING NATURE OF ADDITIONAL
22 RECOMMENDATIONS.—In addition to the deter-
23 mination under subparagraph (F), the reviewer
24 may provide the plan or issuer and the treating
25 health care professional with additional rec-

ommendations in connection with such a determination, but any such recommendations shall not affect (or be treated as part of) the determination and shall not be binding on the plan or issuer.

(e) TIMELINES AND NOTIFICATIONS.—

(1) TIMELINES FOR INDEPENDENT MEDICAL REVIEW.—

(A) PRIOR AUTHORIZATION DETERMINATION.—

(i) IN GENERAL.—The independent medical reviewer (or reviewers) shall make a determination on a denial of a claim for benefits that is referred to the reviewer under subsection (c)(3) in accordance with the medical exigencies of the case and as soon as possible, but in no case later than 14 days after the date of receipt of information under subsection (c)(2) if the review involves a prior authorization of items or services and in no case later than 21 days after the date the request for external review is received.

(ii) EXPEDITED DETERMINATION.—

Notwithstanding clause (i) and subject to

1 clause (iii), the independent medical re-
2 viewer (or reviewers) shall make an expe-
3 dited determination on a denial of a claim
4 for benefits described in clause (i), when a
5 request for such an expedited determina-
6 tion is made by a participant, beneficiary,
7 or enrollee (or authorized representative)
8 at any time during the process for making
9 a determination, and a health care profes-
10 sional certifies, with the request, that a de-
11 termination under the timeline described in
12 clause (i) would seriously jeopardize the
13 life or health of the participant, bene-
14 ficiary, or enrollee or the ability of the par-
15 ticipant, beneficiary, or enrollee to main-
16 tain or regain maximum function. Such de-
17 termination shall be made as soon in ac-
18 cordance with the medical exigencies of the
19 case and as soon as possible, but in no
20 case later than 72 hours after the time the
21 request for external review is received by
22 the qualified external review entity.

23 (iii) ONGOING CARE DETERMINA-
24 TION.—Notwithstanding clause (i), in the
25 case of a review described in such sub-

1 clause that involves a termination or reduc-
 2 tion of care, the notice of the determina-
 3 tion shall be completed not later than 24
 4 hours after the time the request for exter-
 5 nal review is received by the qualified ex-
 6 ternal review entity and before the end of
 7 the approved period of care.

8 (B) RETROSPECTIVE DETERMINATION.—

9 The independent medical reviewer (or review-
 10 ers) shall complete a review in the case of a ret-
 11 rospective determination on an appeal of a de-
 12 nial of a claim for benefits that is referred to
 13 the reviewer under subsection (c)(3) in no case
 14 later than 30 days after the date of receipt of
 15 information under subsection (c)(2) and in no
 16 case later than 60 days after the date the re-
 17 quest for external review is received by the
 18 qualified external review entity.

19 (2) NOTIFICATION OF DETERMINATION.—The

20 external review entity shall ensure that the plan or
 21 issuer, the participant, beneficiary, or enrollee (or
 22 authorized representative) and the treating health
 23 care professional (if any) receives a copy of the writ-
 24 ten determination of the independent medical re-
 25 viewer prepared under subsection (d)(3)(F). Nothing

1 in this paragraph shall be construed as preventing
 2 an entity or reviewer from providing an initial oral
 3 notice of the reviewer's determination.

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

7 (f) COMPLIANCE.—

8 (1) APPLICATION OF DETERMINATIONS.—

9 (A) EXTERNAL REVIEW DETERMINATIONS
 10 BINDING ON PLAN.—The determinations of an
 11 external review entity and an independent med-
 12 ical reviewer under this section shall be binding
 13 upon the plan or issuer involved.

14 (B) COMPLIANCE WITH DETERMINA-
 15 TION.—If the determination of an independent
 16 medical reviewer is to reverse or modify the de-
 17 nial, the plan or issuer, upon the receipt of such
 18 determination, shall authorize coverage to com-
 19 ply with the medical reviewer's determination in
 20 accordance with the timeframe established by
 21 the medical reviewer.

22 (2) FAILURE TO COMPLY.—

23 (A) IN GENERAL.—If a plan or issuer fails
 24 to comply with the timeframe established under
 25 paragraph (1)(B) with respect to a participant,

1 beneficiary, or enrollee, where such failure to
2 comply is caused by the plan or issuer, the par-
3 ticipant, beneficiary, or enrollee may obtain the
4 items or services involved (in a manner con-
5 sistent with the determination of the inde-
6 pendent external reviewer) from any provider
7 regardless of whether such provider is a partici-
8 pating provider under the plan or coverage.

9 (B) REIMBURSEMENT.—

10 (i) IN GENERAL.—Where a partici-
11 pant, beneficiary, or enrollee obtains items
12 or services in accordance with subpara-
13 graph (A), the plan or issuer involved shall
14 provide for reimbursement of the costs of
15 such items or services. Such reimburse-
16 ment shall be made to the treating health
17 care professional or to the participant, ben-
18 eficiary, or enrollee (in the case of a partici-
19 pant, beneficiary, or enrollee who pays for
20 the costs of such items or services).

21 (ii) AMOUNT.—The plan or issuer
22 shall fully reimburse a professional, partici-
23 pant, beneficiary, or enrollee under clause
24 (i) for the total costs of the items or serv-
25 ices provided (regardless of any plan limi-

tations that may apply to the coverage of such items or services) so long as the items or services were provided in a manner consistent with the determination of the independent medical reviewer.

(C) FAILURE TO REIMBURSE.—Where a plan or issuer fails to provide reimbursement to a professional, participant, beneficiary, or enrollee in accordance with this paragraph, the professional, participant, beneficiary, or enrollee may commence a civil action (or utilize other remedies available under law) to recover only the amount of any such reimbursement that is owed by the plan or issuer and any necessary legal costs or expenses (including attorney’s fees) incurred in recovering such reimbursement.

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

(3) PENALTIES AGAINST AUTHORIZED OFFICIALS FOR REFUSING TO AUTHORIZE THE DETERMINATION OF AN EXTERNAL REVIEW ENTITY.—

(A) MONETARY PENALTIES.—

1 (i) IN GENERAL.—In any case in
2 which the determination of an external re-
3 view entity is not followed by a group
4 health plan, or by a health insurance issuer
5 offering health insurance coverage, any
6 person who, acting in the capacity of au-
7 thorizing the benefit, causes such refusal
8 may, in the discretion in a court of com-
9 petent jurisdiction, be liable to an ag-
10 grieved participant, beneficiary, or enrollee
11 for a civil penalty in an amount of up to
12 \$1,000 a day from the date on which the
13 determination was transmitted to the plan
14 or issuer by the external review entity until
15 the date the refusal to provide the benefit
16 is corrected.

17 (ii) ADDITIONAL PENALTY FOR FAIL-
18 ING TO FOLLOW TIMELINE.—In any case
19 in which treatment was not commenced by
20 the plan in accordance with the determina-
21 tion of an independent external reviewer,
22 the Secretary shall assess a civil penalty of
23 \$10,000 against the plan and the plan
24 shall pay such penalty to the participant,
25 beneficiary, or enrollee involved.

1 (B) CEASE AND DESIST ORDER AND
2 ORDER OF ATTORNEY'S FEES.—In any action
3 described in subparagraph (A) brought by a
4 participant, beneficiary, or enrollee with respect
5 to a group health plan, or a health insurance
6 issuer offering health insurance coverage, in
7 which a plaintiff alleges that a person referred
8 to in such subparagraph has taken an action re-
9 sulting in a refusal of a benefit determined by
10 an external appeal entity to be covered, or has
11 failed to take an action for which such person
12 is responsible under the terms and conditions of
13 the plan or coverage and which is necessary
14 under the plan or coverage for authorizing a
15 benefit, the court shall cause to be served on
16 the defendant an order requiring the defend-
17 ant—

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

20 (ii) to pay to the plaintiff a reasonable
21 attorney's fee and other reasonable costs
22 relating to the prosecution of the action on
23 the charges on which the plaintiff prevails.

24 (C) ADDITIONAL CIVIL PENALTIES.—

(i) IN GENERAL.—In addition to any penalty imposed under subparagraph (A) or (B), the appropriate Secretary may assess a civil penalty against a person acting in the capacity of authorizing a benefit determined by an external review entity for one or more group health plans, or health insurance issuers offering health insurance coverage, for—

(I) any pattern or practice of repeated refusal to authorize a benefit determined by an external appeal entity to be covered; or

(II) any pattern or practice of repeated violations of the requirements of this section with respect to such plan or coverage.

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

(I) 25 percent of the aggregate value of benefits shown by the appro-

1 appropriate Secretary to have not been pro-
 2 vided, or unlawfully delayed, in viola-
 3 tion of this section under such pattern
 4 or practice; or

5 (II) \$500,000.

6 (D) REMOVAL AND DISQUALIFICATION.—

7 Any person acting in the capacity of author-
 8 izing benefits who has engaged in any such pat-
 9 tern or practice described in subparagraph
 10 (C)(i) with respect to a plan or coverage, upon
 11 the petition of the appropriate Secretary, may
 12 be removed by the court from such position,
 13 and from any other involvement, with respect to
 14 such a plan or coverage, and may be precluded
 15 from returning to any such position or involve-
 16 ment for a period determined by the court.

17 (4) PROTECTION OF LEGAL RIGHTS.—Nothing

18 in this subsection or subtitle shall be construed as
 19 altering or eliminating any cause of action or legal
 20 rights or remedies of participants, beneficiaries, en-
 21 rollees, and others under State or Federal law (in-
 22 cluding sections 502 and 503 of the Employee Re-
 23 tirement Income Security Act of 1974), including
 24 the right to file judicial actions to enforce rights.

1 (g) QUALIFICATIONS OF INDEPENDENT MEDICAL
2 REVIEWERS.—

3 (1) IN GENERAL.—In referring a denial to 1 or
4 more individuals to conduct independent medical re-
5 view under subsection (c), the qualified external re-
6 view entity shall ensure that—

7 (A) each independent medical reviewer
8 meets the qualifications described in paragraphs
9 (2) and (3);

10 (B) with respect to each review at least 1
11 such reviewer meets the requirements described
12 in paragraphs (4) and (5); and

13 (C) compensation provided by the entity to
14 the reviewer is consistent with paragraph (6).

15 (2) LICENSURE AND EXPERTISE.—Each inde-
16 pendent medical reviewer shall be a physician
17 (allopathic or osteopathic) or health care profes-
18 sional who—

19 (A) is appropriately credentialed or li-
20 censed in 1 or more States to deliver health
21 care services; and

22 (B) typically treats the condition, makes
23 the diagnosis, or provides the type of treatment
24 under review.

25 (3) INDEPENDENCE.—

1 (A) IN GENERAL.—Subject to subpara-
2 graph (B), each independent medical reviewer
3 in a case shall—

4 (i) not be a related party (as defined
5 in paragraph (7));

6 (ii) not have a material familial, fi-
7 nancial, or professional relationship with
8 such a party; and

9 (iii) not otherwise have a conflict of
10 interest with such a party (as determined
11 under regulations).

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

14 (i) prohibit an individual, solely on the
15 basis of affiliation with the plan or issuer,
16 from serving as an independent medical re-
17 viewer if—

18 (I) a non-affiliated individual is
19 not reasonably available;

20 (II) the affiliated individual is
21 not involved in the provision of items
22 or services in the case under review;

23 (III) the fact of such an affili-
24 ation is disclosed to the plan or issuer
25 and the participant, beneficiary, or

1 enrollee (or authorized representative)
 2 and neither party objects; and

3 (IV) the affiliated individual is
 4 not an employee of the plan or issuer
 5 and does not provide services exclu-
 6 sively or primarily to or on behalf of
 7 the plan or issuer;

8 (ii) prohibit an individual who has
 9 staff privileges at the institution where the
 10 treatment involved takes place from serv-
 11 ing as an independent medical reviewer
 12 merely on the basis of such affiliation if
 13 the affiliation is disclosed to the plan or
 14 issuer and the participant, beneficiary, or
 15 enrollee (or authorized representative), and
 16 neither party objects; or

17 (iii) prohibit receipt of compensation
 18 by an independent medical reviewer from
 19 an entity if the compensation is provided
 20 consistent with paragraph (6).

21 (4) PRACTICING HEALTH CARE PROFESSIONAL
 22 IN SAME FIELD.—

23 (A) IN GENERAL.—In a case involving
 24 treatment, or the provision of items or serv-
 25 ices—

1 (i) by a physician, a reviewer shall be
2 a practicing physician (allopathic or osteo-
3 pathic) of the same or similar specialty, as
4 a physician who, acting within the appro-
5 priate scope of practice within the State in
6 which the service is provided or rendered,
7 typically treats the condition, makes the
8 diagnosis, or provides the type of treat-
9 ment under review; or

10 (ii) by a non-physician health care
11 professional, a reviewer (or reviewers) shall
12 include at least one practicing non-physi-
13 cian health care professional of the same
14 or similar specialty as the non-physician
15 health care professional who, acting within
16 the appropriate scope of practice within
17 the State in which the service is provided
18 or rendered, typically treats the condition,
19 makes the diagnosis, or provides the type
20 of treatment under review.

21 (B) PRACTICING DEFINED.—For purposes
22 of this paragraph, the term “practicing” means,
23 with respect to an individual who is a physician
24 or other health care professional that the indi-

1 vidual provides health care services to individual
2 patients on average at least 2 days per week.

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

6 (6) LIMITATIONS ON REVIEWER COMPENSA-
7 TION.—Compensation provided by a qualified exter-
8 nal review entity to an independent medical reviewer
9 in connection with a review under this section
10 shall—

11 (A) not exceed a reasonable level; and

12 (B) not be contingent on the decision ren-
13 dered by the reviewer.

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

19 (A) The plan, plan sponsor, or issuer in-
20 volved, or any fiduciary, officer, director, or em-
21 ployee of such plan, plan sponsor, or issuer.

22 (B) The participant, beneficiary, or en-
23 rollee (or authorized representative).

1 (C) The health care professional that pro-
 2 vides the items or services involved in the de-
 3 nial.

4 (D) The institution at which the items or
 5 services (or treatment) involved in the denial
 6 are provided.

7 (E) The manufacturer of any drug or
 8 other item that is included in the items or serv-
 9 ices involved in the denial.

10 (F) Any other party determined under any
 11 regulations to have a substantial interest in the
 12 denial involved.

13 (h) QUALIFIED EXTERNAL REVIEW ENTITIES.—

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

16 (A) LIMITATION ON PLAN OR ISSUER SE-
 17 LECTION.—The appropriate Secretary shall im-
 18 plement procedures—

19 (i) to assure that the selection process
 20 among qualified external review entities
 21 will not create any incentives for external
 22 review entities to make a decision in a bi-
 23 ased manner; and

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

4 No such selection process under the procedures
 5 implemented by the appropriate Secretary may
 6 give either the patient or the plan or issuer any
 7 ability to determine or influence the selection of
 8 a qualified external review entity to review the
 9 case of any participant, beneficiary, or enrollee.

10 (B) STATE AUTHORITY WITH RESPECT TO
 11 QUALIFIED EXTERNAL REVIEW ENTITIES FOR
 12 HEALTH INSURANCE ISSUERS.—With respect to
 13 health insurance issuers offering health insur-
 14 ance coverage in a State, the State may provide
 15 for external review activities to be conducted by
 16 a qualified external appeal entity that is des-
 17 ignated by the State or that is selected by the
 18 State in a manner determined by the State to
 19 assure an unbiased determination.

20 (2) CONTRACT WITH QUALIFIED EXTERNAL RE-
 21 VIEW ENTITY.—Except as provided in paragraph
 22 (1)(B), the external review process of a plan or
 23 issuer under this section shall be conducted under a
 24 contract between the plan or issuer and 1 or more

1 qualified external review entities (as defined in para-
 2 graph (4)(A)).

3 (3) TERMS AND CONDITIONS OF CONTRACT.—

4 The terms and conditions of a contract under para-
 5 graph (2) shall—

6 (A) be consistent with the standards the
 7 appropriate Secretary shall establish to assure
 8 there is no real or apparent conflict of interest
 9 in the conduct of external review activities; and

10 (B) provide that the costs of the external
 11 review process shall be borne by the plan or
 12 issuer.

13 Subparagraph (B) shall not be construed as apply-
 14 ing to the imposition of a filing fee under subsection
 15 (b)(2)(A)(iv) or costs incurred by the participant,
 16 beneficiary, or enrollee (or authorized representative)
 17 or treating health care professional (if any) in sup-
 18 port of the review, including the provision of addi-
 19 tional evidence or information.

20 (4) QUALIFICATIONS.—

21 (A) IN GENERAL.—In this section, the
 22 term “qualified external review entity” means,
 23 in relation to a plan or issuer, an entity that is
 24 initially certified (and periodically recertified)

1 under subparagraph (C) as meeting the fol-
2 lowing requirements:

3 (i) The entity has (directly or through
4 contracts or other arrangements) sufficient
5 medical, legal, and other expertise and suf-
6 ficient staffing to carry out duties of a
7 qualified external review entity under this
8 section on a timely basis, including making
9 determinations under subsection (b)(2)(A)
10 and providing for independent medical re-
11 views under subsection (d).

12 (ii) The entity is not a plan or issuer
13 or an affiliate or a subsidiary of a plan or
14 issuer, and is not an affiliate or subsidiary
15 of a professional or trade association of
16 plans or issuers or of health care providers.

17 (iii) The entity has provided assur-
18 ances that it will conduct external review
19 activities consistent with the applicable re-
20 quirements of this section and standards
21 specified in subparagraph (C), including
22 that it will not conduct any external review
23 activities in a case unless the independence
24 requirements of subparagraph (B) are met
25 with respect to the case.

(iv) The entity has provided assurances that it will provide information in a timely manner under subparagraph (D).

(v) The entity meets such other requirements as the appropriate Secretary provides by regulation.

(B) INDEPENDENCE REQUIREMENTS.—

(i) IN GENERAL.—Subject to clause (ii), an entity meets the independence requirements of this subparagraph with respect to any case if the entity—

(I) is not a related party (as defined in subsection (g)(7));

(II) does not have a material familial, financial, or professional relationship with such a party; and

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

(ii) EXCEPTION FOR REASONABLE COMPENSATION.—Nothing in clause (i) shall be construed to prohibit receipt by a qualified external review entity of compensation from a plan or issuer for the conduct of external review activities under

1 this section if the compensation is provided
 2 consistent with clause (iii).

3 (iii) LIMITATIONS ON ENTITY COM-
 4 PENSATION.—Compensation provided by a
 5 plan or issuer to a qualified external review
 6 entity in connection with reviews under
 7 this section shall—

8 (I) not exceed a reasonable level;

9 and

10 (II) not be contingent on any de-
 11 cision rendered by the entity or by
 12 any independent medical reviewer.

13 (C) CERTIFICATION AND RECERTIFICATION
 14 PROCESS.—

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

18 (I) under a process that is recog-
 19 nized or approved by the appropriate
 20 Secretary; or

21 (II) by a qualified private stand-
 22 ard-setting organization that is ap-
 23 proved by the appropriate Secretary
 24 under clause (iii).

1 In taking action under subclause (I), the
2 appropriate Secretary shall give deference
3 to entities that are under contract with the
4 Federal Government or with an applicable
5 State authority to perform functions of the
6 type performed by qualified external review
7 entities.

8 (ii) PROCESS.—The appropriate Sec-
9 retary shall not recognize or approve a
10 process under clause (i)(I) unless the proc-
11 ess applies standards (as promulgated in
12 regulations) that ensure that a qualified
13 external review entity—

14 (I) will carry out (and has car-
15 ried out, in the case of recertification)
16 the responsibilities of such an entity
17 in accordance with this section, in-
18 cluding meeting applicable deadlines;

19 (II) will meet (and has met, in
20 the case of recertification) appropriate
21 indicators of fiscal integrity;

22 (III) will maintain (and has
23 maintained, in the case of recertifi-
24 cation) appropriate confidentiality
25 with respect to individually identifi-

able health information obtained in
the course of conducting external re-
view activities; and

(IV) in the case recertification,
shall review the matters described in
clause (iv).

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

(iv) CONSIDERATIONS IN RECERTIFI-
CATIONS.—In conducting recertifications of
a qualified external review entity under
this paragraph, the appropriate Secretary
or organization conducting the recertifi-
cation shall review compliance of the entity
with the requirements for conducting ex-

1 ternal review activities under this section,
2 including the following:

3 (I) Provision of information
4 under subparagraph (D).

5 (II) Adherence to applicable
6 deadlines (both by the entity and by
7 independent medical reviewers it re-
8 fers cases to).

9 (III) Compliance with limitations
10 on compensation (with respect to both
11 the entity and independent medical re-
12 viewers it refers cases to).

13 (IV) Compliance with applicable
14 independence requirements.

15 (V) Compliance with the require-
16 ment of subsection (d)(1) that only
17 medically reviewable decisions shall be
18 the subject of independent medical re-
19 view and with the requirement of sub-
20 section (d)(3) that independent med-
21 ical reviewers may not require cov-
22 erage for specifically excluded bene-
23 fits.

24 (v) PERIOD OF CERTIFICATION OR RE-
25 CERTIFICATION.—A certification or recer-

1 tification provided under this paragraph
2 shall extend for a period not to exceed 2
3 years.

4 (vi) REVOCATION.—A certification or
5 recertification under this paragraph may
6 be revoked by the appropriate Secretary or
7 by the organization providing such certifi-
8 cation upon a showing of cause. The Sec-
9 retary, or organization, shall revoke a cer-
10 tification or deny a recertification with re-
11 spect to an entity if there is a showing that
12 the entity has a pattern or practice of or-
13 dering coverage for benefits that are spe-
14 cifically excluded under the plan or cov-
15 erage.

16 (vii) PETITION FOR DENIAL OR WITH-
17 DRAWAL.—An individual may petition the
18 Secretary, or an organization providing the
19 certification involves, for a denial of recer-
20 tification or a withdrawal of a certification
21 with respect to an entity under this sub-
22 paragraph if there is a pattern or practice
23 of such entity failing to meet a require-
24 ment of this section.

1 (viii) SUFFICIENT NUMBER OF ENTI-
2 TIES.—The appropriate Secretary shall
3 certify and recertify a number of external
4 review entities which is sufficient to ensure
5 the timely and efficient provision of review
6 services.

7 (D) PROVISION OF INFORMATION.—

8 (i) IN GENERAL.—A qualified external
9 review entity shall provide to the appro-
10 priate Secretary, in such manner and at
11 such times as such Secretary may require,
12 such information (relating to the denials
13 which have been referred to the entity for
14 the conduct of external review under this
15 section) as such Secretary determines ap-
16 propriate to assure compliance with the
17 independence and other requirements of
18 this section to monitor and assess the qual-
19 ity of its external review activities and lack
20 of bias in making determinations. Such in-
21 formation shall include information de-
22 scribed in clause (ii) but shall not include
23 individually identifiable medical informa-
24 tion.

1 (ii) INFORMATION TO BE IN-
2 CLUDED.—The information described in
3 this subclause with respect to an entity is
4 as follows:

5 (I) The number and types of de-
6 nials for which a request for review
7 has been received by the entity.

8 (II) The disposition by the entity
9 of such denials, including the number
10 referred to a independent medical re-
11 viewer and the reasons for such dis-
12 positions (including the application of
13 exclusions), on a plan or issuer-spe-
14 cific basis and on a health care spe-
15 cialty-specific basis.

16 (III) The length of time in mak-
17 ing determinations with respect to
18 such denials.

19 (IV) Updated information on the
20 information required to be submitted
21 as a condition of certification with re-
22 spect to the entity's performance of
23 external review activities.

24 (iii) INFORMATION TO BE PROVIDED
25 TO CERTIFYING ORGANIZATION.—

1 (I) IN GENERAL.—In the case of
2 a qualified external review entity
3 which is certified (or recertified)
4 under this subsection by a qualified
5 private standard-setting organization,
6 at the request of the organization, the
7 entity shall provide the organization
8 with the information provided to the
9 appropriate Secretary under clause
10 (i).

11 (II) ADDITIONAL INFORMA-
12 TION.—Nothing in this subparagraph
13 shall be construed as preventing such
14 an organization from requiring addi-
15 tional information as a condition of
16 certification or recertification of an
17 entity.

18 (iv) USE OF INFORMATION.—Informa-
19 tion provided under this subparagraph may
20 be used by the appropriate Secretary and
21 qualified private standard-setting organiza-
22 tions to conduct oversight of qualified ex-
23 ternal review entities, including recertifi-
24 cation of such entities, and shall be made

1 available to the public in an appropriate
2 manner.

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

16 (5) REPORT.—Not later than 12 months after
17 the general effective date referred to in section 501,
18 the General Accounting Office shall prepare and
19 submit to the appropriate committees of Congress a
20 report concerning—

21 (A) the information that is provided under
22 paragraph (3)(D);

23 (B) the number of denials that have been
24 upheld by independent medical reviewers and

1 the number of denials that have been reversed
 2 by such reviewers; and

3 (C) the extent to which independent med-
 4 ical reviewers are requiring coverage for bene-
 5 fits that are specifically excluded under the plan
 6 or coverage.

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

8 (a) GRANTS.—

9 (1) IN GENERAL.—The Secretary of Health and
 10 Human Services (referred to in this section as the
 11 “Secretary”) shall establish a fund, to be known as
 12 the “Health Care Consumer Assistance Fund”, to be
 13 used to award grants to eligible States to carry out
 14 consumer assistance activities (including programs
 15 established by States prior to the enactment of this
 16 Act) designed to provide information, assistance, and
 17 referrals to consumers of health insurance products.

18 (2) STATE ELIGIBILITY.—To be eligible to re-
 19 ceive a grant under this subsection a State shall pre-
 20 pare and submit to the Secretary an application at
 21 such time, in such manner, and containing such in-
 22 formation as the Secretary may require, including a
 23 State plan that describes—

24 (A) the manner in which the State will en-
 25 sure that the health care consumer assistance

1 office (established under paragraph (4)) will
2 educate and assist health care consumers in ac-
3 cessing needed care;

4 (B) the manner in which the State will co-
5 ordinate and distinguish the services provided
6 by the health care consumer assistance office
7 with the services provided by Federal, State and
8 local health-related ombudsman, information,
9 protection and advocacy, insurance, and fraud
10 and abuse programs;

11 (C) the manner in which the State will
12 provide information, outreach, and services to
13 underserved, minority populations with limited
14 English proficiency and populations residing in
15 rural areas;

16 (D) the manner in which the State will
17 oversee the health care consumer assistance of-
18 fice, its activities, product materials and evalu-
19 ate program effectiveness;

20 (E) the manner in which the State will en-
21 sure that funds made available under this sec-
22 tion will be used to supplement, and not sup-
23 plant, any other Federal, State, or local funds
24 expended to provide services for programs de-

scribed under this section and those described
in subparagraphs (C) and (D);

(F) the manner in which the State will ensure that health care consumer office personnel have the professional background and training to carry out the activities of the office; and

(G) the manner in which the State will ensure that consumers have direct access to consumer assistance personnel during regular business hours.

(3) AMOUNT OF GRANT.—

(A) IN GENERAL.—From amounts appropriated under subsection (b) for a fiscal year, the Secretary shall award a grant to a State in an amount that bears the same ratio to such amounts as the number of individuals within the State covered under a group health plan or under health insurance coverage offered by a health insurance issuer bears to the total number of individuals so covered in all States (as determined by the Secretary). Any amounts provided to a State under this subsection that are not used by the State shall be remitted to the Secretary and reallocated in accordance with this subparagraph.

1 (B) MINIMUM AMOUNT.—In no case shall
2 the amount provided to a State under a grant
3 under this subsection for a fiscal year be less
4 than an amount equal to 0.5 percent of the
5 amount appropriated for such fiscal year to
6 carry out this section.

7 (C) NON-FEDERAL CONTRIBUTIONS.—A
8 State will provide for the collection of non-Fed-
9 eral contributions for the operation of the office
10 in an amount that is not less than 25 percent
11 of the amount of Federal funds provided to the
12 State under this section.

13 (4) PROVISION OF FUNDS FOR ESTABLISHMENT
14 OF OFFICE.—

15 (A) IN GENERAL.—From amounts pro-
16 vided under a grant under this subsection, a
17 State shall, directly or through a contract with
18 an independent, nonprofit entity with dem-
19 onstrated experience in serving the needs of
20 health care consumers, provide for the estab-
21 lishment and operation of a State health care
22 consumer assistance office.

23 (B) ELIGIBILITY OF ENTITY.—To be eligi-
24 ble to enter into a contract under subparagraph
25 (A), an entity shall demonstrate that it has the

1 technical, organizational, and professional ca-
 2 capacity to deliver the services described in sub-
 3 section (b) to all public and private health in-
 4 surance participants, beneficiaries, enrollees, or
 5 prospective enrollees.

6 (C) EXISTING STATE ENTITY.—Nothing in
 7 this section shall prevent the funding of an ex-
 8 isting health care consumer assistance program
 9 that otherwise meets the requirements of this
 10 section.

11 (b) USE OF FUNDS.—

12 (1) BY STATE.—A State shall use amounts pro-
 13 vided under a grant awarded under this section to
 14 carry out consumer assistance activities directly or
 15 by contract with an independent, non-profit organi-
 16 zation. An eligible entity may use some reasonable
 17 amount of such grant to ensure the adequate train-
 18 ing of personnel carrying out such activities. To re-
 19 ceive amounts under this subsection, an eligible enti-
 20 ty shall provide consumer assistance services, includ-
 21 ing—

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

24 (B) the dissemination of appropriate edu-
 25 cational materials on available health insurance

1 products and on how best to access health care
 2 and the rights and responsibilities of health
 3 care consumers;

4 (C) the provision of education on effective
 5 methods to promptly and efficiently resolve
 6 questions, problems, and grievances;

7 (D) the coordination of educational and
 8 outreach efforts with health plans, health care
 9 providers, payers, and governmental agencies;

10 (E) referrals to appropriate private and
 11 public entities to resolve questions, problems
 12 and grievances; and

13 (F) the provision of information and as-
 14 sistance, including acting as an authorized rep-
 15 resentative, regarding internal, external, or ad-
 16 ministrative grievances or appeals procedures in
 17 nonlitigative settings to appeal the denial, ter-
 18 mination, or reduction of health care services,
 19 or the refusal to pay for such services, under a
 20 group health plan or health insurance coverage
 21 offered by a health insurance issuer.

22 (2) CONFIDENTIALITY AND ACCESS TO INFOR-
 23 MATION.—

24 (A) STATE ENTITY.—With respect to a
 25 State that directly establishes a health care con-

1 consumer assistance office, such office shall estab-
2 lish and implement procedures and protocols in
3 accordance with applicable Federal and State
4 laws.

5 (B) CONTRACT ENTITY.—With respect to a
6 State that, through contract, establishes a
7 health care consumer assistance office, such of-
8 fice shall establish and implement procedures
9 and protocols, consistent with applicable Fed-
10 eral and State laws, to ensure the confiden-
11 tiality of all information shared by a partici-
12 pant, beneficiary, enrollee, or their personal
13 representative and their health care providers,
14 group health plans, or health insurance insurers
15 with the office and to ensure that no such infor-
16 mation is used by the office, or released or dis-
17 closed to State agencies or outside persons or
18 entities without the prior written authorization
19 (in accordance with section 164.508 of title 45,
20 Code of Federal Regulations) of the individual
21 or personal representative. The office may, con-
22 sistent with applicable Federal and State con-
23 fidentiality laws, collect, use or disclose aggre-
24 gate information that is not individually identi-
25 fiable (as defined in section 164.501 of title 45,

1 Code of Federal Regulations). The office shall
2 provide a written description of the policies and
3 procedures of the office with respect to the
4 manner in which health information may be
5 used or disclosed to carry out consumer assist-
6 ance activities. The office shall provide health
7 care providers, group health plans, or health in-
8 surance issuers with a written authorization (in
9 accordance with section 164.508 of title 45,
10 Code of Federal Regulations) to allow the office
11 to obtain medical information relevant to the
12 matter before the office.

13 (3) AVAILABILITY OF SERVICES.—The health
14 care consumer assistance office of a State shall not
15 discriminate in the provision of information, refer-
16 rals, and services regardless of the source of the in-
17 dividual's health insurance coverage or prospective
18 coverage, including individuals covered under a
19 group health plan or health insurance coverage of-
20 fered by a health insurance issuer, the medicare or
21 medicaid programs under title XVIII or XIX of the
22 Social Security Act (42 U.S.C. 1395 and 1396 et
23 seq.), or under any other Federal or State health
24 care program.

25 (4) DESIGNATION OF RESPONSIBILITIES.—

1 (A) WITHIN EXISTING STATE ENTITY.—If
2 the health care consumer assistance office of a
3 State is located within an existing State regu-
4 latory agency or office of an elected State offi-
5 cial, the State shall ensure that—

6 (i) there is a separate delineation of
7 the funding, activities, and responsibilities
8 of the office as compared to the other
9 funding, activities, and responsibilities of
10 the agency; and

11 (ii) the office establishes and imple-
12 ments procedures and protocols to ensure
13 the confidentiality of all information
14 shared by a participant, beneficiary, or en-
15 rollee or their personal representative and
16 their health care providers, group health
17 plans, or health insurance issuers with the
18 office and to ensure that no information is
19 disclosed to the State agency or office
20 without the written authorization of the in-
21 dividual or their personal representative in
22 accordance with paragraph (2).

23 (B) CONTRACT ENTITY.—In the case of an
24 entity that enters into a contract with a State
25 under subsection (a)(3), the entity shall provide

1 assurances that the entity has no conflict of in-
2 terest in carrying out the activities of the office
3 and that the entity is independent of group
4 health plans, health insurance issuers, pro-
5 viders, payers, and regulators of health care.

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

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

14 (c) REPORT.—Not later than 1 year after the Sec-
15 retary first awards grants under this section, and annually
16 thereafter, the Secretary shall prepare and submit to the
17 appropriate committees of Congress a report concerning
18 the activities funded under this section and the effective-
19 ness of such activities in resolving health care-related
20 problems and grievances.

21 (d) AUTHORIZATION OF APPROPRIATIONS.—There
22 are authorized to be appropriated such sums as may be
23 necessary to carry out this section.

1 **Subtitle B—Access to Care**

2 **SEC. 111. CONSUMER CHOICE OPTION.**

3 (a) IN GENERAL.—If—

4 (1) a health insurance issuer providing health
5 insurance coverage in connection with a group health
6 plan offers to enrollees health insurance coverage
7 which provides for coverage of services only if such
8 services are furnished through health care profes-
9 sionals and providers who are members of a network
10 of health care professionals and providers who have
11 entered into a contract with the issuer to provide
12 such services, or

13 (2) a group health plan offers to participants or
14 beneficiaries health benefits which provide for cov-
15 erage of services only if such services are furnished
16 through health care professionals and providers who
17 are members of a network of health care profes-
18 sionals and providers who have entered into a con-
19 tract with the plan to provide such services—

20 then the issuer or plan shall also offer or arrange to be
21 offered to such enrollees, participants, or beneficiaries (at
22 the time of enrollment and during an annual open season
23 as provided under subsection (c)) the option of health in-
24 surance coverage or health benefits which provide for cov-
25 erage of such services which are not furnished through

1 health care professionals and providers who are members
2 of such a network unless such enrollees, participants, or
3 beneficiaries are offered such non-network coverage
4 through another group health plan or through another
5 health insurance issuer in the group market.

6 (b) ADDITIONAL COSTS.—The amount of any addi-
7 tional premium charged by the health insurance issuer or
8 group health plan for the additional cost of the creation
9 and maintenance of the option described in subsection (a)
10 and the amount of any additional cost sharing imposed
11 under such option shall be borne by the enrollee, partici-
12 pant, or beneficiary unless it is paid by the health plan
13 sponsor or group health plan through agreement with the
14 health insurance issuer.

15 (c) OPEN SEASON.—An enrollee, participant, or ben-
16 eficiary, may change to the offering provided under this
17 section only during a time period determined by the health
18 insurance issuer or group health plan. Such time period
19 shall occur at least annually.

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

21 (a) PRIMARY CARE.—If a group health plan, or a
22 health insurance issuer that offers health insurance cov-
23 erage, requires or provides for designation by a partici-
24 pant, beneficiary, or enrollee of a participating primary
25 care provider, then the plan or issuer shall permit each

1 participant, beneficiary, and enrollee to designate any par-
2 ticipating primary care provider who is available to accept
3 such individual.

4 (b) SPECIALISTS.—

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

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

18 (3) CONSTRUCTION.—Nothing in this sub-
19 section shall be construed as affecting the applica-
20 tion of section 114 (relating to access to specialty
21 care).

22 **SEC. 113. ACCESS TO EMERGENCY CARE.**

23 (a) COVERAGE OF EMERGENCY SERVICES.—

24 (1) IN GENERAL.—If a group health plan, or
25 health insurance coverage offered by a health insur-

1 ance issuer, provides or covers any benefits with re-
2 spect to services in an emergency department of a
3 hospital, the plan or issuer shall cover emergency
4 services (as defined in paragraph (2)(B))—

5 (A) without the need for any prior author-
6 ization determination;

7 (B) whether the health care provider fur-
8 nishing such services is a participating provider
9 with respect to such services;

10 (C) in a manner so that, if such services
11 are provided to a participant, beneficiary, or en-
12 rollee—

13 (i) by a nonparticipating health care
14 provider with or without prior authoriza-
15 tion, or

16 (ii) by a participating health care pro-
17 vider without prior authorization—

18 the participant, beneficiary, or enrollee is not
19 liable for amounts that exceed the amounts of
20 liability that would be incurred if the services
21 were provided by a participating health care
22 provider with prior authorization; and

23 (D) without regard to any other term or
24 condition of such coverage (other than exclusion
25 or coordination of benefits, or an affiliation or

1 waiting period, permitted under section 2701 of
 2 the Public Health Service Act, section 701 of
 3 the Employee Retirement Income Security Act
 4 of 1974, or section 9801 of the Internal Rev-
 5 enue Code of 1986, and other than applicable
 6 cost-sharing).

7 (2) DEFINITIONS.—In this section:

8 (A) EMERGENCY MEDICAL CONDITION.—

9 The term “emergency medical condition” means
 10 a medical condition manifesting itself by acute
 11 symptoms of sufficient severity (including se-
 12 vere pain) such that a prudent layperson, who
 13 possesses an average knowledge of health and
 14 medicine, could reasonably expect the absence
 15 of immediate medical attention to result in a
 16 condition described in clause (i), (ii), or (iii) of
 17 section 1867(e)(1)(A) of the Social Security
 18 Act.

19 (B) EMERGENCY SERVICES.—The term

20 “emergency services” means, with respect to an
 21 emergency medical condition—

22 (i) a medical screening examination

23 (as required under section 1867 of the So-
 24 cial Security Act) that is within the capa-
 25 bility of the emergency department of a

hospital, including ancillary services routinely available to the emergency department to evaluate such emergency medical condition, and

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

(C) STABILIZE.—The term “to stabilize”, with respect to an emergency medical condition (as defined in subparagraph (A)), has the meaning give in section 1867(e)(3) of the Social Security Act (42 U.S.C. 1395dd(e)(3)).

(b) REIMBURSEMENT FOR MAINTENANCE CARE AND POST-STABILIZATION CARE.—A group health plan, and health insurance coverage offered by a health insurance issuer, must provide reimbursement for maintenance care and post-stabilization care in accordance with the requirements of section 1852(d)(2) of the Social Security Act (42 U.S.C. 1395w–22(d)(2)). Such reimbursement shall be provided in a manner consistent with subsection (a)(1)(C).

(c) COVERAGE OF EMERGENCY AMBULANCE SERVICES.—

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

11 (2) EMERGENCY AMBULANCE SERVICES.—For
12 purposes of this subsection, the term “emergency
13 ambulance services” means ambulance services (as
14 defined for purposes of section 1861(s)(7) of the So-
15 cial Security Act) furnished to transport an indi-
16 vidual who has an emergency medical condition (as
17 defined in subsection (a)(2)(A)) to a hospital for the
18 receipt of emergency services (as defined in sub-
19 section (a)(2)(B)) in a case in which the emergency
20 services are covered under the plan or coverage pur-
21 suant to subsection (a)(1) and a prudent layperson,
22 with an average knowledge of health and medicine,
23 could reasonably expect that the absence of such
24 transport would result in placing the health of the
25 individual in serious jeopardy, serious impairment of

1 bodily function, or serious dysfunction of any bodily
2 organ or part.

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

4 (a) TIMELY ACCESS.—

5 (1) IN GENERAL.—A group health plan or
6 health insurance issuer offering health insurance
7 coverage shall ensure that participants, beneficiaries,
8 and enrollees receive timely access to specialists who
9 are appropriate to the condition of, and accessible
10 to, the participant, beneficiary, or enrollee, when
11 such specialty care is a covered benefit under the
12 plan or coverage.

13 (2) RULE OF CONSTRUCTION.—Nothing in
14 paragraph (1) shall be construed—

15 (A) to require the coverage under a group
16 health plan or health insurance coverage of ben-
17 efits or services;

18 (B) to prohibit a plan or issuer from in-
19 cluding providers in the network only to the ex-
20 tent necessary to meet the needs of the plan's
21 or issuer's participants, beneficiaries, or enroll-
22 ees; or

23 (C) to override any State licensure or
24 scope-of-practice law.

25 (3) ACCESS TO CERTAIN PROVIDERS.—

1 (A) IN GENERAL.—With respect to spe-
 2 cialty care under this section, if a participating
 3 specialist is not available and qualified to pro-
 4 vide such care to the participant, beneficiary, or
 5 enrollee, the plan or issuer shall provide for cov-
 6 erage of such care by a nonparticipating spe-
 7 cialist.

8 (B) TREATMENT OF NONPARTICIPATING
 9 PROVIDERS.—If a participant, beneficiary, or
 10 enrollee receives care from a nonparticipating
 11 specialist pursuant to subparagraph (A), such
 12 specialty care shall be provided at no additional
 13 cost to the participant, beneficiary, or enrollee
 14 beyond what the participant, beneficiary, or en-
 15 rollee would otherwise pay for such specialty
 16 care if provided by a participating specialist.

17 (b) REFERRALS.—

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

23 (A) shall be for an appropriate duration of
 24 time or number of referrals, including an au-

thorization for a standing referral where appropriate; and

(B) may not be refused solely because the authorization involves services of a nonparticipating specialist (described in subsection (a)(3)).

(2) REFERRALS FOR ONGOING SPECIAL CONDITIONS.—

(A) IN GENERAL.—Subject to subsection (a)(1), a group health plan or health insurance issuer shall permit a participant, beneficiary, or enrollee who has an ongoing special condition (as defined in subparagraph (B)) to receive a referral to a specialist for the treatment of such condition and such specialist may authorize such referrals, procedures, tests, and other medical services with respect to such condition, or coordinate the care for such condition, subject to the terms of a treatment plan (if any) referred to in subsection (c) with respect to the condition.

(B) ONGOING SPECIAL CONDITION DEFINED.—In this subsection, the term “ongoing special condition” means a condition or disease that—

- 1 (i) is life-threatening, degenerative,
2 potentially disabling, or congenital; and
3 (ii) requires specialized medical care
4 over a prolonged period of time.

5 (c) TREATMENT PLANS.—

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

9 (A) pursuant to a treatment plan, but only
10 if the treatment plan—

11 (i) is developed by the specialist, in
12 consultation with the case manager or pri-
13 mary care provider, and the participant,
14 beneficiary, or enrollee, and

15 (ii) is approved by the plan or issuer
16 in a timely manner, if the plan or issuer
17 requires such approval; and

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

21 (2) NOTIFICATION.—Nothing in paragraph (1)
22 shall be construed as prohibiting a plan or issuer
23 from requiring the specialist to provide the plan or
24 issuer with regular updates on the specialty care

1 provided, as well as all other reasonably necessary
 2 medical information.

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

10 **SEC. 115. PATIENT ACCESS TO OBSTETRICAL AND GYNECO-**
 11 **LOGICAL CARE.**

12 (a) GENERAL RIGHTS.—

13 (1) DIRECT ACCESS.—A group health plan, or
 14 health insurance issuer offering health insurance
 15 coverage, described in subsection (b) may not re-
 16 quire authorization or referral by the plan, issuer, or
 17 any person (including a primary care provider de-
 18 scribed in subsection (b)(2)) in the case of a female
 19 participant, beneficiary, or enrollee who seeks cov-
 20 erage for obstetrical or gynecological care provided
 21 by a participating health care professional who spe-
 22 cializes in obstetrics or gynecology.

23 (2) OBSTETRICAL AND GYNECOLOGICAL
 24 CARE.—A group health plan or health insurance
 25 issuer described in subsection (b) shall treat the pro-

1 vision of obstetrical and gynecological care, and the
2 ordering of related obstetrical and gynecological
3 items and services, pursuant to the direct access de-
4 scribed under paragraph (1), by a participating
5 health care professional who specializes in obstetrics
6 or gynecology as the authorization of the primary
7 care provider.

8 (b) APPLICATION OF SECTION.—A group health plan,
9 or health insurance issuer offering health insurance cov-
10 erage, described in this subsection is a group health plan
11 or coverage that—

12 (1) provides coverage for obstetric or
13 gynecologic care; and

14 (2) requires the designation by a participant,
15 beneficiary, or enrollee of a participating primary
16 care provider.

17 (c) CONSTRUCTION.—Nothing in subsection (a) shall
18 be construed to—

19 (1) waive any exclusions of coverage under the
20 terms and conditions of the plan or health insurance
21 coverage with respect to coverage of obstetrical or
22 gynecological care; or

23 (2) preclude the group health plan or health in-
24 surance issuer involved from requiring that the ob-
25 stetrical or gynecological provider notify the primary

1 care health care professional or the plan or issuer of
2 treatment decisions.

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

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

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

18 **SEC. 117. CONTINUITY OF CARE.**

19 (a) TERMINATION OF PROVIDER.—

20 (1) IN GENERAL.—If—

21 (A) a contract between a group health
22 plan, or a health insurance issuer offering
23 health insurance coverage, and a treating health
24 care provider is terminated (as defined in para-
25 graph (e)(4)), or

1 (B) benefits or coverage provided by a
 2 health care provider are terminated because of
 3 a change in the terms of provider participation
 4 in such plan or coverage—

5 the plan or issuer shall meet the requirements of
 6 paragraph (3) with respect to each continuing care
 7 patient.

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

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

24 (A) notify the continuing care patient in-
 25 volved, or arrange to have the patient notified

1 pursuant to subsection (d)(2), on a timely basis
2 of the termination described in paragraph (1)
3 (or paragraph (2), if applicable) and the right
4 to elect continued transitional care from the
5 provider under this section;

6 (B) provide the patient with an oppor-
7 tunity to notify the plan or issuer of the pa-
8 tient's need for transitional care; and

9 (C) subject to subsection (c), permit the
10 patient to elect to continue to be covered with
11 respect to the course of treatment by such pro-
12 vider with the provider's consent during a tran-
13 sitional period (as provided for under subsection
14 (b)).

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

18 (A) is undergoing a course of treatment
19 for a serious and complex condition from the
20 provider at the time the plan or issuer receives
21 or provides notice of provider, benefit, or cov-
22 erage termination described in paragraph (1)
23 (or paragraph (2), if applicable);

1 (B) is undergoing a course of institutional
 2 or inpatient care from the provider at the time
 3 of such notice;

4 (C) is scheduled to undergo non-elective
 5 surgery from the provider at the time of such
 6 notice;

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

10 (E) is or was determined to be terminally
 11 ill (as determined under section 1861(dd)(3)(A)
 12 of the Social Security Act) at the time of such
 13 notice, but only with respect to a provider that
 14 was treating the terminal illness before the date
 15 of such notice.

16 (b) TRANSITIONAL PERIODS.—

17 (1) SERIOUS AND COMPLEX CONDITIONS.—The
 18 transitional period under this subsection with re-
 19 spect to a continuing care patient described in sub-
 20 section (a)(4)(A) shall extend for up to 90 days (as
 21 determined by the treating health care professional)
 22 from the date of the notice described in subsection
 23 (a)(3)(A).

24 (2) INSTITUTIONAL OR INPATIENT CARE.—The
 25 transitional period under this subsection for a con-

1 continuing care patient described in subsection
 2 (a)(4)(B) shall extend until the earlier of—

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

6 (B) the date of discharge of the patient
 7 from such care or the termination of the period
 8 of institutionalization, or, if later, the date of
 9 completion of reasonable follow-up care.

10 (3) SCHEDULED NON-ELECTIVE SURGERY.—

11 The transitional period under this subsection for a
 12 continuing care patient described in subsection
 13 (a)(4)(C) shall extend until the completion of the
 14 surgery involved and post-surgical follow-up care re-
 15 lating to the surgery and occurring within 90 days
 16 after the date of the surgery.

17 (4) PREGNANCY.—The transitional period
 18 under this subsection for a continuing care patient
 19 described in subsection (a)(4)(D) shall extend
 20 through the provision of post-partum care directly
 21 related to the delivery.

22 (5) TERMINAL ILLNESS.—The transitional pe-
 23 riod under this subsection for a continuing care pa-
 24 tient described in subsection (a)(4)(E) shall extend
 25 for the remainder of the patient's life for care that

1 is directly related to the treatment of the terminal
2 illness or its medical manifestations.

3 (c) PERMISSIBLE TERMS AND CONDITIONS.—A
4 group health plan or health insurance issuer may condi-
5 tion coverage of continued treatment by a provider under
6 this section upon the provider agreeing to the following
7 terms and conditions:

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

22 (2) The treating health care provider agrees to
23 adhere to the quality assurance standards of the
24 plan or issuer responsible for payment under para-
25 graph (1) and to provide to such plan or issuer nec-

1 necessary medical information related to the care pro-
2 vided.

3 (3) The treating health care provider agrees
4 otherwise to adhere to such plan's or issuer's policies
5 and procedures, including procedures regarding re-
6 ferrals and obtaining prior authorization and pro-
7 viding services pursuant to a treatment plan (if any)
8 approved by the plan or issuer.

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

11 (1) to require the coverage of benefits which
12 would not have been covered if the provider involved
13 remained a participating provider; or

14 (2) with respect to the termination of a con-
15 tract under subsection (a) to prevent a group health
16 plan or health insurance issuer from requiring that
17 the health care provider—

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

20 (B) provide the plan or issuer with the
21 name of each participant, beneficiary, or en-
22 rollee who the provider believes is a continuing
23 care patient.

24 (e) DEFINITIONS.—In this section:

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

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

11 (A) any individual who is engaged in the
 12 delivery of health care services in a State and
 13 who is required by State law or regulation to be
 14 licensed or certified by the State to engage in
 15 the delivery of such services in the State; and

16 (B) any entity that is engaged in the deliv-
 17 ery of health care services in a State and that,
 18 if it 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, is so
 21 licensed.

22 (3) SERIOUS AND COMPLEX CONDITION.—The
 23 term “serious and complex condition” means, with
 24 respect to a participant, beneficiary, or enrollee
 25 under the plan or coverage—

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

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

8 (4) TERMINATED.—The term “terminated” in-
 9 cludes, with respect to a contract, the expiration or
 10 nonrenewal of the contract, but does not include a
 11 termination of the contract for failure to meet appli-
 12 cable quality standards or for fraud.

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

14 (a) IN GENERAL.—To the extent that a group health
 15 plan, or health insurance coverage offered by a health in-
 16 surance issuer, provides coverage for benefits with respect
 17 to prescription drugs, and limits such coverage to drugs
 18 included in a formulary, the plan or issuer shall—

19 (1) ensure the participation of physicians and
 20 pharmacists in developing and reviewing such for-
 21 mulary;

22 (2) provide for disclosure of the formulary to
 23 providers; and

24 (3) in accordance with the applicable quality as-
 25 surance and utilization review standards of the plan

1 or issuer, provide for exceptions from the formulary
 2 limitation when a non-formulary alternative is medi-
 3 cally necessary and appropriate and, in the case of
 4 such an exception, apply the same cost-sharing re-
 5 quirements that would have applied in the case of a
 6 drug covered under the formulary.

7 (b) COVERAGE OF APPROVED DRUGS AND MEDICAL
 8 DEVICES.—

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

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

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

23 (ii) is included in the labeling author-
 24 ized by the application in effect for the
 25 drug under section 351 of the Public

1 Health Service Act, without regard to any
 2 postmarketing requirements that may
 3 apply pursuant to such section; or

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

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

17 **SEC. 119. COVERAGE FOR INDIVIDUALS PARTICIPATING IN**
 18 **APPROVED CLINICAL TRIALS.**

19 (a) COVERAGE.—

20 (1) IN GENERAL.—If a group health plan, or
 21 health insurance issuer that is providing health in-
 22 surance coverage, provides coverage to a qualified in-
 23 dividual (as defined in subsection (b)), the plan or
 24 issuer—

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

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

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

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

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

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

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

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

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

16 (2) Either—

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

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

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

4 (c) PAYMENT.—

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

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

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

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

20 (d) APPROVED CLINICAL TRIAL DEFINED.—

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

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

(i) the National Institutes of Health;

(ii) a cooperative group or center of the National Institutes of Health, such as a qualified nongovernmental research entity to which the National Cancer Institute has awarded a center support grant;

(iii) either of the following if the conditions described in paragraph (2) are met—

(I) the Department of Veterans Affairs;

(II) the Department of Defense;

or

(B) approved by the Food and Drug Administration.

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

1 (A) to be comparable to the system of peer
 2 review of studies and investigations used by the
 3 National Institutes of Health; and

4 (B) assures unbiased review of the highest
 5 ethical standards by qualified individuals who
 6 have no interest in the outcome of the review.

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

10 **SEC. 120. REQUIRED COVERAGE FOR MINIMUM HOSPITAL**
 11 **STAY FOR MASTECTOMIES AND LYMPH NODE**
 12 **DISSECTIONS FOR THE TREATMENT OF**
 13 **BREAST CANCER AND COVERAGE FOR SEC-**
 14 **ONDARY CONSULTATIONS.**

15 (a) INPATIENT CARE.—

16 (1) IN GENERAL.—A group health plan, and a
 17 health insurance issuer providing health insurance
 18 coverage, that provides medical and surgical benefits
 19 shall ensure that inpatient coverage with respect to
 20 the treatment of breast cancer is provided for a pe-
 21 riod of time as is determined by the attending physi-
 22 cian, in consultation with the patient, to be medi-
 23 cally necessary and appropriate following—

24 (A) a mastectomy;

25 (B) a lumpectomy; or

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

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

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

15 (c) SECONDARY CONSULTATIONS.—

16 (1) IN GENERAL.—A group health plan, and a
17 health insurance issuer providing health insurance
18 coverage, that provides coverage with respect to
19 medical and surgical services provided in relation to
20 the diagnosis and treatment of cancer shall ensure
21 that full coverage is provided for secondary consulta-
22 tions by specialists in the appropriate medical fields
23 (including pathology, radiology, and oncology) to
24 confirm or refute such diagnosis. Such plan or issuer
25 shall ensure that full coverage is provided for such

1 secondary consultation whether such consultation is
2 based on a positive or negative initial diagnosis. In
3 any case in which the attending physician certifies
4 in writing that services necessary for such a sec-
5 ondary consultation are not sufficiently available
6 from specialists operating under the plan or cov-
7 erage with respect to whose services coverage is oth-
8 erwise provided under such plan or by such issuer,
9 such plan or issuer shall ensure that coverage is pro-
10 vided with respect to the services necessary for the
11 secondary consultation with any other specialist se-
12 lected by the attending physician for such purpose
13 at no additional cost to the individual beyond that
14 which the individual would have paid if the specialist
15 was participating in the network of the plan or
16 issuer.

17 (2) EXCEPTION.—Nothing in paragraph (1)
18 shall be construed as requiring the provision of sec-
19 ondary consultations where the patient determines
20 not to seek such a consultation.

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

24 (1) penalize or otherwise reduce or limit the re-
25 imbursement of a provider or specialist because the

1 provider or specialist provided care to a participant,
 2 beneficiary, or enrollee in accordance with this sec-
 3 tion;

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

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

17 **Subtitle C—Access to Information**

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

19 (a) REQUIREMENT.—

20 (1) DISCLOSURE.—

21 (A) IN GENERAL.—A group health plan,
 22 and a health insurance issuer that provides cov-
 23 erage in connection with health insurance cov-
 24 erage, shall provide for the disclosure to partici-
 25 pants, beneficiaries, and enrollees—

1 (i) of the information described in
2 subsection (b) at the time of the initial en-
3 rollment of the participant, beneficiary, or
4 enrollee under the plan or coverage;

5 (ii) of such information on an annual
6 basis—

7 (I) in conjunction with the elec-
8 tion period of the plan or coverage if
9 the plan or coverage has such an elec-
10 tion period; or

11 (II) in the case of a plan or cov-
12 erage that does not have an election
13 period, in conjunction with the begin-
14 ning of the plan or coverage year; and

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

21 (B) PARTICIPANTS, BENEFICIARIES, AND
22 ENROLLEES.—The disclosure required under
23 subparagraph (A) shall be provided—

1 (i) jointly to each participant, bene-
 2 ficiary, and enrollee who reside at the same
 3 address; or

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

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

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

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

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

1 (B) specific preventive services covered
2 under the plan or coverage if such services are
3 covered;

4 (C) any specific exclusions or express limi-
5 tations of benefits described in section
6 104(d)(3)(C);

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

12 (E) any definition of medical necessity
13 used in making coverage determinations by the
14 plan, issuer, or claims administrator.

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

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

22 (B) any maximum out-of-pocket expense
23 for which the participant, beneficiary, or en-
24 rollee may be liable;

1 (C) any cost-sharing requirements for out-
2 of-network benefits or services received from
3 nonparticipating providers; and

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

9 (3) DISENROLLMENT.—Information relating to
10 the disenrollment of a participant, beneficiary, or en-
11 rollee.

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

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

23 (6) CHOICE OF PRIMARY CARE PROVIDER.—A
24 description of any requirements and procedures to
25 be used by participants, beneficiaries, and enrollees

1 in selecting, accessing, or changing their primary
 2 care provider, including providers both within and
 3 outside of the network (if the plan or issuer permits
 4 out-of-network services), and the right to select a pe-
 5 diatrician as a primary care provider under section
 6 116 for a participant, beneficiary, or enrollee who is
 7 a child if such section applies.

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

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

18 (9) SPECIALTY CARE.—A description of the re-
 19 quirements and procedures to be used by partici-
 20 pants, beneficiaries, and enrollees in accessing spe-
 21 cialty care and obtaining referrals to participating
 22 and nonparticipating specialists, including any limi-
 23 tations on choice of health care professionals re-
 24 ferred to in section 112(b)(2) and the right to timely

1 access to specialists care under section 114 if such
2 section applies.

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

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

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

1 formation 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 Retire-
 14 ment 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 Bipartisan Pa-
24 tient Protection Act (excluding those described in
25 paragraphs (1) through (17)) if such sections apply.

1 The description required under this paragraph may
2 be combined with the notices of the type described
3 in sections 711(d), 713(b), or 606(a)(1) of the Em-
4 ployee Retirement Income Security Act of 1974 and
5 with any other notice provision that the appropriate
6 Secretary determines may be combined, so long as
7 such combination does not result in any reduction
8 in the information that would otherwise be provided
9 to the 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 **SEC. 122. GENETIC INFORMATION.**

4 (a) DEFINITIONS.—In this section:

5 (1) FAMILY MEMBER.—The term “family mem-
6 ber” means with respect to an individual—

7 (A) the spouse of the individual;

8 (B) a dependent child of the individual, in-
9 cluding a child who is born to or placed for
10 adoption with the individual; and

11 (C) all other individuals related by blood to
12 the individual or the spouse or child described
13 in subparagraph (A) or (B).

14 (2) GENETIC INFORMATION.—The term “ge-
15 netic information” means information about genes,
16 gene products, or inherited characteristics that may
17 derive from an individual or a family member of
18 such individual (including information about a re-
19 quest for or the receipt of genetic services by such
20 individual or a family member of such individual).

21 (3) GENETIC SERVICES.—The term “genetic
22 services” means health services, including genetic
23 tests, provided to obtain, assess, or interpret genetic
24 information for diagnostic and therapeutic purposes,
25 and for genetic education and counseling.

1 (4) GENETIC TEST.—The term “genetic test”
2 means the analysis of human DNA, RNA, chro-
3 mosomes, proteins, and certain metabolites, includ-
4 ing analysis of genotypes, mutations, phenotypes, or
5 karyotypes, for the purpose of predicting risk of dis-
6 ease in asymptomatic or undiagnosed individuals.
7 Such term does not include a physical test, such as
8 a chemical, blood, or urine analysis of an individual,
9 including a cholesterol test, or a physical exam of
10 the individual, in order to detect symptoms, clinical
11 signs, or a diagnosis of disease.

12 (5) GROUP HEALTH PLAN, HEALTH INSURANCE
13 ISSUER.—The terms “group health plan” and
14 “health insurance issuer” include a third party ad-
15 ministrator or other person acting for or on behalf
16 of such plan or issuer.

17 (6) PREDICTIVE GENETIC INFORMATION.—

18 (A) IN GENERAL.—The term “predictive
19 genetic information” means—

20 (i) information about an individual’s
21 genetic tests;

22 (ii) information about genetic tests of
23 family members of the individual; or

24 (iii) information about the occurrence
25 of a disease or disorder in family members.

1 (B) LIMITATIONS.—The term “predictive
2 genetic information” shall not include—

3 (i) information about the sex or age of
4 the individual;

5 (ii) information about chemical, blood,
6 or urine analyses of the individual, includ-
7 ing cholesterol tests, unless these analyses
8 are genetic tests, as defined in paragraph
9 (4); or

10 (iii) information about physical exams
11 of the individual, and other information
12 relevant to determining the current health
13 status of the individual.

14 (b) NONDISCRIMINATION.—

15 (1) NO ENROLLMENT RESTRICTION FOR GE-
16 NETIC SERVICES.—A group health plan, and a
17 health insurance issuer offering health insurance
18 coverage, shall not establish rules for eligibility (in-
19 cluding continued eligibility) of any individual to en-
20 roll under the terms of the plan or coverage based
21 on genetic information (or information about a re-
22 quest for or the receipt of genetic services by such
23 individual or a family member of such individual) in
24 relation to the individual or a dependent of the indi-
25 vidual.

1 (2) NO DISCRIMINATION IN RATE BASED ON
2 PREDICTIVE GENETIC INFORMATION.—A group
3 health plan, and a health insurance issuer offering
4 health insurance coverage, shall not deny eligibility
5 or adjust premium or contribution rates on the basis
6 of predictive genetic information concerning an indi-
7 vidual (or information about a request for or the re-
8 ceipt of genetic services by such individual or a fam-
9 ily member of such individual).

10 (c) COLLECTION OF PREDICTIVE GENETIC INFORMA-
11 TION.—

12 (1) LIMITATION ON REQUESTING OR REQUIRING
13 PREDICTIVE GENETIC INFORMATION.—Except as
14 provided in paragraph (2), a group health plan, or
15 a health insurance issuer offering health insurance
16 coverage, shall not request or require predictive ge-
17 netic information concerning an individual or a fam-
18 ily member of the individual (including information
19 about a request for or the receipt of genetic services
20 by such individual or a family member of such indi-
21 vidual).

22 (2) INFORMATION NEEDED FOR DIAGNOSIS,
23 TREATMENT, OR PAYMENT.—

24 (A) IN GENERAL.—Notwithstanding para-
25 graph (1), a group health plan, or a health in-

1 insurance issuer offering health insurance cov-
2 erage, that provides health care items and serv-
3 ices to an individual or dependent may request
4 (but may not require) that such individual or
5 dependent disclose, or authorize the collection
6 or disclosure of, predictive genetic information
7 for purposes of diagnosis, treatment, or pay-
8 ment relating to the provision of health care
9 items and services to such individual or depend-
10 ent.

11 (B) NOTICE OF CONFIDENTIALITY PRAC-
12 TICES AND DESCRIPTION OF SAFEGUARDS.—As
13 a part of a request under subparagraph (A),
14 the group health plan, or a health insurance
15 issuer offering health insurance coverage, shall
16 provide to the individual or dependent a de-
17 scription of the procedures in place to safe-
18 guard the confidentiality, as described in sub-
19 section (d), of such predictive genetic informa-
20 tion.

21 (d) CONFIDENTIALITY WITH RESPECT TO PRE-
22 DICTIVE GENETIC INFORMATION.—

23 (1) NOTICE OF CONFIDENTIALITY PRAC-
24 TICES.—A group health plan, or a health insurance
25 issuer offering health insurance coverage, shall post

1 or provide, in writing and in a clear and conspicuous
 2 manner, notice of the plan or issuer's confidentiality
 3 practices, that shall include—

4 (A) a description of an individual's rights
 5 with respect to predictive genetic information;

6 (B) the procedures established by the plan
 7 or issuer for the exercise of the individual's
 8 rights; and

9 (C) a description of the right to obtain a
 10 copy of the notice of the confidentiality prac-
 11 tices required under this subsection.

12 (2) ESTABLISHMENT OF SAFEGUARDS.—A
 13 group health plan, or a health insurance issuer offer-
 14 ing health insurance coverage, shall establish and
 15 maintain appropriate administrative, technical, and
 16 physical safeguards to protect the confidentiality, se-
 17 curity, accuracy, and integrity of predictive genetic
 18 information created, received, obtained, maintained,
 19 used, transmitted, or disposed of by such plan or
 20 issuer.

21 (3) COMPLIANCE WITH CERTAIN STANDARDS.—
 22 With respect to the establishment and maintenance
 23 of safeguards under this subsection or subsection
 24 (c)(2)(B), a group health plan, or a health insurance
 25 issuer offering health insurance coverage, shall be

1 deemed to be in compliance with such subsections
 2 if such plan or issuer is in compliance with the
 3 standards promulgated by the Secretary of Health
 4 and Human Services under—

5 (A) part C of title XI of the Social Secu-
 6 rity Act (42 U.S.C. 1320d et seq.); or

7 (B) section 264(c) of Health Insurance
 8 Portability and Accountability Act of 1996 (42
 9 U.S.C. 1320d–2 note).

10 (e) SPECIAL RULE IN CASE OF GENETIC INFORMA-
 11 TION.—With respect to health insurance coverage offered
 12 by a health insurance issuer, the provisions of this section
 13 relating to genetic information (including information
 14 about a request for or the receipt of genetic services by
 15 an individual or a family member of such individual) shall
 16 not be construed to supersede any provision of State law
 17 that establishes, implements, or continues in effect a
 18 standard, requirement, or remedy that more completely—

19 (1) protects the confidentiality of genetic infor-
 20 mation (including information about a request for or
 21 the receipt of genetic services by an individual or a
 22 family member of such individual) or the privacy of
 23 an individual or a family member of the individual
 24 with respect to genetic information (including infor-
 25 mation about a request for or the receipt of genetic

1 services by the individual or a family member of
 2 such individual); or

3 (2) prohibits discrimination on the basis of ge-
 4 netic information than does this section.

5 **Subtitle D—Protecting the Doctor-** 6 **Patient Relationship**

7 **SEC. 131. PROHIBITION OF INTERFERENCE WITH CERTAIN** 8 **MEDICAL COMMUNICATIONS.**

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

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

4 **SEC. 132. PROHIBITION OF DISCRIMINATION AGAINST PRO-**
 5 **VIDERS BASED ON LICENSURE.**

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

13 (b) CONSTRUCTION.—Subsection (a) shall not be con-
 14 strued—

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

24 (2) to override any State licensure or scope-of-
 25 practice law; or

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

5 **SEC. 133. PROHIBITION AGAINST IMPROPER INCENTIVE**
 6 **ARRANGEMENTS.**

7 (a) IN GENERAL.—A group health plan and a health
 8 insurance issuer offering health insurance coverage may
 9 not operate any physician incentive plan (as defined in
 10 subparagraph (B) of section 1876(i)(8) of the Social Secu-
 11 rity Act) unless the requirements described in clauses (i),
 12 (ii)(I), and (iii) of subparagraph (A) of such section are
 13 met with respect to such a plan.

14 (b) APPLICATION.—For purposes of carrying out
 15 paragraph (1), any reference in section 1876(i)(8) of the
 16 Social Security Act to the Secretary, an eligible organiza-
 17 tion, or an individual enrolled with the organization shall
 18 be treated as a reference to the applicable authority, a
 19 group health plan or health insurance issuer, respectively,
 20 and a participant, beneficiary, or enrollee with the plan
 21 or organization, respectively.

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

1 **SEC. 134. PAYMENT OF CLAIMS.**

2 A group health plan, and a health insurance issuer
 3 offering group health insurance coverage, shall provide for
 4 prompt payment of claims submitted for health care serv-
 5 ices or supplies furnished to a participant, beneficiary, or
 6 enrollee with respect to benefits covered by the plan or
 7 issuer, in a manner consistent with the provisions of sec-
 8 tion 1842(c)(2) of the Social Security Act (42 U.S.C.
 9 1395u(c)(2)).

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

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

21 (b) PROTECTION FOR QUALITY ADVOCACY BY
 22 HEALTH CARE PROFESSIONALS.—

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

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

8 (B) initiates, cooperates, or otherwise par-
9 ticipates in an investigation or proceeding by
10 such an agency with respect to such care, serv-
11 ices, or conditions.

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

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

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

13 (B) the professional reasonably believes the
14 information to be true;

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

21 (D) subject to subparagraphs (B) and (C)
22 of paragraph (3), the professional has followed
23 reasonable internal procedures of the plan,
24 issuer, or institutional health care provider es-

1 tablished for the purpose of addressing quality
2 concerns before making the disclosure.

3 (3) EXCEPTION AND SPECIAL RULE.—

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

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

20 (C) INTERNAL PROCEDURE EXCEPTION.—
21 Subparagraph (D) of paragraph (2) also shall
22 not apply if—

- 23 (i) the disclosure relates to an immi-
24 nent hazard of loss of life or serious injury
25 to a patient;

1 (ii) the disclosure is made to an ap-
2 propriate private accreditation body pursu-
3 ant to disclosure procedures established by
4 the body; or

5 (iii) the disclosure is in response to an
6 inquiry made in an investigation or pro-
7 ceeding of an appropriate public regulatory
8 agency and the information disclosed is
9 limited to the scope of the investigation or
10 proceeding.

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

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

1 (6) CONSTRUCTIONS.—

2 (A) DETERMINATIONS OF COVERAGE.—

3 Nothing in this subsection shall be construed to
4 prohibit a plan or issuer from making a deter-
5 mination not to pay for a particular medical
6 treatment or service or the services of a type of
7 health care professional.

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

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

23 (7) PROTECTED HEALTH CARE PROFESSIONAL
24 DEFINED.—For purposes of this subsection, the
25 term “protected health care professional” means an

1 individual who is a licensed or certified health care
 2 professional and who—

3 (A) with respect to a group health plan or
 4 health insurance issuer, is an employee of the
 5 plan or issuer or has a contract with the plan
 6 or issuer for provision of services for which ben-
 7 efits are available under the plan or issuer; or

8 (B) with respect to an institutional health
 9 care provider, is an employee of the provider or
 10 has a contract or other arrangement with the
 11 provider respecting the provision of health care
 12 services.

13 **Subtitle E—Definitions**

14 **SEC. 151. DEFINITIONS.**

15 (a) INCORPORATION OF GENERAL DEFINITIONS.—
 16 Except as otherwise provided, the provisions of section
 17 2791 of the Public Health Service Act shall apply for pur-
 18 poses of this title in the same manner as they apply for
 19 purposes of title XXVII of such Act.

20 (b) SECRETARY.—Except as otherwise provided, the
 21 term “Secretary” means the Secretary of Health and
 22 Human Services, in consultation with the Secretary of
 23 Labor and the term “appropriate Secretary” means the
 24 Secretary of Health and Human Services in relation to
 25 carrying out this title under sections 2706 and 2751 of

1 the Public Health Service Act and the Secretary of Labor
 2 in relation to carrying out this title under section 713 of
 3 the Employee Retirement Income Security Act of 1974.

4 (c) ADDITIONAL DEFINITIONS.—For purposes of this
 5 title:

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

8 (A) in the case of a group health plan, the
 9 Secretary of Health and Human Services and
 10 the Secretary of Labor; and

11 (B) in the case of a health insurance issuer
 12 with respect to a specific provision of this title,
 13 the applicable State authority (as defined in
 14 section 2791(d) of the Public Health Service
 15 Act), or the Secretary of Health and Human
 16 Services, if such Secretary is enforcing such
 17 provision under section 2722(a)(2) or
 18 2761(a)(2) of the Public Health Service Act.

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

23 (3) GROUP HEALTH PLAN.—The term “group
 24 health plan” has the meaning given such term in
 25 section 733(a) of the Employee Retirement Income

1 Security Act of 1974, except that such term includes
2 a employee welfare benefit plan treated as a group
3 health plan under section 732(d) of such Act or de-
4 fined as such a plan under section 607(1) of such
5 Act.

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

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

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

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

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

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

21 (10) TERMS AND CONDITIONS.—The term
22 “terms and conditions” includes, with respect to a
23 group health plan or health insurance coverage, re-
24 quirements imposed under this title with respect to
25 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 (c)) 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 and the compliance of the law with a pa-
3 tient protection requirement.

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 501, 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. COVERAGE OF LIMITED SCOPE PLANS.**

18 Only for purposes of applying the requirements of
19 this title under sections 2707 and 2753 of the Public
20 Health Service Act and section 714 of the Employee Re-
21 tirement Income Security Act of 1974, section
22 2791(c)(2)(A), and section 733(c)(2)(A) of the Employee
23 Retirement Income Security Act of 1974 shall be deemed
24 not to apply.

1 **SEC. 155. REGULATIONS.**

2 The Secretaries of Health and Human Services and
3 Labor shall issue such regulations as may be necessary
4 or appropriate to carry out this title. Such regulations
5 shall be issued consistent with section 104 of Health In-
6 surance Portability and Accountability Act of 1996. Such
7 Secretaries may promulgate any interim final rules as the
8 Secretaries determine are appropriate to carry out this
9 title.

10 **SEC. 156. INCORPORATION INTO PLAN OR COVERAGE DOC-**
11 **UMENTS.**

12 The requirements of this title with respect to a group
13 health plan or health insurance coverage are deemed to
14 be incorporated into, and made a part of, such plan or
15 the policy, certificate, or contract providing such coverage
16 and are enforceable under law as if directly included in
17 the documentation of such plan or such policy, certificate,
18 or contract.

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 Bipartisan Pa-
 15 tient Protection Act, and each health insurance issuer
 16 shall comply with patient protection requirements under
 17 such title with respect to group health insurance coverage
 18 it offers, and such requirements shall be deemed to be in-
 19 corporated 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 Bipar-
 9 tisan Patient Protection Act with respect to individual
 10 health insurance coverage it offers, and such requirements
 11 shall 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 Bipartisan Patient Protection Act 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 **SEC. 204. ELIMINATION OF OPTION OF NON-FEDERAL GOV-**
 8 **ERNMENTAL PLANS TO BE EXCEPTED FROM**
 9 **REQUIREMENTS CONCERNING GENETIC IN-**
 10 **FORMATION.**

11 Section 2721(b)(2) of the Public Health Service Act
 12 (42 U.S. C. 300gg–21(b)(2)) is amended—

13 (1) in subparagraph (A), by striking “If the
 14 plan sponsor” and inserting “Except as provided in
 15 subparagraph (D), if the plan sponsor”; and

16 (2) by adding at the end the following:

17 “(D) ELECTION NOT APPLICABLE TO RE-
 18 QUIREMENTS CONCERNING GENETIC INFORMA-
 19 TION.—The election described in subparagraph
 20 (A) shall not be available with respect to the
 21 provisions of subsections (b), (c), and (d) of
 22 section 122 of the Bipartisan Patient Protec-
 23 tion Act and the provisions of section 2702(b)
 24 to the extent that the subsections and section
 25 apply to genetic information (or information

1 about a request for or the receipt of genetic
2 services by an individual or a family member of
3 such individual).”.

4 **TITLE III—APPLICATION OF PA-**
5 **TIENT PROTECTION STAND-**
6 **ARDS TO FEDERAL HEALTH**
7 **CARE PROGRAMS**

8 **SEC. 301. APPLICATION OF PATIENT PROTECTION STAND-**
9 **ARDS TO FEDERAL HEALTH CARE PRO-**
10 **GRAMS.**

11 (a) APPLICATION OF STANDARDS.—

12 (1) IN GENERAL.—Each Federal health care
13 program shall comply with the patient protection re-
14 quirements under title I, and such requirements
15 shall be deemed to be incorporated into this section.

16 (2) CAUSE OF ACTION RELATING TO PROVISION
17 OF HEALTH BENEFITS.—Any individual who receives
18 a health care item or service under a Federal health
19 care program shall have a cause of action against
20 the Federal Government under sections 502(n) and
21 514(d) of the Employee Retirement Income Security
22 Act of 1974, and the provisions of such sections
23 shall be deemed to be incorporated into this section.

24 (3) RULES OF CONSTRUCTION.—For purposes
25 of this subsection—

1 (A) each Federal health care program shall
2 be deemed to be a group health plan;

3 (B) the Federal Government shall be
4 deemed to be the plan sponsor of each Federal
5 health care program; and

6 (C) each individual eligible for benefits
7 under a Federal health care program shall be
8 deemed to be a participant, beneficiary, or en-
9 rollee under that program.

10 (b) FEDERAL HEALTH CARE PROGRAM DEFINED.—

11 In this section, the term “Federal health care program”
12 has the meaning given that term under section 1128B(f)
13 of the Social Security Act (42 U.S.C. 1320a–7b) except
14 that, for purposes of this section, such term includes the
15 Federal employees health benefits program established
16 under chapter 89 of title 5, United States Code.

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 Bipartisan Patient Protection Act (as in effect as of
 18 the date of the enactment of such Act), and such require-
 19 ments shall be deemed to be incorporated into this sub-
 20 section.

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

23 “(1) SATISFACTION OF CERTAIN REQUIRE-
 24 MENTS THROUGH INSURANCE.—For purposes of
 25 subsection (a), insofar as a group health plan pro-

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

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

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

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

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

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

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

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

1 “(H) Section 118 (relating to access to
2 needed prescription drugs).

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

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

11 “(K) Section 134 (relating to payment of
12 claims).

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

1 “(3) INTERNAL APPEALS.—With respect to the
2 internal appeals process required to be established
3 under section 103 of such Act, in the case of a
4 group health plan that provides benefits in the form
5 of health insurance coverage through a health insur-
6 ance issuer, the Secretary shall determine the cir-
7 cumstances under which the plan is not required to
8 provide for such process and system (and is not lia-
9 ble for the issuer’s failure to provide for such proc-
10 ess and system), if the issuer is obligated to provide
11 for (and provides for) such process and system.

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

20 “(5) APPLICATION TO PROHIBITIONS.—Pursu-
21 ant to rules of the Secretary, if a health insurance
22 issuer offers health insurance coverage in connection
23 with a group health plan and takes an action in vio-
24 lation of any of the following sections of the Bipar-
25 tisan Patient Protection Act, the group health plan

1 shall not be liable for such violation unless the plan
2 caused such violation:

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

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

9 “(C) Section 133 (relating to prohibition
10 against improper incentive arrangements).

11 “(D) Section 135 (relating to protection
12 for patient advocacy).

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

17 “(7) TREATMENT OF SUBSTANTIALLY COMPLI-
18 ANT STATE LAWS.—For purposes of applying this
19 subsection, any reference in this subsection to a re-
20 quirement in a section or other provision in the Bi-
21 partisan Patient Protection Act with respect to a
22 health insurance issuer is deemed to include a ref-
23 erence to a requirement under a State law that sub-
24 stantially complies (as determined under section

1 152(c) of such Act) with the requirement in such
2 section or other provisions.

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

10 “(c) ENFORCEMENT OF CERTAIN REQUIREMENTS.—

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

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

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

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

19 “(b) In the case of a group health plan (as defined
 20 in section 733) compliance with the requirements of sub-
 21 title A of title I of the Bipartisan Patient Protection Act,
 22 and compliance with regulations promulgated by the Sec-
 23 retary, in the case of a claims denial shall be deemed com-
 24 pliance with subsection (a) with respect to such claims de-
 25 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:

“Sec. 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. AVAILABILITY OF CIVIL REMEDIES.**

11 (a) AVAILABILITY OF FEDERAL CIVIL REMEDIES IN
 12 CASES NOT INVOLVING MEDICALLY REVIEWABLE DECISIONS.—
 13

14 (1) IN GENERAL.—Section 502 of the Employee
 15 Retirement Income Security Act of 1974 (29 U.S.C.
 16 1132) is amended by adding at the end the following
 17 new subsections:

18 “(n) CAUSE OF ACTION RELATING TO PROVISION OF
 19 HEALTH BENEFITS.—

20 “(1) IN GENERAL.—In any case in which—

21 “(A) a person who is a fiduciary of a
 22 group health plan, a health insurance issuer of-
 23 fering health insurance coverage in connection
 24 with the plan, or an agent of the plan, issuer,
 25 or plan sponsor upon consideration of a claim

1 for benefits of a participant or beneficiary
2 under section 102 of the Bipartisan Patient
3 Protection Act of 2004 (relating to procedures
4 for initial claims for benefits and prior author-
5 ization determinations) or upon review of a de-
6 nial of such a claim under section 103 of such
7 Act (relating to internal appeal of a denial of
8 a claim for benefits), fails to exercise ordinary
9 care in making a decision—

10 “(i) regarding whether an item or
11 service is covered under the terms and con-
12 ditions of the plan or coverage,

13 “(ii) regarding whether an individual
14 is a participant or beneficiary who is en-
15 rolled under the terms and conditions of
16 the plan or coverage (including the applica-
17 bility of any waiting period under the plan
18 or coverage), or

19 “(iii) as to the application of cost-
20 sharing requirements or the application of
21 a specific exclusion or express limitation on
22 the amount, duration, or scope of coverage
23 of items or services under the terms and
24 conditions of the plan or coverage, and

1 “(B) such failure is a proximate cause of
2 personal injury to, or the death of, the partici-
3 pant or beneficiary—

4 such plan, plan sponsor or issuer shall be liable to
5 the participant or beneficiary (or the estate of such
6 participant or beneficiary) for economic and non-
7 economic damages (but not exemplary or punitive
8 damages) in connection with such personal injury or
9 death.

10 “(2) CAUSE OF ACTION MUST NOT INVOLVE
11 MEDICALLY REVIEWABLE DECISION.—

12 “(A) IN GENERAL.—A cause of action is
13 established under paragraph (1)(A) only if the
14 decision referred to in paragraph (1)(A) does
15 not include a medically reviewable decision.

16 “(B) MEDICALLY REVIEWABLE DECI-
17 SION.—For purposes of this subsection, the
18 term ‘medically reviewable decision’ means a de-
19 nial of a claim for benefits under the plan
20 which is described in section 104(d)(2) of the
21 Bipartisan Patient Protection Act of 2004 (re-
22 lating to medically reviewable decisions).

23 “(3) LIMITATION REGARDING CERTAIN TYPES
24 OF ACTIONS SAVED FROM PREEMPTION OF STATE
25 LAW.—A cause of action is not established under

1 paragraph (1)(A) in connection with a failure de-
 2 scribed in paragraph (1)(A) to the extent that a
 3 cause of action under State law (as defined in sec-
 4 tion 514(c)) for such failure would not be preempted
 5 under section 514.

6 “(4) DEFINITIONS.—For purposes of this sub-
 7 section.—

8 “(A) ORDINARY CARE.—The term ‘ordi-
 9 nary care’ means, with respect to a determina-
 10 tion on a claim for benefits, that degree of care,
 11 skill, and diligence that a reasonable and pru-
 12 dent individual would exercise in making a fair
 13 determination on a claim for benefits of like
 14 kind to the claims involved.

15 “(B) PERSONAL INJURY.—The term ‘per-
 16 sonal injury’ means a physical injury and in-
 17 cludes an injury arising out of the treatment
 18 (or failure to treat) a mental illness or disease.

19 “(C) CLAIM FOR BENEFITS; DENIAL.—The
 20 terms ‘claim for benefits’ and ‘denial of a claim
 21 for benefits’ have the meanings provided such
 22 terms in section 102(e) of the Bipartisan Pa-
 23 tient Protection Act of 2004.

24 “(D) TERMS AND CONDITIONS.—The term
 25 ‘terms and conditions’ includes, with respect to

1 a group health plan or health insurance cov-
 2 erage, requirements imposed under title I of the
 3 Bipartisan Patient Protection Act of 2004.

4 “(E) GROUP HEALTH PLAN AND OTHER
 5 RELATED TERMS.—The provisions of sections
 6 732(d) and 733 apply for purposes of this sub-
 7 section in the same manner as they apply for
 8 purposes of part 7, except that the term ‘group
 9 health plan’ includes a group health plan (as
 10 defined in section 607(1)).

11 “(5) EXCLUSION OF EMPLOYERS AND OTHER
 12 PLAN SPONSORS.—

13 “(A) CAUSES OF ACTION AGAINST EM-
 14 PLOYERS AND PLAN SPONSORS PRECLUDED.—
 15 Subject to subparagraph (B), paragraph (1)(A)
 16 does not authorize a cause of action against an
 17 employer or other plan sponsor maintaining the
 18 plan (or against an employee of such an em-
 19 ployer or sponsor acting within the scope of em-
 20 ployment).

21 “(B) CERTAIN CAUSES OF ACTION PER-
 22 MITTED.—Notwithstanding subparagraph (A),
 23 a cause of action may arise against an employer
 24 or other plan sponsor (or against an employee
 25 of such an employer or sponsor acting within

the scope of employment) under paragraph (1)(A), to the extent there was direct participation by the employer or other plan sponsor (or employee) in the decision of the plan under section 102 of the Bipartisan Patient Protection Act of 2004 upon consideration of a claim for benefits or under section 103 of such Act upon review of a denial of a claim for benefits.

“(C) DIRECT PARTICIPATION.—

“(i) IN GENERAL.—For purposes of subparagraph (B), the term ‘direct participation’ means, in connection with a decision described in paragraph (1)(A), the actual making of such decision or the actual exercise of control in making such decision.

“(ii) RULES OF CONSTRUCTION.—For purposes of clause (i), the employer or plan sponsor (or employee) shall not be construed to be engaged in direct participation because of any form of decisionmaking or other conduct that is merely collateral or precedent to the decision described in paragraph (1)(A) on a particular claim for benefits of a participant or beneficiary, including (but not limited to)—

1 “(I) any participation by the em-
2 ployer or other plan sponsor (or em-
3 ployee) in the selection of the group
4 health plan or health insurance cov-
5 erage involved or the third party ad-
6 ministrator or other agent;

7 “(II) any engagement by the em-
8 ployer or other plan sponsor (or em-
9 ployee) in any cost-benefit analysis
10 undertaken in connection with the se-
11 lection of, or continued maintenance
12 of, the plan or coverage involved;

13 “(III) any participation by the
14 employer or other plan sponsor (or
15 employee) in the process of creating,
16 continuing, modifying, or terminating
17 the plan or any benefit under the
18 plan, if such process was not substan-
19 tially focused solely on the particular
20 situation of the participant or bene-
21 ficiary referred to in paragraph
22 (1)(A); and

23 “(IV) any participation by the
24 employer or other plan sponsor (or
25 employee) in the design of any benefit

1 under the plan, including the amount
2 of copayment and limits connected
3 with such benefit.

4 “(iii) IRRELEVANCE OF CERTAIN COL-
5 LATERAL EFFORTS MADE BY EMPLOYER
6 OR PLAN SPONSOR.—For purposes of this
7 subparagraph, an employer or plan sponsor
8 shall not be treated as engaged in direct
9 participation in a decision with respect to
10 any claim for benefits or denial thereof in
11 the case of any particular participant or
12 beneficiary solely by reason of—

13 “(I) any efforts that may have
14 been made by the employer or plan
15 sponsor to advocate for authorization
16 of coverage for that or any other par-
17 ticipant or beneficiary (or any group
18 of participants or beneficiaries), or

19 “(II) any provision that may
20 have been made by the employer or
21 plan sponsor for benefits which are
22 not covered under the terms and con-
23 ditions of the plan for that or any
24 other participant or beneficiary (or

1 any group of participants or bene-
2 ficiaries).

3 “(D) APPLICATION TO CERTAIN PLANS.—

4 “(i) IN GENERAL.—Notwithstanding
5 any other provision of this subsection, no
6 group health plan described in clause (ii)
7 shall be liable under paragraph (1) for the
8 performance of, or the failure to perform,
9 any non-medically reviewable duty under
10 the plan.

11 “(ii) DEFINITION.—A group health
12 plan described in this clause is—

13 “(I) a group health plan that is
14 self-insured and self administered by
15 an employer (including an employee of
16 such an employer acting within the
17 scope of employment); or

18 “(II) a multiemployer plan as de-
19 fined in section 3(37)(A) (including
20 an employee of a contributing em-
21 ployer or of the plan, or a fiduciary of
22 the plan, acting within the scope of
23 employment or fiduciary responsi-
24 bility) that is self-insured and self-ad-
25 ministered.

1 “(6) EXCLUSION OF PHYSICIANS AND OTHER
2 HEALTH CARE PROFESSIONALS.—

3 “(A) IN GENERAL.—No treating physician
4 or other treating health care professional of the
5 participant or beneficiary, and no person acting
6 under the direction of such a physician or
7 health care professional, shall be liable under
8 paragraph (1) for the performance of, or the
9 failure to perform, any non-medically reviewable
10 duty of the plan, the plan sponsor, or any
11 health insurance issuer offering health insur-
12 ance coverage in connection with the plan.

13 “(B) DEFINITIONS.—For purposes of sub-
14 paragraph (A)—

15 “(i) HEALTH CARE PROFESSIONAL.—
16 The term ‘health care professional’ means
17 an individual who is licensed, accredited, or
18 certified under State law to provide speci-
19 fied health care services and who is oper-
20 ating within the scope of such licensure,
21 accreditation, or certification.

22 “(ii) NON-MEDICALLY REVIEWABLE
23 DUTY.—The term ‘non-medically review-
24 able duty’ means a duty the discharge of

1 which does not include the making of a
2 medically reviewable decision.

3 “(7) EXCLUSION OF HOSPITALS.—No treating
4 hospital of the participant or beneficiary shall be lia-
5 ble under paragraph (1) for the performance of, or
6 the failure to perform, any non-medically reviewable
7 duty (as defined in paragraph (6)(B)(ii)) of the
8 plan, the plan sponsor, or any health insurance
9 issuer offering health insurance coverage in connec-
10 tion with the plan.

11 “(8) RULE OF CONSTRUCTION RELATING TO
12 EXCLUSION FROM LIABILITY OF PHYSICIANS,
13 HEALTH CARE PROFESSIONALS, AND HOSPITALS.—
14 Nothing in paragraph (6) or (7) shall be construed
15 to limit the liability (whether direct or vicarious) of
16 the plan, the plan sponsor, or any health insurance
17 issuer offering health insurance coverage in connec-
18 tion with the plan.

19 “(9) REQUIREMENT OF EXHAUSTION.—

20 “(A) IN GENERAL.—A cause of action may
21 not be brought under paragraph (1) in connec-
22 tion with any denial of a claim for benefits of
23 any individual until all administrative processes
24 under sections 102 and 103 of the Bipartisan

1 Patient Protection Act of 2004 (if applicable)
2 have been exhausted.

3 “(B) EXCEPTION FOR NEEDED CARE.—A
4 participant or beneficiary may seek relief exclu-
5 sively in Federal court under subsection
6 502(a)(1)(B) prior to the exhaustion of admin-
7 istrative remedies under sections 102, 103, or
8 104 of the Bipartisan Patient Protection Act
9 (as required under subparagraph (A)) if it is
10 demonstrated to the court that the exhaustion
11 of such remedies would cause irreparable harm
12 to the health of the participant or beneficiary.
13 Notwithstanding the awarding of relief under
14 subsection 502(a)(1)(B) pursuant to this sub-
15 paragraph, no relief shall be available as a re-
16 sult of, or arising under, paragraph (1)(A) or
17 paragraph (10)(B), with respect to a partici-
18 pant or beneficiary, unless the requirements of
19 subparagraph (A) are met.

20 “(C) RECEIPT OF BENEFITS DURING AP-
21 PEALS PROCESS.—Receipt by the participant or
22 beneficiary of the benefits involved in the claim
23 for benefits during the pendency of any admin-
24 istrative processes referred to in subparagraph

1 (A) or of any action commenced under this sub-
 2 section—

3 “(i) shall not preclude continuation of
 4 all such administrative processes to their
 5 conclusion if so moved by any party, and

6 “(ii) shall not preclude any liability
 7 under subsection (a)(1)(C) and this sub-
 8 section in connection with such claim.

9 The court in any action commenced under this
 10 subsection shall take into account any receipt of
 11 benefits during such administrative processes or
 12 such action in determining the amount of the
 13 damages awarded.

14 “(D) ADMISSIBLE.—Any determination
 15 made by a reviewer in an administrative pro-
 16 ceeding under section 103 of the Bipartisan Pa-
 17 tient Protection Act of 2004 shall be admissible
 18 in any Federal court proceeding and shall be
 19 presented to the trier of fact.

20 “(10) STATUTORY DAMAGES.—

21 “(A) IN GENERAL.—The remedies set
 22 forth in this subsection (n) shall be the exclu-
 23 sive remedies for causes of action brought
 24 under this subsection.

“(B) ASSESSMENT OF CIVIL PENALTIES.—

In addition to the remedies provided for in paragraph (1) (relating to the failure to provide contract benefits in accordance with the plan), a civil assessment, in an amount not to exceed \$5,000,000, payable to the claimant may be awarded in any action under such paragraph if the claimant establishes by clear and convincing evidence that the alleged conduct carried out by the defendant demonstrated bad faith and flagrant disregard for the rights of the participant or beneficiary under the plan and was a proximate cause of the personal injury or death that is the subject of the claim.

“(11) LIMITATION ON ATTORNEYS’ FEES.—

“(A) IN GENERAL.—Notwithstanding any other provision of law, or any arrangement, agreement, or contract regarding an attorney’s fee, the amount of an attorney’s contingency fee allowable for a cause of action brought pursuant to this subsection shall not exceed $\frac{1}{3}$ of the total amount of the plaintiff’s recovery (not including the reimbursement of actual out-of-pocket expenses of the attorney).

1 “(B) DETERMINATION BY DISTRICT
 2 COURT.—The last Federal district court in
 3 which the action was pending upon the final
 4 disposition, including all appeals, of the action
 5 shall have jurisdiction to review the attorney’s
 6 fee to ensure that the fee is a reasonable one.

7 “(12) LIMITATION OF ACTION.—Paragraph (1)
 8 shall not apply in connection with any action com-
 9 menced after 3 years after the later of—

10 “(A) the date on which the plaintiff first
 11 knew, or reasonably should have known, of the
 12 personal injury or death resulting from the fail-
 13 ure described in paragraph (1), or

14 “(B) the date as of which the requirements
 15 of paragraph (9) are first met.

16 “(13) TOLLING PROVISION.—The statute of
 17 limitations for any cause of action arising under
 18 State law relating to a denial of a claim for benefits
 19 that is the subject of an action brought in Federal
 20 court under this subsection shall be tolled until such
 21 time as the Federal court makes a final disposition,
 22 including all appeals, of whether such claim should
 23 properly be within the jurisdiction of the Federal
 24 court. The tolling period shall be determined by the

1 applicable Federal or State law, whichever period is
2 greater.

3 “(14) PURCHASE OF INSURANCE TO COVER LI-
4 ABILITY.—Nothing in section 410 shall be construed
5 to preclude the purchase by a group health plan of
6 insurance to cover any liability or losses arising
7 under a cause of action under subsection (a)(1)(C)
8 and this subsection.

9 “(15) EXCLUSION OF DIRECTED RECORD-
10 KEEPERS.—

11 “(A) IN GENERAL.—Subject to subpara-
12 graph (C), paragraph (1) shall not apply with
13 respect to a directed recordkeeper in connection
14 with a group health plan.

15 “(B) DIRECTED RECORDKEEPER.—For
16 purposes of this paragraph, the term ‘directed
17 recordkeeper’ means, in connection with a
18 group health plan, a person engaged in directed
19 recordkeeping activities pursuant to the specific
20 instructions of the plan or the employer or
21 other plan sponsor, including the distribution of
22 enrollment information and distribution of dis-
23 closure materials under this Act or title I of the
24 Bipartisan Patient Protection Act of 2004 and

1 whose duties do not include making decisions
2 on claims for benefits.

3 “(C) LIMITATION.—Subparagraph (A)
4 does not apply in connection with any directed
5 recordkeeper to the extent that the directed rec-
6 ordkeeper fails to follow the specific instruction
7 of the plan or the employer or other plan spon-
8 sor.

9 “(16) EXCLUSION OF HEALTH INSURANCE
10 AGENTS.—Paragraph (1) does not apply with re-
11 spect to a person whose sole involvement with the
12 group health plan is providing advice or administra-
13 tive services to the employer or other plan sponsor
14 relating to the selection of health insurance coverage
15 offered in connection with the plan.

16 “(17) NO EFFECT ON STATE LAW.—No provi-
17 sion of State law (as defined in section 514(c)(1))
18 shall be treated as superseded or otherwise altered,
19 amended, modified, invalidated, or impaired by rea-
20 son of the provisions of subsection (a)(1)(C) and this
21 subsection.

22 “(18) RELIEF FROM LIABILITY FOR EMPLOYER
23 OR OTHER PLAN SPONSOR BY MEANS OF DES-
24 IGNATED DECISIONMAKER.—

1 “(A) IN GENERAL.—Notwithstanding the
2 direct participation (as defined in paragraph
3 (5)(C)(i)) of an employer or plan sponsor, in
4 any case in which there is deemed to be a des-
5 ignated decisionmaker under subparagraph (B)
6 that meets the requirements of subsection
7 (o)(1) for an employer or other plan sponsor—

8 “(i) all liability of such employer or
9 plan sponsor (and any employee thereof
10 acting within the scope of employment)
11 under this subsection in connection with
12 any participant or beneficiary shall be
13 transferred to, and assumed by, the des-
14 ignated decisionmaker, and

15 “(ii) with respect to such liability, the
16 designated decisionmaker shall be sub-
17 stituted for the employer or plan sponsor
18 (or employee) in the action and may not
19 raise any defense that the employer or plan
20 sponsor (or employee) could not raise if
21 such a decisionmaker were not so deemed.

22 “(B) AUTOMATIC DESIGNATION.—A health
23 insurance issuer shall be deemed to be a des-
24 ignated decisionmaker for purposes of subpara-
25 graph (A) with respect to the participants and

beneficiaries of an employer or plan sponsor, whether or not the employer or plan sponsor makes such a designation, and shall be deemed to have assumed unconditionally all liability of the employer or plan sponsor under such designation in accordance with subsection (o), unless the employer or plan sponsor affirmatively enters into a contract to prevent the service of the designated decisionmaker.

“(19) PREVIOUSLY PROVIDED SERVICES.—

“(A) IN GENERAL.—Except as provided in this paragraph, a cause of action shall not arise under paragraph (1) where the denial involved relates to an item or service that has already been fully provided to the participant or beneficiary under the plan or coverage and the claim relates solely to the subsequent denial of payment for the provision of such item or service.

“(B) EXCEPTION.—Nothing in subparagraph (A) shall be construed to—

“(i) prohibit a cause of action under paragraph (1) where the nonpayment involved results in the participant or beneficiary being unable to receive further items or services that are directly related

to the item or service involved in the denial referred to in subparagraph (A) or that are part of a continuing treatment or series of procedures;

“(ii) prohibit a cause of action under paragraph (1) relating to quality of care; or

“(iii) limit liability that otherwise would arise from the provision of the item or services or the performance of a medical procedure.

“(20) EXEMPTION FROM PERSONAL LIABILITY FOR INDIVIDUAL MEMBERS OF BOARDS OF DIRECTORS, JOINT BOARDS OF TRUSTEES, ETC.—Any individual who is—

“(A) a member of a board of directors of an employer or plan sponsor; or

“(B) a member of an association, committee, employee organization, joint board of trustees, or other similar group of representatives of the entities that are the plan sponsor of plan maintained by two or more employers and one or more employee organizations;

shall not be personally liable under this subsection for conduct that is within the scope of employment

1 of the individuals unless the individual acts in a
 2 fraudulent manner for personal enrichment.

3 “(o) REQUIREMENTS FOR DESIGNATED DECISION-
 4 MAKERS OF GROUP HEALTH

5 “(1) IN GENERAL.—For purposes of subsection
 6 (n)(18) and section 514(d)(9), a designated decision-
 7 maker meets the requirements of this paragraph
 8 with respect to any participant or beneficiary if—

9 “(A) such designation is in such form as
 10 may be prescribed in regulations of the Sec-
 11 retary,

12 “(B) the designated decisionmaker—

13 “(i) meets the requirements of para-
 14 graph (2),

15 “(ii) assumes unconditionally all liabil-
 16 ity of the employer or plan sponsor in-
 17 volved (and any employee thereof acting
 18 within the scope of employment) either
 19 arising under subsection (n) or arising in
 20 a cause of action permitted under section
 21 514(d) in connection with actions (and
 22 failures to act) of the employer or plan
 23 sponsor (or employee) occurring during the
 24 period in which the designation under sub-
 25 section (n)(18) or section 514(d)(9) is in

1 effect relating to such participant and ben-
2 eficiary,

3 “(iii) agrees to be substituted for the
4 employer or plan sponsor (or employee) in
5 the action and not to raise any defense
6 with respect to such liability that the em-
7 ployer or plan sponsor (or employee) may
8 not raise, and

9 “(iv) where paragraph (2)(B) applies,
10 assumes unconditionally the exclusive au-
11 thority under the group health plan to
12 make medically reviewable decisions under
13 the plan with respect to such participant
14 or beneficiary, and

15 “(C) the designated decisionmaker and the
16 participants and beneficiaries for whom the de-
17 cisionmaker has assumed liability are identified
18 in the written instrument required under sec-
19 tion 402(a) and as required under section
20 121(b)(19) of the Bipartisan Patient Protection
21 Act.

22 Any liability assumed by a designated decisionmaker
23 pursuant to this subsection shall be in addition to
24 any liability that it may otherwise have under appli-
25 cable law.

1 “(2) QUALIFICATIONS FOR DESIGNATED DECI-
2 SIONMAKERS.—

3 “(A) IN GENERAL.—Subject to subpara-
4 graph (B), an entity is qualified under this
5 paragraph to serve as a designated decision-
6 maker with respect to a group health plan if the
7 entity has the ability to assume the liability de-
8 scribed in paragraph (1) with respect to partici-
9 pants and beneficiaries under such plan, includ-
10 ing requirements relating to the financial obli-
11 gation for timely satisfying the assumed liabil-
12 ity, and maintains with the plan sponsor and
13 the Secretary certification of such ability. Such
14 certification shall be provided to the plan spon-
15 sor or named fiduciary and to the Secretary
16 upon designation under subsection (n)(18)(B)
17 or section 517(d)(9)(B) and not less frequently
18 than annually thereafter, or if such designation
19 constitutes a multiyear arrangement, in con-
20 junction with the renewal of the arrangement.

21 “(B) SPECIAL QUALIFICATION IN THE
22 CASE OF CERTAIN REVIEWABLE DECISIONS.—In
23 the case of a group health plan that provides
24 benefits consisting of medical care to a partici-
25 pant or beneficiary only through health insur-

1 ance coverage offered by a single health insur-
2 ance issue, such issuer is the only entity that
3 may be qualified under this paragraph to serve
4 as a designated decisionmaker with respect to
5 such participant or beneficiary, and shall serve
6 as the designated decisionmaker unless the em-
7 ployer or other plan sponsor acts affirmatively
8 to prevent such service.

9 “(3) REQUIREMENTS RELATING TO FINANCIAL
10 OBLIGATIONS.—For purposes of paragraph (2)(A),
11 the requirements relating to the financial obligation
12 of an entity for liability shall include—

13 “(A) coverage of such entity under an in-
14 surance policy or other arrangement, secured
15 and maintained by such entity, to effectively in-
16 sure such entity against losses arising from pro-
17 fessional liability claims, including those arising
18 from its service as a designated decisionmaker
19 under this part; or

20 “(B) evidence of minimum capital and sur-
21 plus levels that are maintained by such entity
22 to cover any losses as a result of liability arising
23 from its service as a designated decisionmaker
24 under this part.

1 The appropriate amounts of liability insurance and
 2 minimum capital and surplus levels for purposes of
 3 subparagraphs (A) and (B) shall be determined by
 4 an actuary using sound actuarial principles and ac-
 5 counting practices pursuant to established guidelines
 6 of the American Academy of Actuaries and in ac-
 7 cordance with such regulations as the Secretary may
 8 prescribe and shall be maintained throughout the
 9 term for which the designation is in effect. The pro-
 10 visions of this paragraph shall not apply in the case
 11 of a designated decisionmaker that is a group health
 12 plan, plan sponsor, or health insurance issuer and
 13 that is regulated under Federal law or a State finan-
 14 cial solvency law.

15 “(4) LIMITATION ON APPOINTMENT OF TREAT-
 16 ING PHYSICIANS.—A treating physician who directly
 17 delivered the care, treatment, or provided the patient
 18 service that is the subject of a cause of action by a
 19 participant or beneficiary under subsection (n) or
 20 section 514(d) may not be designated as a des-
 21 ignated decisionmaker under this subsection with re-
 22 spect to such participant or beneficiary.”.

23 (2) CONFORMING AMENDMENT.—Section
 24 502(a)(1) of such Act (29 U.S.C. 1132(a)(1)) is
 25 amended—

1 (A) by striking “or” at the end of subpara-
 2 graph (A);

3 (B) in subparagraph (B), by striking
 4 “plan;” and inserting “plan, or”; and

5 (C) by adding at the end the following new
 6 subparagraph:

7 “(C) for the relief provided for in sub-
 8 section (n) of this section.”.

9 (b) RULES RELATING TO ERISA PREEMPTION.—
 10 Section 514 of the Employee Retirement Income Security
 11 Act of 1974 (29 U.S.C. 1144) is amended—

12 (1) by redesignating subsection (d) as sub-
 13 section (f); and

14 (2) by inserting after subsection (c) the fol-
 15 lowing new subsections:

16 “(d) PREEMPTION NOT TO APPLY TO CAUSES OF
 17 ACTION UNDER STATE LAW INVOLVING MEDICALLY RE-
 18 VIEWABLE DECISION.—

19 “(1) NON-PREEMPTION OF CERTAIN CAUSES OF
 20 ACTION.—

21 “(A) IN GENERAL.—Except as provided in
 22 this subsection, nothing in this title (including
 23 section 502) shall be construed to supersede or
 24 otherwise alter, amend, modify, invalidate, or
 25 impair any cause of action under State law of

1 a participant or beneficiary under a group
 2 health plan (or the estate of such a participant
 3 or beneficiary) to recover damages resulting
 4 from personal injury or for wrongful death
 5 against any person if such cause of action
 6 arises by reason of a medically reviewable deci-
 7 sion.

8 “(B) MEDICALLY REVIEWABLE DECI-
 9 SION.—For purposes of subparagraph (A), the
 10 term ‘medically reviewable decision’ means a de-
 11 nial of a claim for benefits under the plan
 12 which is described in section 104(d)(2) of the
 13 Bipartisan Patient Protection Act of 2004 (re-
 14 lating to medically reviewable decisions).

15 “(C) LIMITATION ON PUNITIVE DAM-
 16 AGES.—

17 “(i) IN GENERAL.—Except as pro-
 18 vided in clauses (ii) and (iii), with respect
 19 to a cause of action described in subpara-
 20 graph (A) brought with respect to a partic-
 21 ipant or beneficiary, State law is super-
 22 seded insofar as it provides any punitive,
 23 exemplary, or similar damages if, as of the
 24 time of the personal injury or death, all
 25 the requirements of the following sections

1 of the Bipartisan Patient Protection Act of
2 2004 were satisfied with respect to the
3 participant or beneficiary:

4 “(I) Section 102 (relating to pro-
5 cedures for initial claims for benefits
6 and prior authorization determina-
7 tions).

8 “(II) Section 103 of such Act
9 (relating to internal appeals of claims
10 denials).

11 “(III) Section 104 of such Act
12 (relating to independent external ap-
13 peals procedures).

14 “(ii) EXCEPTION FOR CERTAIN AC-
15 TIONS FOR WRONGFUL DEATH.—Clause (i)
16 shall not apply with respect to an action
17 for wrongful death if the applicable State
18 law provides (or has been construed to pro-
19 vide) for damages in such an action which
20 are only punitive or exemplary in nature.

21 “(iii) EXCEPTION FOR WILLFUL OR
22 WANTON DISREGARD FOR THE RIGHTS OR
23 SAFETY OF OTHERS.—Clause (i) shall not
24 apply with respect to any cause of action
25 described in subparagraph (A) if, in such

1 action, the plaintiff establishes by clear
2 and convincing evidence that conduct car-
3 ried out by the defendant with willful or
4 wanton disregard for the rights or safety
5 of others was a proximate cause of the per-
6 sonal injury or wrongful death that is the
7 subject of the action.

8 “(2) DEFINITIONS.—For purposes of this sub-
9 section and subsection (e)—

10 “(A) GROUP HEALTH PLAN AND OTHER
11 RELATED TERMS.—The provisions of sections
12 732(d) and 733 apply for purposes of this sub-
13 section in the same manner as they apply for
14 purposes of part 7, except that the term ‘group
15 health plan’ includes a group health plan (as
16 defined in section 607(1)).

17 “(B) PERSONAL INJURY.—The term ‘per-
18 sonal injury’ means a physical injury and in-
19 cludes an injury arising out of the treatment
20 (or failure to treat) a mental illness or disease.

21 “(C) CLAIM FOR BENEFIT; DENIAL.—The
22 terms ‘claim for benefits’ and ‘denial of a claim
23 for benefits’ shall have the meaning provided
24 such terms under section 102(e) of the Bipar-
25 tisan Patient Protection Act of 2004.

1 “(3) EXCLUSION OF EMPLOYERS AND OTHER
2 PLAN SPONSORS.—

3 “(A) CAUSES OF ACTION AGAINST EM-
4 PLOYERS AND PLAN SPONSORS PRECLUDED.—
5 Subject to subparagraph (B), paragraph (1)
6 does not apply with respect to—

7 “(i) any cause of action against an
8 employer or other plan sponsor maintain-
9 ing the plan (or against an employee of
10 such an employer or sponsor acting within
11 the scope of employment), or

12 “(ii) a right of recovery, indemnity, or
13 contribution by a person against an em-
14 ployer or other plan sponsor (or such an
15 employee) for damages assessed against
16 the person pursuant to a cause of action to
17 which paragraph (1) applies.

18 “(B) CERTAIN CAUSES OF ACTION PER-
19 MITTED.—Notwithstanding subparagraph (A),
20 paragraph (1) applies with respect to any cause
21 of action that is brought by a participant or
22 beneficiary under a group health plan (or the
23 estate of such a participant or beneficiary) to
24 recover damages resulting from personal injury
25 or for wrongful death against any employer or

1 other plan sponsor maintaining the plan (or
 2 against an employee of such an employer or
 3 sponsor acting within the scope of employment)
 4 if such cause of action arises by reason of a
 5 medically reviewable decision, to the extent that
 6 there was direct participation by the employer
 7 or other plan sponsor (or employee) in the deci-
 8 sion.

9 “(C) DIRECT PARTICIPATION.—

10 “(i) DIRECT PARTICIPATION IN DECI-
 11 SIONS.—For purposes of subparagraph
 12 (B), the term ‘direct participation’ means,
 13 in connection with a decision described in
 14 subparagraph (B), the actual making of
 15 such decision or the actual exercise of con-
 16 trol in making such decision or in the con-
 17 duct constituting the failure.

18 “(ii) RULES OF CONSTRUCTION.—For
 19 purposes of clause (i), the employer or plan
 20 sponsor (or employee) shall not be con-
 21 strued to be engaged in direct participation
 22 because of any form of decisionmaking or
 23 other conduct that is merely collateral or
 24 precedent to the decision described in sub-
 25 paragraph (B) on a particular claim for

1 benefits of a particular participant or bene-
2 ficiary, including (but not limited to)—

3 “(I) any participation by the em-
4 ployer or other plan sponsor (or em-
5 ployee) in the selection of the group
6 health plan or health insurance cov-
7 erage involved or the third party ad-
8 ministrator or other agent;

9 “(II) any engagement by the em-
10 ployer or other plan sponsor (or em-
11 ployee) in any cost-benefit analysis
12 undertaken in connection with the se-
13 lection of, or continued maintenance
14 of, the plan or coverage involved;

15 “(III) any participation by the
16 employer or other plan sponsor (or
17 employee) in the process of creating,
18 continuing, modifying, or terminating
19 the plan or any benefit under the
20 plan, if such process was not substan-
21 tially focused solely on the particular
22 situation of the participant or bene-
23 ficiary referred to in paragraph
24 (1)(A); and

1 “(IV) any participation by the
2 employer or other plan sponsor (or
3 employee) in the design of any benefit
4 under the plan, including the amount
5 of copayment and limits connected
6 with such benefit.

7 “(iii) IRRELEVANCE OF CERTAIN COL-
8 LATERAL EFFORTS MADE BY EMPLOYER
9 OR PLAN SPONSOR.—For purposes of this
10 subparagraph, an employer or plan sponsor
11 shall not be treated as engaged in direct
12 participation in a decision with respect to
13 any claim for benefits or denial thereof in
14 the case of any particular participant or
15 beneficiary solely by reason of—

16 “(I) any efforts that may have
17 been made by the employer or plan
18 sponsor to advocate for authorization
19 of coverage for that or any other par-
20 ticipant or beneficiary (or any group
21 of participants or beneficiaries), or

22 “(II) any provision that may
23 have been made by the employer or
24 plan sponsor for benefits which are
25 not covered under the terms and con-

1 ditions of the plan for that or any
 2 other participant or beneficiary (or
 3 any group of participants or bene-
 4 ficiaries).

5 “(4) REQUIREMENT OF EXHAUSTION.—

6 “(A) IN GENERAL.—Except as provided in
 7 subparagraph (D), a cause of action may not be
 8 brought under paragraph (1) in connection with
 9 any denial of a claim for benefits of any indi-
 10 vidual until all administrative processes under
 11 sections 102, 103, and 104 of the Bipartisan
 12 Patient Protection Act of 2004 (if applicable)
 13 have been exhausted.

14 “(B) LATE MANIFESTATION OF INJURY.—

15 “(i) IN GENERAL.—A participant or
 16 beneficiary shall not be precluded from
 17 pursuing a review under section 104 of the
 18 Bipartisan Patient Protection Act regard-
 19 ing an injury that such participant or ben-
 20 eficiary has experienced if the external re-
 21 view entity first determines that the injury
 22 of such participant or beneficiary is a late
 23 manifestation of an earlier injury.

24 “(ii) DEFINITION.—In this subpara-
 25 graph, the term ‘late manifestation of an

1 earlier injury’ means an injury sustained
2 by the participant or beneficiary which was
3 not known, and should not have been
4 known, by such participant or beneficiary
5 by the latest date that the requirements of
6 subparagraph (A) should have been met
7 regarding the claim for benefits which was
8 denied.

9 “(C) EXCEPTION FOR NEEDED CARE.—A
10 participant or beneficiary may seek relief exclu-
11 sively in Federal court under subsection
12 502(a)(1)(B) prior to the exhaustion of admin-
13 istrative remedies under sections 102, 103, or
14 104 of the Bipartisan Patient Protection Act
15 (as required under subparagraph (A)) if it is
16 demonstrated to the court that the exhaustion
17 of such remedies would cause irreparable harm
18 to the health of the participant or beneficiary.
19 Notwithstanding the awarding of relief under
20 subsection 502(a)(1)(B) pursuant to this sub-
21 paragraph, no relief shall be available as a re-
22 sult of, or arising under, paragraph (1)(A) un-
23 less the requirements of subparagraph (A) are
24 met.

25 “(D) FAILURE TO REVIEW.—

1 “(i) IN GENERAL.—If the external re-
2 view entity fails to make a determination
3 within the time required under section
4 104(e)(1)(A)(i), a participant or bene-
5 ficiary may bring an action under section
6 514(d) after 10 additional days after the
7 date on which such time period has expired
8 and the filing of such action shall not af-
9 fect the duty of the independent medical
10 reviewer (or reviewers) to make a deter-
11 mination pursuant to section
12 104(e)(1)(A)(i).

13 “(ii) EXPEDITED DETERMINATION.—
14 If the external review entity fails to make
15 a determination within the time required
16 under section 104(e)(1)(A)(ii), a partici-
17 pant or beneficiary may bring an action
18 under this subsection and the filing of such
19 an action shall not affect the duty of the
20 independent medical reviewer (or review-
21 ers) to make a determination pursuant to
22 section 104(e)(1)(A)(ii).

23 “(E) RECEIPT OF BENEFITS DURING AP-
24 PEALS PROCESS.—Receipt by the participant or
25 beneficiary of the benefits involved in the claim

1 for benefits during the pendency of any admin-
 2 istrative processes referred to in subparagraph
 3 (A) or of any action commenced under this sub-
 4 section—

5 “(i) shall not preclude continuation of
 6 all such administrative processes to their
 7 conclusion if so moved by any party, and

8 “(ii) shall not preclude any liability
 9 under subsection (a)(1)(C) and this sub-
 10 section in connection with such claim.

11 “(F) ADMISSIBLE.—Any determination
 12 made by a reviewer in an administrative pro-
 13 ceeding under section 104 of the Bipartisan Pa-
 14 tient Protection Act of 2004 shall be admissible
 15 in any Federal or State court proceeding and
 16 shall be presented to the trier of fact.

17 “(5) TOLLING PROVISION.—The statute of limi-
 18 tations for any cause of action arising under section
 19 502(n) relating to a denial of a claim for benefits
 20 that is the subject of an action brought in State
 21 court shall be tolled until such time as the State
 22 court makes a final disposition, including all ap-
 23 peals, of whether such claim should properly be
 24 within the jurisdiction of the State court. The tolling

1 period shall be determined by the applicable Federal
2 or State law, whichever period is greater.

3 “(6) EXCLUSION OF DIRECTED RECORD-
4 KEEPERS.—

5 “(A) IN GENERAL.—Subject to subpara-
6 graph (C), paragraph (1) shall not apply with
7 respect to a directed recordkeeper in connection
8 with a group health plan.

9 “(B) DIRECTED RECORDKEEPER.—For
10 purposes of this paragraph, the term ‘directed
11 recordkeeper’ means, in connection with a
12 group health plan, a person engaged in directed
13 recordkeeping activities pursuant to the specific
14 instructions of the plan or the employer or
15 other plan sponsor, including the distribution of
16 enrollment information and distribution of dis-
17 closure materials under this Act or title I of the
18 Bipartisan Patient Protection Act of 2004 and
19 whose duties do not include making decisions
20 on claims for benefits.

21 “(C) LIMITATION.—Subparagraph (A)
22 does not apply in connection with any directed
23 recordkeeper to the extent that the directed rec-
24 ordkeeper fails to follow the specific instruction

1 of the plan or the employer or other plan spon-
2 sor.

3 “(7) CONSTRUCTION.—Nothing in this sub-
4 section shall be construed as—

5 “(A) saving from preemption a cause of
6 action under State law for the failure to provide
7 a benefit for an item or service which is specifi-
8 cally excluded under the group health plan in-
9 volved, except to the extent that—

10 “(i) the application or interpretation
11 of the exclusion involves a determination
12 described in section 104(d)(2) of the Bi-
13 partisan Patient Protection Act of 2004,
14 or

15 “(ii) the provision of the benefit for
16 the item or service is required under Fed-
17 eral law or under applicable State law con-
18 sistent with subsection (b)(2)(B);

19 “(B) preempting a State law which re-
20 quires an affidavit or certificate of merit in a
21 civil action;

22 “(C) affecting a cause of action or remedy
23 under State law in connection with the provi-
24 sion or arrangement of excepted benefits (as de-

1 fined in section 733(c)), other than those de-
2 scribed in section 733(c)(2)(A); or

3 “(D) affecting a cause of action under
4 State law other than a cause of action described
5 in paragraph (1)(A).

6 “(8) PURCHASE OF INSURANCE TO COVER LI-
7 ABILITY.—Nothing in section 410 shall be construed
8 to preclude the purchase by a group health plan of
9 insurance to cover any liability or losses arising
10 under a cause of action described in paragraph
11 (1)(A).

12 “(9) RELIEF FROM LIABILITY FOR EMPLOYER
13 OR OTHER PLAN SPONSOR BY MEANS OF DES-
14 IGNATED DECISIONMAKER.—

15 “(A) IN GENERAL.—Paragraph (1) shall
16 not apply with respect to any cause of action
17 described in paragraph (1)(A) under State law
18 insofar as such cause of action provides for li-
19 ability of an employer or plan sponsor (or an
20 employee thereof acting within the scope of em-
21 ployment) with respect to a participant or bene-
22 ficiary, if with respect to the employer or plan
23 sponsor there is deemed to be a designated de-
24 cisionmaker that meets the requirements of sec-
25 tion 502(o)(1) with respect to such participant

1 or beneficiary. Such paragraph (1) shall apply
2 with respect to any cause of action described in
3 paragraph (1)(A) under State law against the
4 designated decisionmaker of such employer or
5 other plan sponsor with respect to the partici-
6 pant or beneficiary.

7 “(B) AUTOMATIC DESIGNATION.—A health
8 insurance issuer shall be deemed to be a des-
9 ignated decisionmaker for purposes of subpara-
10 graph (A) with respect to the participants and
11 beneficiaries of an employer or plan sponsor,
12 whether or not the employer or plan sponsor
13 makes such a designation, and shall be deemed
14 to have assumed unconditionally all liability of
15 the employer or plan sponsor under such des-
16 ignation in accordance with subsection (o), un-
17 less the employer or plan sponsor affirmatively
18 enters into a contract to prevent the service of
19 the designated decisionmaker.

20 “(10) PREVIOUSLY PROVIDED SERVICES.—

21 “(A) IN GENERAL.—Except as provided in
22 this paragraph, a cause of action shall not arise
23 under paragraph (1) where the denial involved
24 relates to an item or service that has already
25 been fully provided to the participant or bene-

1 ficiary under the plan or coverage and the claim
2 relates solely to the subsequent denial of pay-
3 ment for the provision of such item or service.

4 “(B) EXCEPTION.—Nothing in subpara-
5 graph (A) shall be construed to—

6 “(i) prohibit a cause of action under
7 paragraph (1) where the nonpayment in-
8 volved results in the participant or bene-
9 ficiary being unable to receive further
10 items or services that are directly related
11 to the item or service involved in the denial
12 referred to in subparagraph (A) or that
13 are part of a continuing treatment or se-
14 ries of procedures;

15 “(ii) prohibit a cause of action under
16 paragraph (1) relating to quality of care;
17 or

18 “(iii) limit liability that otherwise
19 would arise from the provision of the item
20 or services or the performance of a medical
21 procedure.

22 “(11) EXEMPTION FROM PERSONAL LIABILITY
23 FOR INDIVIDUAL MEMBERS OF BOARDS OF DIREC-
24 TORS, JOINT BOARDS OF TRUSTEES, ETC.—Any indi-
25 vidual who is—

1 “(A) a member of a board of directors of
2 an employer or plan sponsor; or

3 “(B) a member of an association, com-
4 mittee, employee organization, joint board of
5 trustees, or other similar group of representa-
6 tives of the entities that are the plan sponsor
7 of plan maintained by two or more employers
8 and one or more employee organizations—

9 shall not be personally liable under this subsection
10 for conduct that is within the scope of employment
11 of the individuals unless the individual acts in a
12 fraudulent manner for personal enrichment.

13 “(12) CHOICE OF LAW.—A cause of action
14 brought under paragraph (1) shall be governed by
15 the law (including choice of law rules) of the State
16 in which the plaintiff resides.

17 “(13) LIMITATION ON ATTORNEYS’ FEES.—

18 “(A) IN GENERAL.—Notwithstanding any
19 other provision of law, or any arrangement,
20 agreement, or contract regarding an attorney’s
21 fee, the amount of an attorney’s contingency fee
22 allowable for a cause of action brought under
23 paragraph (1) shall not exceed $\frac{1}{3}$ of the total
24 amount of the plaintiff’s recovery (not including

1 the reimbursement of actual out-of-pocket ex-
2 penses of the attorney).

3 “(B) DETERMINATION BY COURT.—The
4 last court in which the action was pending upon
5 the final disposition, including all appeals, of
6 the action may review the attorney’s fee to en-
7 sure that the fee is a reasonable one.

8 “(C) NO PREEMPTION OF STATE LAW.—
9 Subparagraph (A) shall not apply with respect
10 to a cause of action under paragraph (1) that
11 is brought in a State that has a law or frame-
12 work of laws with respect to the amount of an
13 attorney’s contingency fee that may be incurred
14 for the representation of a participant or bene-
15 ficiary (or the estate of such participant or ben-
16 eficiary) who brings such a cause of action.

17 “(e) RULES OF CONSTRUCTION RELATING TO
18 HEALTH CARE.—Nothing in this title shall be construed
19 as—

20 “(1) affecting any State law relating to the
21 practice of medicine or the provision of, or the fail-
22 ure to provide, medical care, or affecting any action
23 (whether the liability is direct or vicarious) based
24 upon such a State law,

1 “(2) superseding any State law permitted under
 2 section 152(b)(1)(A) of the Bipartisan Patient Pro-
 3 tection Act of 2004, or

4 “(3) affecting any applicable State law with re-
 5 spect to limitations on monetary damages.”.

6 (c) EFFECTIVE DATE.—The amendments made by
 7 this section shall apply to acts and omissions (from which
 8 a cause of action arises) occurring on or after the date
 9 that is 6 months after the date of enactment of this Act.

10 **SEC. 403. LIMITATION ON CERTAIN CLASS ACTION LITIGA-**
 11 **TION.**

12 Section 502 of the Employee Retirement Income Se-
 13 curity Act of 1974 (29 U.S.C. 1132), as amended by sec-
 14 tion 402, is further amended by adding at the end the
 15 following:

16 “(p) LIMITATION ON CLASS ACTION LITIGATION.—

17 “(1) IN GENERAL.—Any claim or cause of ac-
 18 tion that is maintained under this section in connec-
 19 tion with a group health plan, or health insurance
 20 coverage issued in connection with a group health
 21 plan, as a class action, derivative action, or as an ac-
 22 tion on behalf of any group of 2 or more claimants,
 23 may be maintained only if the class, the derivative
 24 claimant, or the group of claimants is limited to the
 25 participants or beneficiaries of a group health plan

1 established by only 1 plan sponsor. No action main-
 2 tained by such class, such derivative claimant, or
 3 such group of claimants may be joined in the same
 4 proceeding with any action maintained by another
 5 class, derivative claimant, or group of claimants or
 6 consolidated for any purpose with any other pro-
 7 ceeding. In this paragraph, the terms ‘group health
 8 plan’ and ‘health insurance coverage’ have the mean-
 9 ings given such terms in section 733.

10 “(2) EFFECTIVE DATE.—This subsection shall
 11 apply to all civil actions that are filed on or after the
 12 date that is 6 months after the date of enactment
 13 of the Bipartisan Patient Protection Act of 2004.”.

14 **SEC. 404. LIMITATIONS ON ACTIONS.**

15 Section 502 of the Employee Retirement Income Se-
 16 curity Act of 1974 (29 U.S.C. 1132) (as amended by sec-
 17 tion 402(a)) is amended further by adding at the end the
 18 following new subsection:

19 “(q) LIMITATIONS ON ACTIONS RELATING TO GROUP
 20 HEALTH PLANS.—

21 “(1) IN GENERAL.—Except as provided in para-
 22 graph (2), no action may be brought under sub-
 23 section (a)(1)(B), (a)(2), or (a)(3) by a participant
 24 or beneficiary seeking relief based on the application
 25 of any provision in section 101, subtitle B, or sub-

1 title D of title I of the Bipartisan Patient Protection
2 Act (as incorporated under section 714).

3 “(2) CERTAIN ACTIONS ALLOWABLE.—An ac-
4 tion may be brought under subsection (a)(1)(B),
5 (a)(2), or (a)(3) by a participant or beneficiary seek-
6 ing relief based on the application of section 101,
7 113, 114, 115, 116, 117, 118(a)(3), 119, or 120 of
8 the Bipartisan Patient Protection Act (as incor-
9 porated under section 714) to the individual cir-
10 cumstances of that participant or beneficiary, except
11 that—

12 “(A) such an action may not be brought or
13 maintained as a class action; and

14 “(B) in such an action, relief may only
15 provide for the provision of (or payment of)
16 benefits, items, or services denied to the indi-
17 vidual participant or beneficiary involved (and
18 for attorney’s fees and the costs of the action,
19 at the discretion of the court) and shall not pro-
20 vide for any other relief to the participant or
21 beneficiary or for any relief to any other person.

22 “(3) OTHER PROVISIONS UNAFFECTED.—Noth-
23 ing in this subsection shall be construed as affecting
24 subsections (a)(1)(C) and (n) or section 514(d).

1 “(4) ENFORCEMENT BY SECRETARY UNAF-
 2 FECTED.—Nothing in this subsection shall be con-
 3 strued as affecting any action brought by the Sec-
 4 retary.”.

5 **SEC. 405. COOPERATION BETWEEN FEDERAL AND STATE**
 6 **AUTHORITIES.**

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

11 **“SEC. 735. COOPERATION BETWEEN FEDERAL AND STATE**
 12 **AUTHORITIES.**

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

21 “(b) DELEGATIONS.—Any department, agency, or in-
 22 strumentality of a State to which authority is delegated
 23 pursuant to an agreement entered into under this section
 24 may, if authorized under State law and to the extent con-

1 sistent with such agreement, exercise the powers of the
 2 Secretary under this title which relate to such authority.”.

3 **SEC. 406. SENSE OF THE SENATE CONCERNING THE IMPOR-**
 4 **TANCE OF CERTAIN UNPAID SERVICES.**

5 It is the sense of the Senate that the court should
 6 consider the loss of a nonwage earning spouse or parent
 7 as an economic loss for the purposes of this section. Fur-
 8 thermore, the court should define the compensation for the
 9 loss not as minimum services, but, rather, in terms that
 10 fully compensate for the true and whole replacement cost
 11 to the family.

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

15 **SEC. 501. EFFECTIVE DATES.**

16 (a) GROUP HEALTH COVERAGE.—

17 (1) IN GENERAL.—Subject to paragraph (2)
 18 and subsection (d), the amendments made by sec-
 19 tions 201(a), 401, and 403 (and title I insofar as it
 20 relates to such sections) shall apply with respect to
 21 group health plans, and health insurance coverage
 22 offered in connection with group health plans, for
 23 plan years beginning on or after the date that is 6
 24 months after the date of enactment of this Act (in

1 this section referred to as the “general effective
2 date”).

3 (2) TREATMENT OF COLLECTIVE BARGAINING
4 AGREEMENTS.—In the case of a group health plan
5 maintained pursuant to one or more collective bar-
6 gaining agreements between employee representa-
7 tives and one or more employers ratified before the
8 date of the enactment of this Act, the amendments
9 made by sections 201(a), 401, and 403 (and title I
10 insofar as it relates to such sections) shall not apply
11 to plan years beginning before the later of—

12 (A) the date on which the last collective
13 bargaining agreements relating to the plan ter-
14 minates (excluding any extension thereof agreed
15 to after the date of the enactment of this Act);
16 or

17 (B) the general effective date—
18 but shall apply not later than 1 year after the gen-
19 eral effective date. For purposes of subparagraph
20 (A), any plan amendment made pursuant to a collec-
21 tive bargaining agreement relating to the plan which
22 amends the plan solely to conform to any require-
23 ment added by this Act shall not be treated as a ter-
24 mination of such collective bargaining agreement.

1 (b) INDIVIDUAL HEALTH INSURANCE COVERAGE.—

2 Subject to subsection (d), the amendments made by sec-
3 tion 202 shall apply with respect to individual health in-
4 surance coverage offered, sold, issued, renewed, in effect,
5 or operated in the individual market on or after the gen-
6 eral effective date.

7 (c) TREATMENT OF RELIGIOUS NONMEDICAL PRO-
8 VIDERS.—

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

11 (A) restrict or limit the right of group
12 health plans, and of health insurance issuers of-
13 fering health insurance coverage, to include as
14 providers religious nonmedical providers;

15 (B) require such plans or issuers to—

16 (i) utilize medically based eligibility
17 standards or criteria in deciding provider
18 status of religious nonmedical providers;

19 (ii) use medical professionals or cri-
20 teria to decide patient access to religious
21 nonmedical providers;

22 (iii) utilize medical professionals or
23 criteria in making decisions in internal or
24 external appeals regarding coverage for
25 care by religious nonmedical providers; or

1 (iv) compel a participant or bene-
2 ficiary to undergo a medical examination
3 or test as a condition of receiving health
4 insurance coverage for treatment by a reli-
5 gious nonmedical provider; or

6 (C) require such plans or issuers to ex-
7 clude religious nonmedical providers because
8 they do not provide medical or other required
9 data, if such data is inconsistent with the reli-
10 gious nonmedical treatment or nursing care
11 provided by the provider.

12 (2) RELIGIOUS NONMEDICAL PROVIDER.—For
13 purposes of this subsection, the term “religious non-
14 medical provider” means a provider who provides no
15 medical care but who provides only religious non-
16 medical treatment or religious nonmedical nursing
17 care.

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

21 (1) subsection (a) with respect to a group
22 health plan that is maintained as of the general ef-
23 fective date, not later than 30 days before the begin-
24 ning of the first plan year to which title I applies

1 in connection with the plan under such subsection;
2 or

3 (2) subsection (b) with respect to a individual
4 health insurance coverage that is in effect as of the
5 general effective date, not later than 30 days before
6 the first date as of which title I applies to the cov-
7 erage under such subsection.

8 **SEC. 502. COORDINATION IN IMPLEMENTATION.**

9 The Secretary of Labor and the Secretary of Health
10 and Human Services shall ensure, through the execution
11 of an interagency memorandum of understanding among
12 such Secretaries, that—

13 (1) regulations, rulings, and interpretations
14 issued by such Secretaries relating to the same mat-
15 ter over which such Secretaries have responsibility
16 under the provisions of this Act (and the amend-
17 ments made thereby) are administered so as to have
18 the same effect at all times; and

19 (2) coordination of policies relating to enforcing
20 the same requirements through such Secretaries in
21 order to have a coordinated enforcement strategy
22 that avoids duplication of enforcement efforts and
23 assigns priorities in enforcement.

1 **SEC. 503. SEVERABILITY.**

2 If any provision of this Act, an amendment made by
 3 this Act, or the application of such provision or amend-
 4 ment to any person or circumstance is held to be unconsti-
 5 tutional, the remainder of this Act, the amendments made
 6 by this Act, and the application of the provisions of such
 7 to any person or circumstance shall not be affected there-
 8 by.

9 **TITLE VI—MISCELLANEOUS**
 10 **PROVISIONS**

11 **SEC. 601. NO IMPACT ON SOCIAL SECURITY TRUST FUND.**

12 (a) IN GENERAL.—Nothing in this Act (or an amend-
 13 ment made by this Act) shall be construed to alter or
 14 amend the Social Security Act (or any regulation promul-
 15 gated under that Act).

16 (b) TRANSFERS.—

17 (1) ESTIMATE OF SECRETARY.—The Secretary
 18 of the Treasury shall annually estimate the impact
 19 that the enactment of this Act has on the income
 20 and balances of the trust funds established under
 21 section 201 of the Social Security Act (42 U.S.C.
 22 401).

23 (2) TRANSFER OF FUNDS.—If, under para-
 24 graph (1), the Secretary of the Treasury estimates
 25 that the enactment of this Act has a negative impact
 26 on the income and balances of the trust funds estab-

1 lished under section 201 of the Social Security Act
2 (42 U.S.C. 401), the Secretary shall transfer, not
3 less frequently than quarterly, from the general reve-
4 nues of the Federal Government an amount suffi-
5 cient so as to ensure that the income and balances
6 of such trust funds are not reduced as a result of
7 the enactment of such Act.

8 **SEC. 602. CUSTOMS USER FEES.**

9 Section 13031(j)(3) of the Consolidated Omnibus
10 Budget Reconciliation Act of 1985 (19 U.S.C. 58c(j)(3))
11 is amended by striking “March 31, 2004” and inserting
12 “December 31, 2014”.

13 **SEC. 603. FISCAL YEAR 2005 MEDICARE PAYMENTS.**

14 Notwithstanding any other provision of law, any let-
15 ter of credit under part B of title XVIII of the Social Se-
16 curity Act (42 U.S.C. 1395j et seq.) that would otherwise
17 be sent to the Treasury or the Federal Reserve Board on
18 September 30, 2005, by a carrier with a contract under
19 section 1842 of that Act (42 U.S.C. 1395u) shall be sent
20 on October 1, 2005.

21 **SEC. 604. SENSE OF SENATE WITH RESPECT TO PARTICIPA-**
22 **TION IN CLINICAL TRIALS AND ACCESS TO**
23 **SPECIALTY CARE.**

24 (a) FINDINGS.—The Senate finds the following:

1 (1) Breast cancer is the most common form of
2 cancer among women, excluding skin cancers.

3 (2) During 2004, 215,900 new cases of female
4 invasive breast cancer will be diagnosed, and 40,110
5 women will die from the disease.

6 (3) In addition, 1,450 male breast cancer cases
7 are projected to be diagnosed, and 470 men will die
8 from the disease.

9 (4) Breast cancer is the second leading cause of
10 cancer death among all women.

11 (5) This year 9,200 children are expected to be
12 diagnosed with cancer.

13 (6) 1,510 children are expected to die from can-
14 cer this year.

15 (7) There are approximately 400,000 people di-
16 agnosed with multiple sclerosis in the United States
17 and 200 more cases are diagnosed each week.

18 (8) Parkinson's disease is a progressive disorder
19 of the central nervous system affecting 1,500,000 in
20 the United States.

21 (9) An estimated 230,110 men will be diag-
22 nosed with prostate cancer this year.

23 (10) 29,500 men will die from prostate cancer
24 this year. It is the leading cause of cancer in men
25 and the second leading cause of death.

1 (11) While information obtained from clinical
2 trials is essential to finding cures for diseases, it is
3 still research which carries the risk of fatal results.
4 Future efforts should be taken to protect the health
5 and safety of adults and children who enroll in clin-
6 ical trials.

7 (12) While employers and health plans should
8 be responsible for covering the routine costs associ-
9 ated with federally approved or funded clinical trials,
10 such employers and health plans should not be held
11 legally responsible for the design, implementation, or
12 outcome of such clinical trials, consistent with any
13 applicable State or Federal liability statutes.

14 (b) SENSE OF THE SENATE.—It is the sense of the
15 Senate that—

16 (1) men and women battling life-threatening,
17 deadly diseases, including advanced breast or ovar-
18 ian cancer, should have the opportunity to partici-
19 pate in a federally approved or funded clinical trial
20 recommended by their physician;

21 (2) an individual should have the opportunity to
22 participate in a federally approved or funded clinical
23 trial recommended by their physician if—

24 (A) that individual—

1 (i) has a life-threatening or serious ill-
2 ness for which no standard treatment is ef-
3 fective;

4 (ii) is eligible to participate in a feder-
5 ally approved or funded clinical trial ac-
6 cording to the trial protocol with respect to
7 treatment of the illness;

8 (B) that individual's participation in the
9 trial offers meaningful potential for significant
10 clinical benefit for the individual; and

11 (C) either—

12 (i) the referring physician is a partici-
13 pating health care professional and has
14 concluded that the individual's participa-
15 tion in the trial would be appropriate,
16 based upon the individual meeting the con-
17 ditions described in subparagraph (A); or

18 (ii) the participant, beneficiary, or en-
19 rollee provides medical and scientific infor-
20 mation establishing that the individual's
21 participation in the trial would be appro-
22 priate, based upon the individual meeting
23 the conditions described in subparagraph
24 (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. 605. SENSE OF THE SENATE REGARDING FAIR REVIEW**
 17 **PROCESS.**

18 (a) FINDINGS.—The Senate 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 SENATE.—It is the sense of the
 13 Senate 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. 606. ANNUAL REVIEW.**

8 (a) IN GENERAL.—Not later than 24 months after
9 the general effective date referred to in section 501(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) LIMITATION WITH RESPECT TO CERTAIN
20 PLANS.—If the Secretary, in any report submitted under
21 subsection (a), determines that more than 1,000,000 indi-
22 viduals in the United States have lost their health insur-
23 ance coverage as a result of the enactment of this Act,
24 as compared to the number of individuals with health in-
25 surance coverage in the 12-month period preceding the

1 date of enactment of this Act, section 402 of this Act shall
2 be repealed effective on the date that is 12 month after
3 the date on which the report is submitted, and the submis-
4 sion of any further reports under subsection (a) shall not
5 be required.

6 (c) FUNDING.—From funds appropriated to the De-
7 partment of Health and Human Services for fiscal years
8 2005 and 2006, the Secretary of Health and Human Serv-
9 ices shall provide for such funding as the Secretary deter-
10 mines necessary for the conduct of the study of the Na-
11 tional Academy of Sciences under this section.

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