

June 29, 2001

Ordered to be printed as passed

107TH CONGRESS
1ST SESSION

S. 1052

AN ACT

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”.

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

Sec. 1. Short title; table of contents.

TITLE I—IMPROVING MANAGED CARE

Subtitle A—Utilization Review; Claims; and Internal and External Appeals

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

Subtitle B—Access to Care

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

Subtitle C—Access to Information

- Sec. 121. Patient access to information.
- 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 2002 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.
- Sec. 607. Definition of born-alive infant.

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

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

7 (a) COMPLIANCE WITH REQUIREMENTS.—

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

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

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

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

7 (b) WRITTEN POLICIES AND CRITERIA.—

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

12 (2) USE OF WRITTEN CRITERIA.—

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

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

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

16 (c) CONDUCT OF PROGRAM ACTIVITIES.—

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

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

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

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

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

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

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

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

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

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

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

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

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

12 (2) ACCESS TO INFORMATION.—

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

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

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

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

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

6 (b) TIMELINE FOR MAKING DETERMINATIONS.—

7 (1) PRIOR AUTHORIZATION DETERMINATION.—

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

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

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

18 (C) ONGOING CARE.—

19 (i) CONCURRENT REVIEW.—

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

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

12 (II) CONTENTS OF NOTICE.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

16 (a) RIGHT TO INTERNAL APPEAL.—

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

21 (2) TIME FOR APPEAL.—

22 (A) IN GENERAL.—A group health plan, or
23 health insurance issuer offering health insur-
24 ance coverage, shall ensure that a participant,
25 beneficiary, or enrollee (or authorized represent-

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

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

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

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

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

4 (b) TIMELINES FOR MAKING DETERMINATIONS.—

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

22 (2) ACCESS TO INFORMATION.—

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

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

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

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

3 (A) IN GENERAL.—A group health plan, or
4 health insurance issuer offering health insur-
5 ance coverage, shall make a determination on
6 an appeal of a denial of a claim for benefits
7 under this subsection in accordance with the
8 medical exigencies of the case and as soon as
9 possible, but in no case later than 14 days from
10 the date on which the plan or issuer receives in-
11 formation that is reasonably necessary to enable
12 the plan or issuer to make a determination on
13 the appeal and in no case later than 28 days
14 after the date the request for the appeal is re-
15 ceived.

16 (B) EXPEDITED DETERMINATION.—Not-
17 withstanding subparagraph (A), a group health
18 plan, or health insurance issuer offering health
19 insurance coverage, shall expedite a prior au-
20 thorization determination on an appeal of a de-
21 nial of a claim for benefits described in sub-
22 paragraph (A), when a request for such an ex-
23 pedited determination is made by a participant,
24 beneficiary, or enrollee (or authorized represent-
25 ative) at any time during the process for mak-

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

14 (C) ONGOING CARE DETERMINATIONS.—

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

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

6 (ii) RULE OF CONSTRUCTION.—Clause

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

11 (4) RETROSPECTIVE DETERMINATION.—A

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

21 (c) CONDUCT OF REVIEW.—

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

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

7 (A) shall be made by a physician
8 (allopathic or osteopathic); or

9 (B) in a claim for benefits provided by a
10 non-physician health professional, shall be made
11 by reviewer (or reviewers) including at least one
12 practicing non-physician health professional of
13 the same or similar specialty;

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

19 (d) NOTICE OF DETERMINATION.—

20 (1) IN GENERAL.—Written notice of a deter-
21 mination made under an internal appeal of a denial
22 of a claim for benefits shall be issued to the partici-
23 pant, beneficiary, or enrollee (or authorized rep-
24 resentative) and the treating health care professional
25 in accordance with the medical exigencies of the case

1 and as soon as possible, but in no case later than
2 2 days after the date of completion of the review (or,
3 in the case described in subparagraph (B) or (C) of
4 subsection (b)(3), within the 72-hour or applicable
5 period referred to in such subparagraph).

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

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

23 (A) the specific reasons for the determina-
24 tion (including a summary of the clinical or sci-

1 entific evidence used in making the determina-
2 tion);

3 (B) the procedures for obtaining additional
4 information concerning the determination; and

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

8 **SEC. 104. INDEPENDENT EXTERNAL APPEALS PROCE-**
9 **DURES.**

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

16 (b) **INITIATION OF THE INDEPENDENT EXTERNAL**
17 **REVIEW PROCESS.**—

18 (1) **TIME TO FILE.**—A request for an inde-
19 pendent external review under this section shall be
20 filed with the plan or issuer not later than 180 days
21 after the date on which the participant, beneficiary,
22 or enrollee receives notice of the denial under section
23 103(d) or notice of waiver of internal review under
24 section 103(a)(4) or the date on which the plan or
25 issuer has failed to make a timely decision under

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

7 (2) FILING OF REQUEST.—

8 (A) IN GENERAL.—Subject to the suc-
9 ceeding provisions of this subsection, a group
10 health plan, and a health insurance issuer offer-
11 ing health insurance coverage, may—

12 (i) except as provided in subparagraph

13 (B)(i), require that a request for review be
14 in writing;

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

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

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

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

14 (B) REQUIREMENTS AND EXCEPTION RE-
15 LATING TO GENERAL RULE.—

16 (i) ORAL REQUESTS PERMITTED IN
17 EXPEDITED OR CONCURRENT CASES.—In
18 the case of an expedited or concurrent ex-
19 ternal review as provided for under sub-
20 section (e), the request may be made oral-
21 ly. A group health plan, or health insur-
22 ance issuer offering health insurance cov-
23 erage, may require that the participant,
24 beneficiary, or enrollee (or authorized rep-
25 resentative) provide written confirmation

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

13 (ii) EXCEPTION TO FILING FEE RE-
14 QUIREMENT.—

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

24 (II) FEE NOT REQUIRED.—Pay-
25 ment of a filing fee shall not be re-

1 required under subparagraph (A)(iv) if
 2 the plan or issuer waives the internal
 3 appeals process under section
 4 103(a)(4).

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

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

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

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

1 mation described in section 103(d)(3)(A)), to a
2 qualified external review entity selected in accord-
3 ance with this section.

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

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

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

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

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

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

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

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

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

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

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

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

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

23 (i) NOTICE IN CASE OF DENIAL OF
24 REFERRAL.—If the entity under this para-
25 graph does not make a referral to an inde-

1 pendent medical reviewer, the entity shall
2 provide notice to the plan or issuer, the
3 participant, beneficiary, or enrollee (or au-
4 thorized representative) filing the request,
5 and the treating health care professional
6 (if any) that the denial is not subject to
7 independent medical review. Such notice—

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

12 (II) shall include the reasons for
13 the determination;

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

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

20 (ii) GENERAL TIMELINE FOR DETER-
21 MINATIONS.—Upon receipt of information
22 under paragraph (2), the qualified external
23 review entity, and if required the inde-
24 pendent medical reviewer, shall make a de-
25 termination within the overall timeline that

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

11 (d) INDEPENDENT MEDICAL REVIEW.—

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

19 (2) MEDICALLY REVIEWABLE DECISIONS.—A
20 denial of a claim for benefits is eligible for inde-
21 pendent medical review if the benefit for the item or
22 service for which the claim is made would be a cov-
23 ered benefit under the terms and conditions of the
24 plan or coverage but for one (or more) of the fol-
25 lowing determinations:

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

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

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

21 (3) INDEPENDENT MEDICAL REVIEW DETER-
22 MINATION.—

23 (A) IN GENERAL.—An independent med-
24 ical reviewer under this section shall make a
25 new independent determination with respect to

1 whether or not the denial of a claim for a ben-
2 efit that is the subject of the review should be
3 upheld, reversed, or modified.

4 (B) STANDARD FOR DETERMINATION.—

5 The independent medical reviewer's determina-
6 tion relating to the medical necessity and ap-
7 propriateness, or the experimental or investiga-
8 tion nature, or the evaluation of the medical
9 facts of the item, service, or condition shall be
10 based on the medical condition of the partici-
11 pant, beneficiary, or enrollee (including the
12 medical records of the participant, beneficiary,
13 or enrollee) and valid, relevant scientific evi-
14 dence and clinical evidence, including peer-re-
15 viewed medical literature or findings and in-
16 cluding expert opinion.

17 (C) NO COVERAGE FOR EXCLUDED BENE-
18 FITS.—

19 Nothing in this subsection shall be con-
20 strued to permit an independent medical re-
21 viewer to require that a group health plan, or
22 health insurance issuer offering health insur-
23 ance coverage, provide coverage for items or
24 services for which benefits are specifically ex-
25 cluded or expressly limited under the plan or
 coverage in the plain language of the plan docu-

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

18 (D) EVIDENCE AND INFORMATION TO BE
19 USED IN MEDICAL REVIEWS.—In making a de-
20 termination under this subsection, the inde-
21 pendent medical reviewer shall also consider ap-
22 propriate and available evidence and informa-
23 tion, including the following:

24 (i) The determination made by the
25 plan or issuer with respect to the claim

1 upon internal review and the evidence,
2 guidelines, or rationale used by the plan or
3 issuer in reaching such determination.

4 (ii) The recommendation of the treat-
5 ing health care professional and the evi-
6 dence, guidelines, and rationale used by
7 the treating health care professional in
8 reaching such recommendation.

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

15 (iv) The plan or coverage document.

16 (E) INDEPENDENT DETERMINATION.—In
17 making determinations under this subtitle, a
18 qualified external review entity and an inde-
19 pendent medical reviewer shall—

20 (i) consider the claim under review
21 without deference to the determinations
22 made by the plan or issuer or the rec-
23 ommendation of the treating health care
24 professional (if any); and

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

10 (F) DETERMINATION OF INDEPENDENT
11 MEDICAL REVIEWER.—An independent medical
12 reviewer shall, in accordance with the deadlines
13 described in subsection (e), prepare a written
14 determination to uphold, reverse, or modify the
15 denial under review. Such written determination
16 shall include—

17 (i) the determination of the reviewer;

18 (ii) the specific reasons of the re-
19 viewer for such determination, including a
20 summary of the clinical or scientific evi-
21 dence used in making the determination;
22 and

23 (iii) with respect to a determination to
24 reverse or modify the denial under review,
25 a timeframe within which the plan or

1 issuer must comply with such determina-
2 tion.

3 (G) NONBINDING NATURE OF ADDITIONAL
4 RECOMMENDATIONS.—In addition to the deter-
5 mination under subparagraph (F), the reviewer
6 may provide the plan or issuer and the treating
7 health care professional with additional rec-
8 ommendations in connection with such a deter-
9 mination, but any such recommendations shall
10 not affect (or be treated as part of) the deter-
11 mination and shall not be binding on the plan
12 or issuer.

13 (e) TIMELINES AND NOTIFICATIONS.—

14 (1) TIMELINES FOR INDEPENDENT MEDICAL
15 REVIEW.—

16 (A) PRIOR AUTHORIZATION DETERMINA-
17 TION.—

18 (i) IN GENERAL.—The independent
19 medical reviewer (or reviewers) shall make
20 a determination on a denial of a claim for
21 benefits that is referred to the reviewer
22 under subsection (c)(3) in accordance with
23 the medical exigencies of the case and as
24 soon as possible, but in no case later than
25 14 days after the date of receipt of infor-

1 mation under subsection (c)(2) if the re-
2 view involves a prior authorization of items
3 or services and in no case later than 21
4 days after the date the request for external
5 review is received.

6 (ii) EXPEDITED DETERMINATION.—

7 Notwithstanding clause (i) and subject to
8 clause (iii), the independent medical re-
9 viewer (or reviewers) shall make an expe-
10 dited determination on a denial of a claim
11 for benefits described in clause (i), when a
12 request for such an expedited determina-
13 tion is made by a participant, beneficiary,
14 or enrollee (or authorized representative)
15 at any time during the process for making
16 a determination, and a health care profes-
17 sional certifies, with the request, that a de-
18 termination under the timeline described in
19 clause (i) would seriously jeopardize the
20 life or health of the participant, bene-
21 ficiary, or enrollee or the ability of the par-
22 ticipant, beneficiary, or enrollee to main-
23 tain or regain maximum function. Such de-
24 termination shall be made as soon in ac-
25 cordance with the medical exigencies of the

1 case and as soon as possible, but in no
2 case later than 72 hours after the time the
3 request for external review is received by
4 the qualified external review entity.

5 (iii) ONGOING CARE DETERMINA-
6 TION.—Notwithstanding clause (i), in the
7 case of a review described in such sub-
8 clause that involves a termination or reduc-
9 tion of care, the notice of the determina-
10 tion shall be completed not later than 24
11 hours after the time the request for exter-
12 nal review is received by the qualified ex-
13 ternal review entity and before the end of
14 the approved period of care.

15 (B) RETROSPECTIVE DETERMINATION.—

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

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

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

14 (f) COMPLIANCE.—

15 (1) APPLICATION OF DETERMINATIONS.—

16 (A) EXTERNAL REVIEW DETERMINATIONS
17 BINDING ON PLAN.—The determinations of an
18 external review entity and an independent med-
19 ical reviewer under this section shall be binding
20 upon the plan or issuer involved.

21 (B) COMPLIANCE WITH DETERMINA-
22 TION.—If the determination of an independent
23 medical reviewer is to reverse or modify the de-
24 nial, the plan or issuer, upon the receipt of such
25 determination, shall authorize coverage to com-

1 ply with the medical reviewer’s determination in
2 accordance with the timeframe established by
3 the medical reviewer.

4 (2) FAILURE TO COMPLY.—

5 (A) IN GENERAL.—If a plan or issuer fails
6 to comply with the timeframe established under
7 paragraph (1)(B) with respect to a participant,
8 beneficiary, or enrollee, where such failure to
9 comply is caused by the plan or issuer, the par-
10 ticipant, beneficiary, or enrollee may obtain the
11 items or services involved (in a manner con-
12 sistent with the determination of the inde-
13 pendent external reviewer) from any provider
14 regardless of whether such provider is a partici-
15 pating provider under the plan or coverage.

16 (B) REIMBURSEMENT.—

17 (i) IN GENERAL.—Where a partici-
18 pant, beneficiary, or enrollee obtains items
19 or services in accordance with subpara-
20 graph (A), the plan or issuer involved shall
21 provide for reimbursement of the costs of
22 such items or services. Such reimburse-
23 ment shall be made to the treating health
24 care professional or to the participant, ben-
25 eficiary, or enrollee (in the case of a partici-

1 participant, beneficiary, or enrollee who pays for
2 the costs of such items or services).

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

13 (C) FAILURE TO REIMBURSE.—Where a
14 plan or issuer fails to provide reimbursement to
15 a professional, participant, beneficiary, or en-
16 rollee in accordance with this paragraph, the
17 professional, participant, beneficiary, or enrollee
18 may commence a civil action (or utilize other
19 remedies available under law) to recover only
20 the amount of any such reimbursement that is
21 owed by the plan or issuer and any necessary
22 legal costs or expenses (including attorney’s
23 fees) incurred in recovering such reimburse-
24 ment.

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

4 (3) PENALTIES AGAINST AUTHORIZED OFFI-
5 CIALS FOR REFUSING TO AUTHORIZE THE DETER-
6 MINATION OF AN EXTERNAL REVIEW ENTITY.—

7 (A) MONETARY PENALTIES.—

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

24 (ii) ADDITIONAL PENALTY FOR FAIL-
25 ING TO FOLLOW TIMELINE.—In any case

1 in which treatment was not commenced by
2 the plan in accordance with the determina-
3 tion of an independent external reviewer,
4 the Secretary shall assess a civil penalty of
5 \$10,000 against the plan and the plan
6 shall pay such penalty to the participant,
7 beneficiary, or enrollee involved.

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

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

3 (ii) to pay to the plaintiff a reasonable
4 attorney's fee and other reasonable costs
5 relating to the prosecution of the action on
6 the charges on which the plaintiff prevails.

7 (C) ADDITIONAL CIVIL PENALTIES.—

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

17 (I) any pattern or practice of re-
18 peated refusal to authorize a benefit
19 determined by an external appeal enti-
20 ty to be covered; or

21 (II) any pattern or practice of re-
22 peated violations of the requirements
23 of this section with respect to such
24 plan or coverage.

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

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

13 (II) \$500,000.

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

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

9 (g) QUALIFICATIONS OF INDEPENDENT MEDICAL
10 REVIEWERS.—

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

15 (A) each independent medical reviewer
16 meets the qualifications described in paragraphs
17 (2) and (3);

18 (B) with respect to each review at least 1
19 such reviewer meets the requirements described
20 in paragraphs (4) and (5); and

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

23 (2) LICENSURE AND EXPERTISE.—Each inde-
24 pendent medical reviewer shall be a physician

1 (allopathic or osteopathic) or health care profes-
2 sional who—

3 (A) is appropriately credentialed or li-
4 censed in 1 or more States to deliver health
5 care services; and

6 (B) typically treats the condition, makes
7 the diagnosis, or provides the type of treatment
8 under review.

9 (3) INDEPENDENCE.—

10 (A) IN GENERAL.—Subject to subpara-
11 graph (B), each independent medical reviewer
12 in a case shall—

13 (i) not be a related party (as defined
14 in paragraph (7));

15 (ii) not have a material familial, fi-
16 nancial, or professional relationship with
17 such a party; and

18 (iii) not otherwise have a conflict of
19 interest with such a party (as determined
20 under regulations).

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

23 (i) prohibit an individual, solely on the
24 basis of affiliation with the plan or issuer,

1 from serving as an independent medical re-
2 viewer if—

3 (I) a non-affiliated individual is
4 not reasonably available;

5 (II) the affiliated individual is
6 not involved in the provision of items
7 or services in the case under review;

8 (III) the fact of such an affili-
9 ation is disclosed to the plan or issuer
10 and the participant, beneficiary, or
11 enrollee (or authorized representative)
12 and neither party objects; and

13 (IV) the affiliated individual is
14 not an employee of the plan or issuer
15 and does not provide services exclu-
16 sively or primarily to or on behalf of
17 the plan or issuer;

18 (ii) prohibit an individual who has
19 staff privileges at the institution where the
20 treatment involved takes place from serv-
21 ing as an independent medical reviewer
22 merely on the basis of such affiliation if
23 the affiliation is disclosed to the plan or
24 issuer and the participant, beneficiary, or

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

3 (iii) prohibit receipt of compensation
4 by an independent medical reviewer from
5 an entity if the compensation is provided
6 consistent with paragraph (6).

7 (4) PRACTICING HEALTH CARE PROFESSIONAL
8 IN SAME FIELD.—

9 (A) IN GENERAL.—In a case involving
10 treatment, or the provision of items or
11 services—

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

21 (ii) by a non-physician health care
22 professional, a reviewer (or reviewers) shall
23 include at least one practicing non-physi-
24 cian health care professional of the same
25 or similar specialty as the non-physician

1 health care professional who, acting within
2 the appropriate scope of practice within
3 the State in which the service is provided
4 or rendered, typically treats the condition,
5 makes the diagnosis, or provides the type
6 of treatment under review.

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

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

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

21 (A) not exceed a reasonable level; and

22 (B) not be contingent on the decision ren-
23 dered by the reviewer.

24 (7) RELATED PARTY DEFINED.—For purposes
25 of this section, the term “related party” means, with

1 respect to a denial of a claim under a plan or cov-
2 erage relating to a participant, beneficiary, or en-
3 rollee, any of the following:

4 (A) The plan, plan sponsor, or issuer in-
5 volved, or any fiduciary, officer, director, or em-
6 ployee of such plan, plan sponsor, or issuer.

7 (B) The participant, beneficiary, or en-
8 rollee (or authorized representative).

9 (C) The health care professional that pro-
10 vides the items or services involved in the de-
11 nial.

12 (D) The institution at which the items or
13 services (or treatment) involved in the denial
14 are provided.

15 (E) The manufacturer of any drug or
16 other item that is included in the items or serv-
17 ices involved in the denial.

18 (F) Any other party determined under any
19 regulations to have a substantial interest in the
20 denial involved.

21 (h) QUALIFIED EXTERNAL REVIEW ENTITIES.—

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

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

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

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

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

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

1 State in a manner determined by the State to
2 assure an unbiased determination.

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

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

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

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

20 Subparagraph (B) shall not be construed as apply-
21 ing to the imposition of a filing fee under subsection
22 (b)(2)(A)(iv) or costs incurred by the participant,
23 beneficiary, or enrollee (or authorized representative)
24 or treating health care professional (if any) in sup-

1 port of the review, including the provision of addi-
2 tional evidence or information.

3 (4) QUALIFICATIONS.—

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

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

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

24 (iii) The entity has provided assur-
25 ances that it will conduct external review

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

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

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

14 (B) INDEPENDENCE REQUIREMENTS.—

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

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

21 (II) does not have a material fa-
22 miliary, financial, or professional rela-
23 tionship with such a party; and

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

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

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

17 (I) not exceed a reasonable level;

18 and

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

22 (C) CERTIFICATION AND RECERTIFICATION
23 PROCESS.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

14 (II) Adherence to applicable
15 deadlines (both by the entity and by
16 independent medical reviewers it re-
17 fers cases to).

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

22 (IV) Compliance with applicable
23 independence requirements.

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

1 medically reviewable decisions shall be
2 the subject of independent medical re-
3 view and with the requirement of sub-
4 section (d)(3) that independent med-
5 ical reviewers may not require cov-
6 erage for specifically excluded bene-
7 fits.

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

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

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

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

16 (D) PROVISION OF INFORMATION.—

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

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

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

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

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

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

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

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

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

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

1 certification or recertification of an
2 entity.

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

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

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

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

8 (B) the number of denials that have been
9 upheld by independent medical reviewers and
10 the number of denials that have been reversed
11 by such reviewers; and

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

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

17 (a) GRANTS.—

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

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

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

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

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

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

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

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

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

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

20 (3) AMOUNT OF GRANT.—

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

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

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

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

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

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

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

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

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

20 (b) USE OF FUNDS.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

9 (4) DESIGNATION OF RESPONSIBILITIES.—

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

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

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

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

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

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

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

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

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

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

8 **Subtitle B—Access to Care**

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

10 (a) IN GENERAL.—If—

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

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

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

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

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

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

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

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

12 (b) SPECIALISTS.—

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

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

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

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

6 (a) COVERAGE OF EMERGENCY SERVICES.—

7 (1) IN GENERAL.—If a group health plan, or
8 health insurance coverage offered by a health insur-
9 ance issuer, provides or covers any benefits with re-
10 spect to services in an emergency department of a
11 hospital, the plan or issuer shall cover emergency
12 services (as defined in paragraph (2)(B))—

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

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

18 (C) in a manner so that, if such services
19 are provided to a participant, beneficiary, or
20 enrollee—

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

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

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

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

15 (2) DEFINITIONS.—In this section:

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

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

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

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

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

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

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

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

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

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

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

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

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

12 (a) **TIMELY ACCESS.**—

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

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

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

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

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

8 (3) ACCESS TO CERTAIN PROVIDERS.—

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

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

25 (b) REFERRALS.—

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

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

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

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

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

1 ject to the terms of a treatment plan (if any)
2 referred to in subsection (c) with respect to the
3 condition.

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

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

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

12 (c) TREATMENT PLANS.—

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

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

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

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

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

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

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

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

19 (a) GENERAL RIGHTS.—

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

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

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

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

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

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

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

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

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

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

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

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

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

2 (a) **TERMINATION OF PROVIDER.—**

3 (1) **IN GENERAL.—If—**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 (b) TRANSITIONAL PERIODS.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

5 (e) DEFINITIONS.—In this section:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3 (a) **COVERAGE.**—

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

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

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

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

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

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

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

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

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

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

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

22 (2) Either—

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

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

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

10 (c) PAYMENT.—

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

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

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

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

1 (d) APPROVED CLINICAL TRIAL DEFINED.—

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

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

8 (i) the National Institutes of Health;

9 (ii) a cooperative group or center of
10 the National Institutes of Health, such as
11 a qualified nongovernmental research enti-
12 ty to which the National Cancer Institute
13 has awarded a center support grant;

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

17 (I) the Department of Veterans
18 Affairs;

19 (II) the Department of Defense;

20 or

21 (B) approved by the Food and Drug Ad-
22 ministration.

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

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

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

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

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

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

18 (a) INPATIENT CARE.—

19 (1) IN GENERAL.—A group health plan, and a
 20 health insurance issuer providing health insurance
 21 coverage, that provides medical and surgical benefits
 22 shall ensure that inpatient coverage with respect to
 23 the treatment of breast cancer is provided for a pe-
 24 riod of time as is determined by the attending physi-

1 cian, in consultation with the patient, to be medi-
2 cally necessary and appropriate following—

3 (A) a mastectomy;

4 (B) a lumpectomy; or

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

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

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

19 (c) SECONDARY CONSULTATIONS.—

20 (1) IN GENERAL.—A group health plan, and a
21 health insurance issuer providing health insurance
22 coverage, that provides coverage with respect to
23 medical and surgical services provided in relation to
24 the diagnosis and treatment of cancer shall ensure
25 that full coverage is provided for secondary consulta-

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

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

1 (d) PROHIBITION ON PENALTIES OR INCENTIVES.—

2 A group health plan, and a health insurance issuer pro-
3 viding health insurance coverage, may not—

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

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

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

22 **Subtitle C—Access to Information**

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

24 (a) REQUIREMENT.—

25 (1) DISCLOSURE.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 113, if such section applies, and any educational in-
2 formation that the plan or issuer may provide re-
3 garding the appropriate use of emergency services.

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

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

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

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

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

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

22 (18) NOTICE OF REQUIREMENTS.—A descrip-
23 tion of any rights of participants, beneficiaries, and
24 enrollees that are established by the Bipartisan Pa-
25 tient Protection Act (excluding those described in

1 paragraphs (1) through (17)) if such sections apply.
2 The description required under this paragraph may
3 be combined with the notices of the type described
4 in sections 711(d), 713(b), or 606(a)(1) of the Em-
5 ployee Retirement Income Security Act of 1974 and
6 with any other notice provision that the appropriate
7 Secretary determines may be combined, so long as
8 such combination does not result in any reduction in
9 the information that would otherwise be provided to
10 the recipient.

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

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

24 (c) ADDITIONAL INFORMATION.—The informational
25 materials to be provided upon the request of a participant,

1 beneficiary, or enrollee shall include for each option avail-
2 able under a group health plan or health insurance cov-
3 erage the following:

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

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

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

22 (4) UTILIZATION REVIEW ACTIVITIES.—A de-
23 scription of procedures used and requirements (in-
24 cluding circumstances, timeframes, and appeals
25 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 if
2 such plan or issuer is in compliance with the stand-
3 ards promulgated by the Secretary of Health and
4 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
14 construed—

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 (e)) with
9 a patient protection requirement (as defined in para-
10 graph (3)) and does not prevent the application of
11 other requirements under this Act (except in the
12 case of other substantially compliant requirements),
13 in applying the requirements of this title under sec-
14 tion 2707 and 2753 (as applicable) of the Public
15 Health Service Act (as added by title II), subject to
16 subsection (a)(2)—

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

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

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

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

4 (3) DEFINITIONS.—In this section:

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

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

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

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

1 required 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)
8 unless—

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 enter
20 into an agreement with the Secretary for the delegation
21 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 DECI-
 13 SIONS.—

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 2001 (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 2001 (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 2001.

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 2001.

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

1 the scope of employment) under paragraph
2 (1)(A), to the extent there was direct partici-
3 tion by the employer or other plan sponsor (or
4 employee) in the decision of the plan under sec-
5 tion 102 of the Bipartisan Patient Protection
6 Act of 2001 upon consideration of a claim for
7 benefits or under section 103 of such Act upon
8 review of a denial of a claim for benefits.

9 “(C) DIRECT PARTICIPATION.—

10 “(i) IN GENERAL.—For purposes of
11 subparagraph (B), the term ‘direct partici-
12 pation’ means, in connection with a deci-
13 sion described in paragraph (1)(A), the ac-
14 tual making of such decision or the actual
15 exercise of control in making such decision.

16 “(ii) RULES OF CONSTRUCTION.—For
17 purposes of clause (i), the employer or plan
18 sponsor (or employee) shall not be con-
19 strued to be engaged in direct participation
20 because of any form of decisionmaking or
21 other conduct that is merely collateral or
22 precedent to the decision described in
23 paragraph (1)(A) on a particular claim for
24 benefits of a participant or beneficiary, in-
25 cluding (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 ministrators 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 2001 (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
2 subsection—

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 2001 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.

1 “(B) ASSESSMENT OF CIVIL PENALTIES.—

2 In addition to the remedies provided for in
3 paragraph (1) (relating to the failure to provide
4 contract benefits in accordance with the plan),
5 a civil assessment, in an amount not to exceed
6 \$5,000,000, payable to the claimant may be
7 awarded in any action under such paragraph if
8 the claimant establishes by clear and convincing
9 evidence that the alleged conduct carried out by
10 the defendant demonstrated bad faith and fla-
11 grant disregard for the rights of the participant
12 or beneficiary under the plan and was a proxi-
13 mate cause of the personal injury or death that
14 is the subject of the claim.

15 “(11) LIMITATION ON ATTORNEYS’ FEES.—

16 “(A) IN GENERAL.—Notwithstanding any
17 other provision of law, or any arrangement,
18 agreement, or contract regarding an attorney’s
19 fee, the amount of an attorney’s contingency fee
20 allowable for a cause of action brought pursu-
21 ant to this subsection shall not exceed $\frac{1}{3}$ of the
22 total amount of the plaintiff’s recovery (not in-
23 cluding the reimbursement of actual out-of-
24 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 2001 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 re-
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

1 beneficiaries of an employer or plan sponsor,
2 whether or not the employer or plan sponsor
3 makes such a designation, and shall be deemed
4 to have assumed unconditionally all liability of
5 the employer or plan sponsor under such des-
6 ignation in accordance with subsection (o), un-
7 less the employer or plan sponsor affirmatively
8 enters into a contract to prevent the service of
9 the designated decisionmaker.

10 “(19) PREVIOUSLY PROVIDED SERVICES.—

11 “(A) IN GENERAL.—Except as provided in
12 this paragraph, a cause of action shall not arise
13 under paragraph (1) where the denial involved
14 relates to an item or service that has already
15 been fully provided to the participant or bene-
16 ficiary under the plan or coverage and the claim
17 relates solely to the subsequent denial of pay-
18 ment for the provision of such item or service.

19 “(B) EXCEPTION.—Nothing in subpara-
20 graph (A) shall be construed to—

21 “(i) prohibit a cause of action under
22 paragraph (1) where the nonpayment in-
23 volved results in the participant or bene-
24 ficiary being unable to receive further
25 items or services that are directly related

1 to the item or service involved in the denial
2 referred to in subparagraph (A) or that
3 are part of a continuing treatment or se-
4 ries of procedures;

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

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

12 “(20) EXEMPTION FROM PERSONAL LIABILITY
13 FOR INDIVIDUAL MEMBERS OF BOARDS OF DIREC-
14 TORS, JOINT BOARDS OF TRUSTEES, ETC.—Any indi-
15 vidual who is—

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

18 “(B) a member of an association, com-
19 mittee, employee organization, joint board of
20 trustees, or other similar group of representa-
21 tives of the entities that are the plan sponsor
22 of plan maintained by two or more employers
23 and one or more employee organizations;

24 shall not be personally liable under this subsection
25 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 (e) 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 2001 (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 2001 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 2001.

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 “(iv) 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 2001 (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
4 subsection—

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 2001 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 2001 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 2001,
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 beneficiary 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 2001, 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 October 1,
9 2002.

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
12 January 1, 2002.”.

13 **SEC. 404. LIMITATIONS ON ACTIONS.**

14 Section 502 of the Employee Retirement Income Se-
15 curity Act of 1974 (29 U.S.C. 1132) (as amended by sec-
16 tion 402(a)) is amended further by adding at the end the
17 following new subsection:

18 “(q) LIMITATIONS ON ACTIONS RELATING TO GROUP
19 HEALTH PLANS.—

20 “(1) IN GENERAL.—Except as provided in para-
21 graph (2), no action may be brought under sub-
22 section (a)(1)(B), (a)(2), or (a)(3) by a participant
23 or beneficiary seeking relief based on the application
24 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 enter
14 into an agreement with the Secretary for the delegation
15 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 October 1, 2002 (in
 24 this section referred to as the “general effective
 25 date”).

1 (2) TREATMENT OF COLLECTIVE BARGAINING
2 AGREEMENTS.—In the case of a group health plan
3 maintained pursuant to one or more collective bar-
4 gaining agreements between employee representa-
5 tives and one or more employers ratified before the
6 date of the enactment of this Act, the amendments
7 made by sections 201(a), 401, and 403 (and title I
8 insofar as it relates to such sections) shall not apply
9 to plan years beginning before the later of—

10 (A) the date on which the last collective
11 bargaining agreements relating to the plan ter-
12 minates (excluding any extension thereof agreed
13 to after the date of the enactment of this Act);
14 or

15 (B) the general effective date;
16 but shall apply not later than 1 year after the gen-
17 eral effective date. For purposes of subparagraph
18 (A), any plan amendment made pursuant to a collec-
19 tive bargaining agreement relating to the plan which
20 amends the plan solely to conform to any require-
21 ment added by this Act shall not be treated as a ter-
22 mination of such collective bargaining agreement.

23 (b) INDIVIDUAL HEALTH INSURANCE COVERAGE.—
24 Subject to subsection (d), the amendments made by sec-
25 tion 202 shall apply with respect to individual health in-

1 surance coverage offered, sold, issued, renewed, in effect,
2 or operated in the individual market on or after the gen-
3 eral effective date.

4 (c) TREATMENT OF RELIGIOUS NONMEDICAL PRO-
5 VIDERS.—

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

8 (A) restrict or limit the right of group
9 health plans, and of health insurance issuers of-
10 fering health insurance coverage, to include as
11 providers religious nonmedical providers;

12 (B) require such plans or issuers to—

13 (i) utilize medically based eligibility
14 standards or criteria in deciding provider
15 status of religious nonmedical providers;

16 (ii) use medical professionals or cri-
17 teria to decide patient access to religious
18 nonmedical providers;

19 (iii) utilize medical professionals or
20 criteria in making decisions in internal or
21 external appeals regarding coverage for
22 care by religious nonmedical providers; or

23 (iv) compel a participant or bene-
24 ficiary to undergo a medical examination
25 or test as a condition of receiving health

1 insurance coverage for treatment by a reli-
2 gious nonmedical provider; or

3 (C) require such plans or issuers to ex-
4 clude religious nonmedical providers because
5 they do not provide medical or other required
6 data, if such data is inconsistent with the reli-
7 gious nonmedical treatment or nursing care
8 provided by the provider.

9 (2) RELIGIOUS NONMEDICAL PROVIDER.—For
10 purposes of this subsection, the term “religious non-
11 medical provider” means a provider who provides no
12 medical care but who provides only religious non-
13 medical treatment or religious nonmedical nursing
14 care.

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

18 (1) subsection (a) with respect to a group
19 health plan that is maintained as of the general ef-
20 fective date, not later than 30 days before the begin-
21 ning of the first plan year to which title I applies
22 in connection with the plan under such subsection;
23 or

24 (2) subsection (b) with respect to a individual
25 health insurance coverage that is in effect as of the

1 general effective date, not later than 30 days before
2 the first date as of which title I applies to the cov-
3 erage under such subsection.

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

5 The Secretary of Labor and the Secretary of Health
6 and Human Services shall ensure, through the execution
7 of an interagency memorandum of understanding among
8 such Secretaries, that—

9 (1) regulations, rulings, and interpretations
10 issued by such Secretaries relating to the same mat-
11 ter over which such Secretaries have responsibility
12 under the provisions of this Act (and the amend-
13 ments made thereby) are administered so as to have
14 the same effect at all times; and

15 (2) coordination of policies relating to enforcing
16 the same requirements through such Secretaries in
17 order to have a coordinated enforcement strategy
18 that avoids duplication of enforcement efforts and
19 assigns priorities in enforcement.

20 **SEC. 503. SEVERABILITY.**

21 If any provision of this Act, an amendment made by
22 this Act, or the application of such provision or amend-
23 ment to any person or circumstance is held to be unconsti-
24 tutional, the remainder of this Act, the amendments made
25 by this Act, and the application of the provisions of such

1 to any person or circumstance shall not be affected there-
2 by.

3 **TITLE VI—MISCELLANEOUS** 4 **PROVISIONS**

5 **SEC. 601. NO IMPACT ON SOCIAL SECURITY TRUST FUND.**

6 (a) IN GENERAL.—Nothing in this Act (or an amend-
7 ment made by this Act) shall be construed to alter or
8 amend the Social Security Act (or any regulation promul-
9 gated under that Act).

10 (b) TRANSFERS.—

11 (1) ESTIMATE OF SECRETARY.—The Secretary
12 of the Treasury shall annually estimate the impact
13 that the enactment of this Act has on the income
14 and balances of the trust funds established under
15 section 201 of the Social Security Act (42 U.S.C.
16 401).

17 (2) TRANSFER OF FUNDS.—If, under para-
18 graph (1), the Secretary of the Treasury estimates
19 that the enactment of this Act has a negative impact
20 on the income and balances of the trust funds estab-
21 lished under section 201 of the Social Security Act
22 (42 U.S.C. 401), the Secretary shall transfer, not
23 less frequently than quarterly, from the general reve-
24 nues of the Federal Government an amount suffi-
25 cient so as to ensure that the income and balances

1 of such trust funds are not reduced as a result of
2 the enactment of such Act.

3 **SEC. 602. CUSTOMS USER FEES.**

4 Section 13031(j)(3) of the Consolidated Omnibus
5 Budget Reconciliation Act of 1985 (19 U.S.C. 58c(j)(3))
6 is amended by striking “2003” and inserting “2011, ex-
7 cept that fees may not be charged under paragraphs (9)
8 and (10) of such subsection after March 31, 2006”.

9 **SEC. 603. FISCAL YEAR 2002 MEDICARE PAYMENTS.**

10 Notwithstanding any other provision of law, any let-
11 ter of credit under part B of title XVIII of the Social Se-
12 curity Act (42 U.S.C. 1395j et seq.) that would otherwise
13 be sent to the Treasury or the Federal Reserve Board on
14 September 30, 2002, by a carrier with a contract under
15 section 1842 of that Act (42 U.S.C. 1395u) shall be sent
16 on October 1, 2002.

17 **SEC. 604. SENSE OF SENATE WITH RESPECT TO PARTICIPA-**
18 **TION IN CLINICAL TRIALS AND ACCESS TO**
19 **SPECIALTY CARE.**

20 (a) FINDINGS.—The Senate finds the following:

21 (1) Breast cancer is the most common form of
22 cancer among women, excluding skin cancers.

23 (2) During 2001, 182,800 new cases of female
24 invasive breast cancer will be diagnosed, and 40,800
25 women will die from the disease.

1 (3) In addition, 1,400 male breast cancer cases
2 are projected to be diagnosed, and 400 men will die
3 from the disease.

4 (4) Breast cancer is the second leading cause of
5 cancer death among all women and the leading
6 cause of cancer death among women between ages
7 40 and 55.

8 (5) This year 8,600 children are expected to be
9 diagnosed with cancer.

10 (6) 1,500 children are expected to die from can-
11 cer this year.

12 (7) There are approximately 333,000 people di-
13 agnosed with multiple sclerosis in the United States
14 and 200 more cases are diagnosed each week.

15 (8) Parkinson's disease is a progressive disorder
16 of the central nervous system affecting 1,000,000 in
17 the United States.

18 (9) An estimated 198,100 men will be diag-
19 nosed with prostate cancer this year.

20 (10) 31,500 men will die from prostate cancer
21 this year. It is the second leading cause of cancer in
22 men.

23 (11) While information obtained from clinical
24 trials is essential to finding cures for diseases, it is
25 still research which carries the risk of fatal results.

1 Future efforts should be taken to protect the health
2 and safety of adults and children who enroll in clin-
3 ical trials.

4 (12) While employers and health plans should
5 be responsible for covering the routine costs associ-
6 ated with federally approved or funded clinical trials,
7 such employers and health plans should not be held
8 legally responsible for the design, implementation, or
9 outcome of such clinical trials, consistent with any
10 applicable State or Federal liability statutes.

11 (b) SENSE OF THE SENATE.—It is the sense of the
12 Senate that—

13 (1) men and women battling life-threatening,
14 deadly diseases, including advanced breast or ovar-
15 ian cancer, should have the opportunity to partici-
16 pate in a federally approved or funded clinical trial
17 recommended by their physician;

18 (2) an individual should have the opportunity to
19 participate in a federally approved or funded clinical
20 trial recommended by their physician if—

21 (A) that individual—

22 (i) has a life-threatening or serious ill-
23 ness for which no standard treatment is ef-
24 fective;

1 (ii) is eligible to participate in a feder-
2 ally approved or funded clinical trial ac-
3 cording to the trial protocol with respect to
4 treatment of the illness;

5 (B) that individual's participation in the
6 trial offers meaningful potential for significant
7 clinical benefit for the individual; and

8 (C) either—

9 (i) the referring physician is a partici-
10 pating health care professional and has
11 concluded that the individual's participa-
12 tion in the trial would be appropriate,
13 based upon the individual meeting the con-
14 ditions described in subparagraph (A); or

15 (ii) the participant, beneficiary, or en-
16 rollee provides medical and scientific infor-
17 mation establishing that the individual's
18 participation in the trial would be appro-
19 priate, based upon the individual meeting
20 the conditions described in subparagraph
21 (A);

22 (3) a child with a life-threatening illness, in-
23 cluding cancer, should be allowed to participate in a
24 federally approved or funded clinical trial if that

1 participation meets the requirements of paragraph
2 (2);

3 (4) a child with a rare cancer should be allowed
4 to go to a cancer center capable of providing high
5 quality care for that disease; and

6 (5) a health maintenance organization's deci-
7 sion that an in-network physician without the nec-
8 essary expertise can provide care for a seriously ill
9 patient, including a woman battling cancer, should
10 be appealable to an independent, impartial body, and
11 that this same right should be available to all Ameri-
12 cans in need of access to high quality specialty care.

13 **SEC. 605. SENSE OF THE SENATE REGARDING FAIR REVIEW**
14 **PROCESS.**

15 (a) FINDINGS.—The Senate finds the following:

16 (1) A fair, timely, impartial independent exter-
17 nal appeals process is essential to any meaningful
18 program of patient protection.

19 (2) The independence and objectivity of the re-
20 view organization and review process must be en-
21 sured.

22 (3) It is incompatible with a fair and inde-
23 pendent appeals process to allow a health mainte-
24 nance organization to select the review organization

1 that is entrusted with providing a neutral and unbi-
2 ased medical review.

3 (4) The American Arbitration Association and
4 arbitration standards adopted under chapter 44 of
5 title 28, United States Code (28 U.S.C. 651 et seq.)
6 both prohibit, as inherently unfair, the right of one
7 party to a dispute to choose the judge in that dis-
8 pute.

9 (b) SENSE OF THE SENATE.—It is the sense of the
10 Senate that—

11 (1) every patient who is denied care by a health
12 maintenance organization or other health insurance
13 company should be entitled to a fair, speedy, impar-
14 tial appeal to a review organization that has not
15 been selected by the health plan;

16 (2) the States should be empowered to maintain
17 and develop the appropriate process for selection of
18 the independent external review entity;

19 (3) a child battling a rare cancer whose health
20 maintenance organization has denied a covered
21 treatment recommended by its physician should be
22 entitled to a fair and impartial external appeal to a
23 review organization that has not been chosen by the
24 organization or plan that has denied the care; and

1 (4) patient protection legislation should not pre-
2 empt existing State laws in States where there al-
3 ready are strong laws in place regarding the selec-
4 tion of independent review organizations.

5 **SEC. 606. ANNUAL REVIEW.**

6 (a) **IN GENERAL.**—Not later than 24 months after
7 the general effective date referred to in section 501(a)(1),
8 and annually thereafter for each of the succeeding 4 cal-
9 endar years (or until a repeal is effective under subsection
10 (b)), the Secretary of Health and Human Services shall
11 request that the Institute of Medicine of the National
12 Academy of Sciences prepare and submit to the appro-
13 priate committees of Congress a report concerning the im-
14 pact of this Act, and the amendments made by this Act,
15 on the number of individuals in the United States with
16 health insurance coverage.

17 (b) **LIMITATION WITH RESPECT TO CERTAIN**
18 **PLANS.**—If the Secretary, in any report submitted under
19 subsection (a), determines that more than 1,000,000 indi-
20 viduals in the United States have lost their health insur-
21 ance coverage as a result of the enactment of this Act,
22 as compared to the number of individuals with health in-
23 surance coverage in the 12-month period preceding the
24 date of enactment of this Act, section 402 of this Act shall
25 be repealed effective on the date that is 12 month after

1 the date on which the report is submitted, and the submis-
2 sion of any further reports under subsection (a) shall not
3 be required.

4 (c) FUNDING.—From funds appropriated to the De-
5 partment of Health and Human Services for fiscal years
6 2003 and 2004, the Secretary of Health and Human Serv-
7 ices shall provide for such funding as the Secretary deter-
8 mines necessary for the conduct of the study of the Na-
9 tional Academy of Sciences under this section.

10 **SEC. 607. DEFINITION OF BORN-ALIVE INFANT.**

11 (a) IN GENERAL.—Chapter 1 of title 1, United
12 States Code, is amended by adding at the end the fol-
13 lowing:

14 **“§ 8. ‘Person’, ‘human being’, ‘child’, and ‘individual’**
15 **as including born-alive infant**

16 “(a) In determining the meaning of any Act of Con-
17 gress, or of any ruling, regulation, or interpretation of the
18 various administrative bureaus and agencies of the United
19 States, the words ‘person’, ‘human being’, ‘child’, and ‘in-
20 dividual’, shall include every infant member of the species
21 homo sapiens who is born alive at any stage of develop-
22 ment.

23 “(b) As used in this section, the term ‘born alive’,
24 with respect to a member of the species homo sapiens,
25 means the complete expulsion or extraction from his or

1 her mother of that member, at any stage of development,
2 who after such expulsion or extraction breathes or has a
3 beating heart, pulsation of the umbilical cord, or definite
4 movement of voluntary muscles, regardless of whether the
5 umbilical cord has been cut, and regardless of whether the
6 expulsion or extraction occurs as a result of natural or
7 induced labor, caesarean section, or induced abortion.

8 “(c) Nothing in this section shall be construed to af-
9 firm, deny, expand, or contract any legal status or legal
10 right applicable to any member of the species homo sapi-
11 ens at any point prior to being born alive as defined in
12 this section.”.

13 (b) CLERICAL AMENDMENT.—The table of sections
14 at the beginning of chapter 1 of title 1, United States
15 Code, is amended by adding at the end the following new
16 item:

“8. ‘Person’, ‘human being’, ‘child’, and ‘individual’ as including born-alive in-
fant.”.

Passed the Senate June 29, 2001.

Attest:

Secretary.

107TH CONGRESS
1ST SESSION

S. 1052

AN ACT

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.

June 29, 2001

Ordered to be printed as passed