

107TH CONGRESS
1ST SESSION

H. R. 2563

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

IN THE HOUSE OF REPRESENTATIVES

JULY 19, 2001

Mr. GANSKE (for himself, Mr. DINGELL, Mr. NORWOOD, Mr. BERRY, Mr. LEACH, Mr. BROWN of Ohio, Mrs. ROUKEMA, Mr. JOHN, Mrs. MORELLA, Mr. ANDREWS, Mr. GILMAN, Mr. RANGEL, Mr. LATOURETTE, Mr. STENHOLM, Mr. HORN, Mr. SANDLIN, Mr. BARR of Georgia, Mr. STUPAK, Mr. SMITH of New Jersey, Mr. PALLONE, Mr. TOWNS, Ms. ESHOO, Mrs. CAPPES, Mr. GREEN of Texas, Mr. GORDON, Ms. MCCARTHY of Missouri, Mr. ENGEL, Mr. MOORE, Mr. STRICKLAND, Mr. MARKEY, Mr. SAWYER, Mrs. DAVIS of California, Mr. BARRETT of Wisconsin, Mr. WYNN, Mr. STARK, Mr. WAXMAN, Mr. RUSH, Mr. BOUCHER, Mr. HALL of Texas, Mr. BISHOP, Mr. TURNER, Ms. HARMAN, Mr. PASCRELL, Mrs. MCCARTHY of New York, Mr. FRANK, Mr. MATSUI, Mr. COYNE, Mr. McDERMOTT, Mr. CARDIN, Mr. LEVIN, Mr. McNULTY, Mr. JEFFERSON, Mr. LEWIS of Georgia, Mr. KLECZKA, Mrs. THURMAN, Mr. BOSWELL, Mr. CROWLEY, Mr. TIERNEY, Mr. HOEFFEL, Mr. MEEHAN, Mr. DOYLE, Ms. DEGETTE, Mr. MATHESON, Mr. KUCINICH, Ms. PELOSI, Mr. BERMAN, Mr. THOMPSON of California, Mr. GEORGE MILLER of California, and Mr. ROSS) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Education and the Workforce, and Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend the Public Health Service Act, the Employee Retirement Income Security Act of 1974, and the Internal

Revenue Code of 1986 to protect consumers in managed care plans and other health coverage.

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

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

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

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

Sec. 1. Short title; table of contents.

TITLE I—IMPROVING MANAGED CARE

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

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

Subtitle B—Access to Care

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

Subtitle C—Access to Information

- Sec. 121. Patient access to information.

Subtitle D—Protecting the Doctor-Patient Relationship

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

Sec. 135. Protection for patient advocacy.

Subtitle E—Definitions

- Sec. 151. Definitions.
 Sec. 152. Preemption; State flexibility; construction.
 Sec. 153. Exclusions.
 Sec. 154. Treatment of excepted benefits.
 Sec. 155. Regulations.
 Sec. 156. Incorporation into plan or coverage documents.
 Sec. 157. Preservation of protections.

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

- Sec. 201. Application to group health plans and group health insurance coverage.
 Sec. 202. Application to individual health insurance coverage.
 Sec. 203. Cooperation between Federal and State authorities.

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

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

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

- Sec. 401. Application of patient protection standards to group health plans and group health insurance coverage under the Employee Retirement Income Security Act of 1974.
 Sec. 402. 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—AMENDMENTS TO THE INTERNAL REVENUE CODE OF
 1986

Subtitle A—Application of Patient Protection Provisions

- Sec. 501. Application of requirements to group health plans under the Internal Revenue Code of 1986.
 Sec. 502. Conforming enforcement for women's health and cancer rights.

Subtitle B—Health Care Coverage Access Tax Incentives

- Sec. 511. Expanded availability of Archer MSAs.
 Sec. 512. Deduction for 100 percent of health insurance costs of self-employed individuals.
 Sec. 513. Credit for health insurance expenses of small businesses.
 Sec. 514. Certain grants by private foundations to qualified health benefit purchasing coalitions.
 Sec. 515. State grant program for market innovation.

TITLE VI—EFFECTIVE DATES; COORDINATION IN
IMPLEMENTATION

- Sec. 601. Effective dates.
Sec. 602. Coordination in implementation.
Sec. 603. Severability.

TITLE VII—MISCELLANEOUS PROVISIONS

- Sec. 701. No impact on Social Security Trust Fund.
Sec. 702. Customs user fees.
Sec. 703. Fiscal year 2002 medicare payments.
Sec. 704. Sense of Senate with respect to participation in clinical trials and access to specialty care.
Sec. 705. Sense of the Senate regarding fair review process.
Sec. 706. Annual review.
Sec. 707. 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

1 entities to conduct utilization review activities on be-
2 half of the plan or issuer, so long as such activities
3 are conducted in accordance with a utilization review
4 program that meets the requirements of this section.

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

14 (b) WRITTEN POLICIES AND CRITERIA.—

15 (1) WRITTEN POLICIES.—A utilization review
16 program shall be conducted consistent with written
17 policies and procedures that govern all aspects of the
18 program.

19 (2) USE OF WRITTEN CRITERIA.—

20 (A) IN GENERAL.—Such a program shall
21 utilize written clinical review criteria developed
22 with input from a range of appropriate actively
23 practicing health care professionals, as deter-
24 mined by the plan, pursuant to the program.
25 Such criteria shall include written clinical re-

1 view criteria that are based on valid clinical evi-
2 dence where available and that are directed spe-
3 cifically at meeting the needs of at-risk popu-
4 lations and covered individuals with chronic
5 conditions or severe illnesses, including gender-
6 specific criteria and pediatric-specific criteria
7 where available and appropriate.

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

18 (C) REVIEW OF SAMPLE OF CLAIMS DENI-
19 ALS.—Such a program shall provide for a peri-
20 odic evaluation of the clinical appropriateness of
21 at least a sample of denials of claims for bene-
22 fits.

23 (e) CONDUCT OF PROGRAM ACTIVITIES.—

24 (1) ADMINISTRATION BY HEALTH CARE PRO-
25 FESSIONALS.—A utilization review program shall be

1 administered by qualified health care professionals
2 who shall oversee review decisions.

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

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

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

18 (C) PROHIBITION OF CONFLICTS.—Such a
19 program shall not permit a health care profes-
20 sional who is providing health care services to
21 an individual to perform utilization review ac-
22 tivities in connection with the health care serv-
23 ices being provided to the individual.

24 (3) ACCESSIBILITY OF REVIEW.—Such a pro-
25 gram shall provide that appropriate personnel per-

1 forming utilization review activities under the pro-
2 gram, including the utilization review administrator,
3 are reasonably accessible by toll-free telephone dur-
4 ing normal business hours to discuss patient care
5 and allow response to telephone requests, and that
6 appropriate provision is made to receive and respond
7 promptly to calls received during other hours.

8 (4) LIMITS ON FREQUENCY.—Such a program
9 shall not provide for the performance of utilization
10 review activities with respect to a class of services
11 furnished to an individual more frequently than is
12 reasonably required to assess whether the services
13 under review are medically necessary and appro-
14 priate.

15 **SEC. 102. PROCEDURES FOR INITIAL CLAIMS FOR BENE-**
16 **FITS AND PRIOR AUTHORIZATION DETER-**
17 **MINATIONS.**

18 (a) PROCEDURES OF INITIAL CLAIMS FOR BENE-
19 FITS.—

20 (1) IN GENERAL.—A group health plan, and a
21 health insurance issuer offering health insurance
22 coverage, shall—

23 (A) make a determination on an initial
24 claim for benefits by a participant, beneficiary,
25 or enrollee (or authorized representative) re-

1 regarding payment or coverage for items or serv-
2 ices under the terms and conditions of the plan
3 or coverage involved, including any cost-sharing
4 amount that the participant, beneficiary, or en-
5 rollee is required to pay with respect to such
6 claim for benefits; and

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

18 (2) ACCESS TO INFORMATION.—

19 (A) TIMELY PROVISION OF NECESSARY IN-
20 FORMATION.—With respect to an initial claim
21 for benefits, the participant, beneficiary, or en-
22 rollee (or authorized representative) and the
23 treating health care professional (if any) shall
24 provide the plan or issuer with access to infor-
25 mation requested by the plan or issuer that is

1 necessary to make a determination relating to
2 the claim. Such access shall be provided not
3 later than 5 days after the date on which the
4 request for information is received, or, in a case
5 described in subparagraph (B) or (C) of sub-
6 section (b)(1), by such earlier time as may be
7 necessary to comply with the applicable timeline
8 under such subparagraph.

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

21 (3) ORAL REQUESTS.—In the case of a claim
22 for benefits involving an expedited or concurrent de-
23 termination, a participant, beneficiary, or enrollee
24 (or authorized representative) may make an initial
25 claim for benefits orally, but a group health plan, or

1 health insurance issuer offering health insurance
2 coverage, may require that the participant, bene-
3 ficiary, or enrollee (or authorized representative)
4 provide written confirmation of such request in a
5 timely manner on a form provided by the plan or
6 issuer. In the case of such an oral request for bene-
7 fits, the making of the request (and the timing of
8 such request) shall be treated as the making at that
9 time of a claim for such benefits without regard to
10 whether and when a written confirmation of such re-
11 quest is made.

12 (b) TIMELINE FOR MAKING DETERMINATIONS.—

13 (1) PRIOR AUTHORIZATION DETERMINATION.—

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

1 case later than 28 days after the date of the
2 claim for benefits is received.

3 (B) EXPEDITED DETERMINATION.—Not-
4 withstanding subparagraph (A), a group health
5 plan, and a health insurance issuer offering
6 health insurance coverage, shall expedite a prior
7 authorization determination on a claim for ben-
8 efits described in such subparagraph when a re-
9 quest for such an expedited determination is
10 made by a participant, beneficiary, or enrollee
11 (or authorized representative) at any time dur-
12 ing the process for making a determination and
13 a health care professional certifies, with the re-
14 quest, that a determination under the proce-
15 dures described in subparagraph (A) would seri-
16 ously jeopardize the life or health of the partici-
17 pant, beneficiary, or enrollee or the ability of
18 the participant, beneficiary, or enrollee to main-
19 tain or regain maximum function. Such deter-
20 mination shall be made in accordance with the
21 medical exigencies of the case and as soon as
22 possible, but in no case later than 72 hours
23 after the time the request is received by the
24 plan or issuer under this subparagraph.

25 (C) ONGOING CARE.—

1 (i) CONCURRENT REVIEW.—

2 (I) IN GENERAL.—Subject to
3 clause (ii), in the case of a concurrent
4 review of ongoing care (including hos-
5 pitalization), which results in a termi-
6 nation or reduction of such care, the
7 plan or issuer must provide by tele-
8 phone and in printed form notice of
9 the concurrent review determination
10 to the individual or the individual's
11 designee and the individual's health
12 care provider in accordance with the
13 medical exigencies of the case and as
14 soon as possible, with sufficient time
15 prior to the termination or reduction
16 to allow for an appeal under section
17 103(b)(3) to be completed before the
18 termination or reduction takes effect.

19 (II) CONTENTS OF NOTICE.—
20 Such notice shall include, with respect
21 to ongoing health care items and serv-
22 ices, the number of ongoing services
23 approved, the new total of approved
24 services, the date of onset of services,
25 and the next review date, if any, as

1 well as a statement of the individual's
2 rights to further appeal.

3 (ii) RULE OF CONSTRUCTION.—Clause
4 (i) shall not be construed as requiring
5 plans or issuers to provide coverage of care
6 that would exceed the coverage limitations
7 for such care.

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

19 (c) NOTICE OF A DENIAL OF A CLAIM FOR BENE-
20 FITS.—Written notice of a denial made under an initial
21 claim for benefits shall be issued to the participant, bene-
22 ficiary, or enrollee (or authorized representative) and the
23 treating health care professional in accordance with the
24 medical exigencies of the case and as soon as possible, but
25 in no case later than 2 days after the date of the deter-

1 mination (or, in the case described in subparagraph (B)
2 or (C) of subsection (b)(1), within the 72-hour or applica-
3 ble period referred to in such subparagraph).

4 (d) REQUIREMENTS OF NOTICE OF DETERMINA-
5 TIONS.—The written notice of a denial of a claim for bene-
6 fits determination under subsection (c) shall be provided
7 in printed form and written in a manner calculated to be
8 understood by the participant, beneficiary, or enrollee and
9 shall include—

10 (1) the specific reasons for the determination
11 (including a summary of the clinical or scientific evi-
12 dence used in making the determination);

13 (2) the procedures for obtaining additional in-
14 formation concerning the determination; and

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

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

19 (1) AUTHORIZED REPRESENTATIVE.—The term
20 “authorized representative” means, with respect to
21 an individual who is a participant, beneficiary, or en-
22 rollee, any health care professional or other person
23 acting on behalf of the individual with the individ-
24 ual’s consent or without such consent if the indi-
25 vidual is medically unable to provide such consent.

1 (2) CLAIM FOR BENEFITS.—The term “claim
2 for benefits” means any request for coverage (in-
3 cluding authorization of coverage), for eligibility, or
4 for payment in whole or in part, for an item or serv-
5 ice under a group health plan or health insurance
6 coverage.

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

14 (4) TREATING HEALTH CARE PROFESSIONAL.—
15 The term “treating health care professional” means,
16 with respect to services to be provided to a partici-
17 pant, beneficiary, or enrollee, a health care profes-
18 sional who is primarily responsible for delivering
19 those services to the participant, beneficiary, or en-
20 rollee.

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

22 (a) RIGHT TO INTERNAL APPEAL.—

23 (1) IN GENERAL.—A participant, beneficiary, or
24 enrollee (or authorized representative) may appeal

1 any denial of a claim for benefits under section 102
2 under the procedures described in this section.

3 (2) TIME FOR APPEAL.—

4 (A) IN GENERAL.—A group health plan,
5 and a health insurance issuer offering health in-
6 surance coverage, shall ensure that a partici-
7 pant, beneficiary, or enrollee (or authorized rep-
8 resentative) has a period of not less than 180
9 days beginning on the date of a denial of a
10 claim for benefits under section 102 in which to
11 appeal such denial under this section.

12 (B) DATE OF DENIAL.—For purposes of
13 subparagraph (A), the date of the denial shall
14 be deemed to be the date as of which the partici-
15 pant, beneficiary, or enrollee knew of the denial
16 of the claim for benefits.

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

23 (4) PLAN WAIVER OF INTERNAL REVIEW.—A
24 group health plan, or health insurance issuer offer-
25 ing health insurance coverage, may waive the inter-

1 nal review process under this section. In such case
2 the plan or issuer shall provide notice to the partici-
3 pant, beneficiary, or enrollee (or authorized rep-
4 resentative) involved, the participant, beneficiary, or
5 enrollee (or authorized representative) involved shall
6 be relieved of any obligation to complete the internal
7 review involved, and may, at the option of such par-
8 ticipant, beneficiary, enrollee, or representative pro-
9 ceed directly to seek further appeal through external
10 review under section 104 or otherwise.

11 (b) TIMELINES FOR MAKING DETERMINATIONS.—

12 (1) ORAL REQUESTS.—In the case of an appeal
13 of a denial of a claim for benefits under this section
14 that involves an expedited or concurrent determina-
15 tion, a participant, beneficiary, or enrollee (or au-
16 thorized representative) may request such appeal
17 orally. A group health plan, or health insurance
18 issuer offering health insurance coverage, may re-
19 quire that the participant, beneficiary, or enrollee
20 (or authorized representative) provide written con-
21 firmation of such request in a timely manner on a
22 form provided by the plan or issuer. In the case of
23 such an oral request for an appeal of a denial, the
24 making of the request (and the timing of such re-
25 quest) shall be treated as the making at that time

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

4 (2) ACCESS TO INFORMATION.—

5 (A) TIMELY PROVISION OF NECESSARY IN-
6 FORMATION.—With respect to an appeal of a
7 denial of a claim for benefits, the participant,
8 beneficiary, or enrollee (or authorized represent-
9 ative) and the treating health care professional
10 (if any) shall provide the plan or issuer with
11 access to information requested by the plan or
12 issuer that is necessary to make a determina-
13 tion relating to the appeal. Such access shall
14 be provided not later than 5 days after the date
15 on which the request for information is re-
16 ceived, or, in a case described in subparagraph
17 (B) or (C) of paragraph (3), by such earlier
18 time as may be necessary to comply with the
19 applicable timeline under such subparagraph.

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

1 the medical exigencies of the case and as soon
2 as possible, based on the available information,
3 and failure to comply with the time limit estab-
4 lished by this paragraph shall not remove the
5 obligation of the plan or issuer to comply with
6 the requirements of this section.

7 (3) PRIOR AUTHORIZATION DETERMINA-
8 TIONS.—

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

23 (B) EXPEDITED DETERMINATION.—Not-
24 withstanding subparagraph (A), a group health
25 plan, and a health insurance issuer offering

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

21 (C) ONGOING CARE DETERMINATIONS.—

22 (i) IN GENERAL.—Subject to clause
23 (ii), in the case of a concurrent review de-
24 termination described in section
25 102(b)(1)(C)(i)(I), which results in a ter-

1 mination or reduction of such care, the
2 plan or issuer must provide notice of the
3 determination on the appeal under this
4 section by telephone and in printed form to
5 the individual or the individual's designee
6 and the individual's health care provider in
7 accordance with the medical exigencies of
8 the case and as soon as possible, with suf-
9 ficient time prior to the termination or re-
10 duction to allow for an external appeal
11 under section 104 to be completed before
12 the termination or reduction takes effect.

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

18 (4) RETROSPECTIVE DETERMINATION.—A
19 group health plan, and a health insurance issuer of-
20 fering health insurance coverage, shall make a retro-
21 spective determination on an appeal of a denial of a
22 claim for benefits in no case later than 30 days after
23 the date on which the plan or issuer receives nec-
24 essary information that is reasonably necessary to
25 enable the plan or issuer to make a determination on

1 the appeal and in no case later than 60 days after
2 the date the request for the appeal is received.

3 (c) CONDUCT OF REVIEW.—

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

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

14 (A) shall be made by a physician
15 (allopathic or osteopathic); or

16 (B) in a claim for benefits provided by a
17 non-physician health professional, shall be made
18 by reviewer (or reviewers) including at least one
19 practicing non-physician health professional of
20 the same or similar specialty;

21 with appropriate expertise (including, in the case of
22 a child, appropriate pediatric expertise) and acting
23 within the appropriate scope of practice within the
24 State in which the service is provided or rendered,
25 who was not involved in the initial determination.

1 (d) NOTICE OF DETERMINATION.—

2 (1) IN GENERAL.—Written notice of a deter-
3 mination made under an internal appeal of a denial
4 of a claim for benefits shall be issued to the partici-
5 pant, beneficiary, or enrollee (or authorized rep-
6 resentative) and the treating health care professional
7 in accordance with the medical exigencies of the case
8 and as soon as possible, but in no case later than
9 2 days after the date of completion of the review (or,
10 in the case described in subparagraph (B) or (C) of
11 subsection (b)(3), within the 72-hour or applicable
12 period referred to in such subparagraph).

13 (2) FINAL DETERMINATION.—The decision by a
14 plan or issuer under this section shall be treated as
15 the final determination of the plan or issuer on a de-
16 nial of a claim for benefits. The failure of a plan or
17 issuer to issue a determination on an appeal of a de-
18 nial of a claim for benefits under this section within
19 the applicable timeline established for such a deter-
20 mination shall be treated as a final determination on
21 an appeal of a denial of a claim for benefits for pur-
22 poses of proceeding to external review under section
23 104.

24 (3) REQUIREMENTS OF NOTICE.—With respect
25 to a determination made under this section, the no-

1 tice described in paragraph (1) shall be provided in
2 printed form and written in a manner calculated to
3 be understood by the participant, beneficiary, or en-
4 rollee and shall include—

5 (A) the specific reasons for the determina-
6 tion (including a summary of the clinical or sci-
7 entific evidence used in making the determina-
8 tion);

9 (B) the procedures for obtaining additional
10 information concerning the determination; and

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

14 **SEC. 104. INDEPENDENT EXTERNAL APPEALS PROCE-**
15 **DURES.**

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

22 (b) **INITIATION OF THE INDEPENDENT EXTERNAL**
23 **REVIEW PROCESS.**—

24 (1) **TIME TO FILE.**—A request for an inde-
25 pendent external review under this section shall be

1 filed with the plan or issuer not later than 180 days
2 after the date on which the participant, beneficiary,
3 or enrollee receives notice of the denial under section
4 103(d) or notice of waiver of internal review under
5 section 103(a)(4) or the date on which the plan or
6 issuer has failed to make a timely decision under
7 section 103(d)(2) and notifies the participant or
8 beneficiary that it has failed to make a timely deci-
9 sion and that the beneficiary must file an appeal
10 with an external review entity within 180 days if the
11 participant or beneficiary desires to file such an ap-
12 peal.

13 (2) FILING OF REQUEST.—

14 (A) IN GENERAL.—Subject to the suc-
15 ceeding provisions of this subsection, a group
16 health plan, or health insurance issuer offering
17 health insurance coverage, may—

18 (i) except as provided in subparagraph

19 (B)(i), require that a request for review be
20 in writing;

21 (ii) limit the filing of such a request
22 to the participant, beneficiary, or enrollee
23 involved (or an authorized representative);

24 (iii) except if waived by the plan or
25 issuer under section 103(a)(4), condition

1 access to an independent external review
2 under this section upon a final determina-
3 tion of a denial of a claim for benefits
4 under the internal review procedure under
5 section 103;

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

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

19 (B) REQUIREMENTS AND EXCEPTION RE-
20 LATING TO GENERAL RULE.—

21 (i) ORAL REQUESTS PERMITTED IN
22 EXPEDITED OR CONCURRENT CASES.—In
23 the case of an expedited or concurrent ex-
24 ternal review as provided for under sub-
25 section (e), the request for such review

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

18 (ii) EXCEPTION TO FILING FEE RE-
19 QUIREMENT.—

20 (I) INDIGENCY.—Payment of a
21 filing fee shall not be required under
22 subparagraph (A)(iv) where there is a
23 certification (in a form and manner
24 specified in guidelines established by
25 the appropriate Secretary) that the

1 participant, beneficiary, or enrollee is
2 indigent (as defined in such guide-
3 lines).

4 (II) FEE NOT REQUIRED.—Pay-
5 ment of a filing fee shall not be re-
6 quired under subparagraph (A)(iv) if
7 the plan or issuer waives the internal
8 appeals process under section
9 103(a)(4).

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

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

23 (c) REFERRAL TO QUALIFIED EXTERNAL REVIEW
24 ENTITY UPON REQUEST.—

1 (1) IN GENERAL.—Upon the filing of a request
2 for independent external review with the group
3 health plan, or health insurance issuer offering
4 health insurance coverage, the plan or issuer shall
5 immediately refer such request, and forward the
6 plan or issuer’s initial decision (including the infor-
7 mation described in section 103(d)(3)(A)), to a
8 qualified external review entity selected in accord-
9 ance with this section.

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

1 (3) SCREENING OF REQUESTS BY QUALIFIED
2 EXTERNAL REVIEW ENTITIES.—

3 (A) IN GENERAL.—With respect to a re-
4 quest referred to a qualified external review en-
5 tity under paragraph (1) relating to a denial of
6 a claim for benefits, the entity shall refer such
7 request for the conduct of an independent med-
8 ical review unless the entity determines that—

9 (i) any of the conditions described in
10 clauses (ii) or (iii) of subsection (b)(2)(A)
11 have not been met;

12 (ii) the denial of the claim for benefits
13 does not involve a medically reviewable de-
14 cision under subsection (d)(2);

15 (iii) the denial of the claim for bene-
16 fits relates to a decision regarding whether
17 an individual is a participant, beneficiary,
18 or enrollee who is enrolled under the terms
19 and conditions of the plan or coverage (in-
20 cluding the applicability of any waiting pe-
21 riod under the plan or coverage); or

22 (iv) the denial of the claim for bene-
23 fits is a decision as to the application of
24 cost-sharing requirements or the applica-
25 tion of a specific exclusion or express limi-

1 tation on the amount, duration, or scope of
2 coverage of items or services under the
3 terms and conditions of the plan or cov-
4 erage unless the decision is a denial de-
5 scribed in subsection (d)(2).

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

13 (B) PROCESS FOR MAKING DETERMINA-
14 TIONS.—

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

22 (ii) USE OF APPROPRIATE PER-
23 SONNEL.—A qualified external review enti-
24 ty shall use appropriately qualified per-

1 sonnel to make determinations under this
2 section.

3 (C) NOTICES AND GENERAL TIMELINES
4 FOR DETERMINATION.—

5 (i) NOTICE IN CASE OF DENIAL OF
6 REFERRAL.—If the entity under this para-
7 graph does not make a referral to an inde-
8 pendent medical reviewer, the entity shall
9 provide notice to the plan or issuer, the
10 participant, beneficiary, or enrollee (or au-
11 thorized representative) filing the request,
12 and the treating health care professional
13 (if any) that the denial is not subject to
14 independent medical review. Such notice—

15 (I) shall be written (and, in addi-
16 tion, may be provided orally) in a
17 manner calculated to be understood
18 by a participant or enrollee;

19 (II) shall include the reasons for
20 the determination;

21 (III) include any relevant terms
22 and conditions of the plan or cov-
23 erage; and

1 (IV) include a description of any
2 further recourse available to the indi-
3 vidual.

4 (ii) GENERAL TIMELINE FOR DETER-
5 MINATIONS.—Upon receipt of information
6 under paragraph (2), the qualified external
7 review entity, and if required the inde-
8 pendent medical reviewer, shall make a de-
9 termination within the overall timeline that
10 is applicable to the case under review as
11 described in subsection (e), except that if
12 the entity determines that a referral to an
13 independent medical reviewer is not re-
14 quired, the entity shall provide notice of
15 such determination to the participant, ben-
16 eficiary, or enrollee (or authorized rep-
17 resentative) within such timeline and with-
18 in 2 days of the date of such determina-
19 tion.

20 (d) INDEPENDENT MEDICAL REVIEW.—

21 (1) IN GENERAL.—If a qualified external review
22 entity determines under subsection (c) that a denial
23 of a claim for benefits is eligible for independent
24 medical review, the entity shall refer the denial in-
25 volved to an independent medical reviewer for the

1 conduct of an independent medical review under this
2 subsection.

3 (2) MEDICALLY REVIEWABLE DECISIONS.—A
4 denial of a claim for benefits is eligible for inde-
5 pendent medical review if the benefit for the item or
6 service for which the claim is made would be a cov-
7 ered benefit under the terms and conditions of the
8 plan or coverage but for one (or more) of the fol-
9 lowing determinations:

10 (A) DENIALS BASED ON MEDICAL NECES-
11 SITY AND APPROPRIATENESS.—A determination
12 that the item or service is not covered because
13 it is not medically necessary and appropriate or
14 based on the application of substantially equiva-
15 lent terms.

16 (B) DENIALS BASED ON EXPERIMENTAL
17 OR INVESTIGATIONAL TREATMENT.—A deter-
18 mination that the item or service is not covered
19 because it is experimental or investigational or
20 based on the application of substantially equiva-
21 lent terms.

22 (C) DENIALS OTHERWISE BASED ON AN
23 EVALUATION OF MEDICAL FACTS.—A deter-
24 mination that the item or service or condition
25 is not covered based on grounds that require an

1 evaluation of the medical facts by a health care
2 professional in the specific case involved to de-
3 termine the coverage and extent of coverage of
4 the item or service or condition.

5 (3) INDEPENDENT MEDICAL REVIEW DETER-
6 MINATION.—

7 (A) IN GENERAL.—An independent med-
8 ical reviewer under this section shall make a
9 new independent determination with respect to
10 whether or not the denial of a claim for a ben-
11 efit that is the subject of the review should be
12 upheld, reversed, or modified.

13 (B) STANDARD FOR DETERMINATION.—
14 The independent medical reviewer's determina-
15 tion relating to the medical necessity and ap-
16 propriateness, or the experimental or investiga-
17 tional nature, or the evaluation of the medical
18 facts, of the item, service, or condition involved
19 shall be based on the medical condition of the
20 participant, beneficiary, or enrollee (including
21 the medical records of the participant, bene-
22 ficiary, or enrollee) and valid, relevant scientific
23 evidence and clinical evidence, including peer-re-
24 viewed medical literature or findings and in-
25 cluding expert opinion.

1 (C) NO COVERAGE FOR EXCLUDED BENE-
2 FITS.—Nothing in this subsection shall be con-
3 strued to permit an independent medical re-
4 viewer to require that a group health plan, or
5 health insurance issuer offering health insur-
6 ance coverage, provide coverage for items or
7 services for which benefits are specifically ex-
8 cluded or expressly limited under the plan or
9 coverage in the plain language of the plan docu-
10 ment (and which are disclosed under section
11 121(b)(1)(C)). Notwithstanding any other pro-
12 vision of this Act, any exclusion of an exact
13 medical procedure, any exact time limit on the
14 duration or frequency of coverage, and any
15 exact dollar limit on the amount of coverage
16 that is specifically enumerated and defined (in
17 the plain language of the plan or coverage docu-
18 ments) under the plan or coverage offered by a
19 group health plan or health insurance issuer of-
20 fering health insurance coverage and that is
21 disclosed under section 121(b)(1) shall be con-
22 sidered to govern the scope of the benefits that
23 may be required: *Provided*, That the terms and
24 conditions of the plan or coverage relating to

1 such an exclusion or limit are in compliance
2 with the requirements of law.

3 (D) EVIDENCE AND INFORMATION TO BE
4 USED IN MEDICAL REVIEWS.—In making a de-
5 termination under this subsection, the inde-
6 pendent medical reviewer shall also consider ap-
7 propriate and available evidence and informa-
8 tion, including the following:

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

14 (ii) The recommendation of the treat-
15 ing health care professional and the evi-
16 dence, guidelines, and rationale used by
17 the treating health care professional in
18 reaching such recommendation.

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

25 (iv) The plan or coverage document.

1 (E) INDEPENDENT DETERMINATION.—In
2 making determinations under this section, a
3 qualified external review entity and an inde-
4 pendent medical reviewer shall—

5 (i) consider the claim under review
6 without deference to the determinations
7 made by the plan or issuer or the rec-
8 ommendation of the treating health care
9 professional (if any); and

10 (ii) consider, but not be bound by, the
11 definition used by the plan or issuer of
12 “medically necessary and appropriate”, or
13 “experimental or investigational”, or other
14 substantially equivalent terms that are
15 used by the plan or issuer to describe med-
16 ical necessity and appropriateness or ex-
17 perimental or investigational nature of the
18 treatment.

19 (F) DETERMINATION OF INDEPENDENT
20 MEDICAL REVIEWER.—An independent medical
21 reviewer shall, in accordance with the deadlines
22 described in subsection (e), prepare a written
23 determination to uphold, reverse, or modify the
24 denial under review. Such written determination
25 shall include—

- 1 (i) the determination of the reviewer;
2 (ii) the specific reasons of the re-
3 viewer for such determination, including a
4 summary of the clinical or scientific evi-
5 dence used in making the determination;
6 and
7 (iii) with respect to a determination to
8 reverse or modify the denial under review,
9 a timeframe within which the plan or
10 issuer must comply with such determina-
11 tion.

12 (G) NONBINDING NATURE OF ADDITIONAL
13 RECOMMENDATIONS.—In addition to the deter-
14 mination under subparagraph (F), the reviewer
15 may provide the plan or issuer and the treating
16 health care professional with additional rec-
17 ommendations in connection with such a deter-
18 mination, but any such recommendations shall
19 not affect (or be treated as part of) the deter-
20 mination and shall not be binding on the plan
21 or issuer.

22 (e) TIMELINES AND NOTIFICATIONS.—

23 (1) TIMELINES FOR INDEPENDENT MEDICAL
24 REVIEW.—

1 (A) PRIOR AUTHORIZATION DETERMINA-
2 TION.—

3 (i) IN GENERAL.—The independent
4 medical reviewer (or reviewers) shall make
5 a determination on a denial of a claim for
6 benefits that is referred to the reviewer
7 under subsection (c)(3) in accordance with
8 the medical exigencies of the case and as
9 soon as possible, but in no case later than
10 14 days after the date of receipt of infor-
11 mation under subsection (c)(2) if the re-
12 view involves a prior authorization of items
13 or services and in no case later than 21
14 days after the date the request for external
15 review is received.

16 (ii) EXPEDITED DETERMINATION.—
17 Notwithstanding clause (i) and subject to
18 clause (iii), the independent medical re-
19 viewer (or reviewers) shall make an expe-
20 dited determination on a denial of a claim
21 for benefits described in clause (i), when a
22 request for such an expedited determina-
23 tion is made by a participant, beneficiary,
24 or enrollee (or authorized representative)
25 at any time during the process for making

1 a determination, and a health care profes-
2 sional certifies, with the request, that a de-
3 termination under the timeline described in
4 clause (i) would seriously jeopardize the
5 life or health of the participant, bene-
6 ficiary, or enrollee or the ability of the par-
7 ticipant, beneficiary, or enrollee to main-
8 tain or regain maximum function. Such de-
9 termination shall be made in accordance
10 with the medical exigencies of the case and
11 as soon as possible, but in no case later
12 than 72 hours after the time the request
13 for external review is received by the quali-
14 fied external review entity.

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

1 (B) RETROSPECTIVE DETERMINATION.—

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

12 (2) NOTIFICATION OF DETERMINATION.—The
13 external review entity shall ensure that the plan or
14 issuer, the participant, beneficiary, or enrollee (or
15 authorized representative) and the treating health
16 care professional (if any) receives a copy of the writ-
17 ten determination of the independent medical re-
18 viewer prepared under subsection (d)(3)(F). Nothing
19 in this paragraph shall be construed as preventing
20 an entity or reviewer from providing an initial oral
21 notice of the reviewer's determination.

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

25 (f) COMPLIANCE.—

1 (1) APPLICATION OF DETERMINATIONS.—

2 (A) EXTERNAL REVIEW DETERMINATIONS
3 BINDING ON PLAN.—The determinations of an
4 external review entity and an independent med-
5 ical reviewer under this section shall be binding
6 upon the plan or issuer involved.

7 (B) COMPLIANCE WITH DETERMINA-
8 TION.—If the determination of an independent
9 medical reviewer is to reverse or modify the de-
10 nial, the plan or issuer, upon the receipt of such
11 determination, shall authorize coverage to com-
12 ply with the medical reviewer’s determination in
13 accordance with the timeframe established by
14 the medical reviewer.

15 (2) FAILURE TO COMPLY.—

16 (A) IN GENERAL.—If a plan or issuer fails
17 to comply with the timeframe established under
18 paragraph (1)(B) with respect to a participant,
19 beneficiary, or enrollee, where such failure to
20 comply is caused by the plan or issuer, the par-
21 ticipant, beneficiary, or enrollee may obtain the
22 items or services involved (in a manner con-
23 sistent with the determination of the inde-
24 pendent external reviewer) from any provider

1 regardless of whether such provider is a partici-
2 pating provider under the plan or coverage.

3 (B) REIMBURSEMENT.—

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

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

1 (C) FAILURE TO REIMBURSE.—Where a
2 plan or issuer fails to provide reimbursement to
3 a professional, participant, beneficiary, or en-
4 rollee in accordance with this paragraph, the
5 professional, participant, beneficiary, or enrollee
6 may commence a civil action (or utilize other
7 remedies available under law) to recover only
8 the amount of any such reimbursement that is
9 owed by the plan or issuer and any necessary
10 legal costs or expenses (including attorney’s
11 fees) incurred in recovering such reimburse-
12 ment.

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

16 (3) PENALTIES AGAINST AUTHORIZED OFFI-
17 CIALS FOR REFUSING TO AUTHORIZE THE DETER-
18 MINATION OF AN EXTERNAL REVIEW ENTITY.—

19 (A) MONETARY PENALTIES.—

20 (i) IN GENERAL.—In any case in
21 which the determination of an external re-
22 view entity is not followed by a group
23 health plan, or by a health insurance issuer
24 offering health insurance coverage, any
25 person who, acting in the capacity of au-

1 thorizing the benefit, causes such refusal
2 may, in the discretion of a court of com-
3 petent jurisdiction, be liable to an ag-
4 grieved participant, beneficiary, or enrollee
5 for a civil penalty in an amount of up to
6 \$1,000 a day from the date on which the
7 determination was transmitted to the plan
8 or issuer by the external review entity until
9 the date the refusal to provide the benefit
10 is corrected.

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

20 (B) CEASE AND DESIST ORDER AND
21 ORDER OF ATTORNEY’S FEES.—In any action
22 described in subparagraph (A) brought by a
23 participant, beneficiary, or enrollee with respect
24 to a group health plan, or a health insurance
25 issuer offering health insurance coverage, in

1 which a plaintiff alleges that a person referred
2 to in such subparagraph has taken an action re-
3 sulting in a refusal of a benefit determined by
4 an external appeal entity to be covered, or has
5 failed to take an action for which such person
6 is responsible under the terms and conditions of
7 the plan or coverage and which is necessary
8 under the plan or coverage for authorizing a
9 benefit, the court shall cause to be served on
10 the defendant an order requiring the
11 defendant—

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

14 (ii) to pay to the plaintiff a reasonable
15 attorney's fee and other reasonable costs
16 relating to the prosecution of the action on
17 the charges on which the plaintiff prevails.

18 (C) ADDITIONAL CIVIL PENALTIES.—

19 (i) IN GENERAL.—In addition to any
20 penalty imposed under subparagraph (A)
21 or (B), the appropriate Secretary may as-
22 sess a civil penalty against a person acting
23 in the capacity of authorizing a benefit de-
24 termined by an external review entity for
25 one or more group health plans, or health

1 insurance issuers offering health insurance
2 coverage, for—

3 (I) any pattern or practice of re-
4 peated refusal to authorize a benefit
5 determined by an external appeal enti-
6 ty to be covered; or

7 (II) any pattern or practice of re-
8 peated violations of the requirements
9 of this section with respect to such
10 plan or coverage.

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

17 (I) 25 percent of the aggregate
18 value of benefits shown by the appro-
19 priate Secretary to have not been pro-
20 vided, or unlawfully delayed, in viola-
21 tion of this section under such pattern
22 or practice; or

23 (II) \$500,000.

24 (D) REMOVAL AND DISQUALIFICATION.—

25 Any person acting in the capacity of author-

1 izing benefits who has engaged in any such pat-
2 tern or practice described in subparagraph
3 (C)(i) with respect to a plan or coverage, upon
4 the petition of the appropriate Secretary, may
5 be removed by the court from such position,
6 and from any other involvement, with respect to
7 such a plan or coverage, and may be precluded
8 from returning to any such position or involve-
9 ment for a period determined by the court.

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

18 (g) QUALIFICATIONS OF INDEPENDENT MEDICAL
19 REVIEWERS.—

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

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

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

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

9 (2) LICENSURE AND EXPERTISE.—Each inde-
10 pendent medical reviewer shall be a physician
11 (allopathic or osteopathic) or health care profes-
12 sional who—

13 (A) is appropriately credentialed or li-
14 censed in 1 or more States to deliver health
15 care services; and

16 (B) typically treats the condition, makes
17 the diagnosis, or provides the type of treatment
18 under review.

19 (3) INDEPENDENCE.—

20 (A) IN GENERAL.—Subject to subpara-
21 graph (B), each independent medical reviewer
22 in a case shall—

23 (i) not be a related party (as defined
24 in paragraph (7));

1 (ii) not have a material familial, fi-
2 nancial, or professional relationship with
3 such a party; and

4 (iii) not otherwise have a conflict of
5 interest with such a party (as determined
6 under regulations).

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

9 (i) prohibit an individual, solely on the
10 basis of affiliation with the plan or issuer,
11 from serving as an independent medical re-
12 viewer if—

13 (I) a non-affiliated individual is
14 not reasonably available;

15 (II) the affiliated individual is
16 not involved in the provision of items
17 or services in the case under review;

18 (III) the fact of such an affili-
19 ation is disclosed to the plan or issuer
20 and the participant, beneficiary, or
21 enrollee (or authorized representative)
22 and neither party objects; and

23 (IV) the affiliated individual is
24 not an employee of the plan or issuer
25 and does not provide services exclu-

1 sively or primarily to or on behalf of
2 the plan or issuer;

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

12 (iii) prohibit receipt of compensation
13 by an independent medical reviewer from
14 an entity if the compensation is provided
15 consistent with paragraph (6).

16 (4) PRACTICING HEALTH CARE PROFESSIONAL
17 IN SAME FIELD.—

18 (A) IN GENERAL.—In a case involving
19 treatment, or the provision of items or
20 services—

21 (i) by a physician, a reviewer shall be
22 a practicing physician (allopathic or osteo-
23 pathic) of the same or similar specialty, as
24 a physician who, acting within the appro-
25 priate scope of practice within the State in

1 which the service is provided or rendered,
2 typically treats the condition, makes the
3 diagnosis, or provides the type of treat-
4 ment under review; or

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

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

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

1 (6) LIMITATIONS ON REVIEWER COMPENSA-
2 TION.—Compensation provided by a qualified exter-
3 nal review entity to an independent medical reviewer
4 in connection with a review under this section
5 shall—

6 (A) not exceed a reasonable level; and

7 (B) not be contingent on the decision ren-
8 dered by the reviewer.

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

14 (A) The plan, plan sponsor, or issuer in-
15 volved, or any fiduciary, officer, director, or em-
16 ployee of such plan, plan sponsor, or issuer.

17 (B) The participant, beneficiary, or en-
18 rollee (or authorized representative).

19 (C) The health care professional that pro-
20 vides the items or services involved in the de-
21 nial.

22 (D) The institution at which the items or
23 services (or treatment) involved in the denial
24 are provided.

1 (E) The manufacturer of any drug or
2 other item that is included in the items or serv-
3 ices involved in the denial.

4 (F) Any other party determined under any
5 regulations to have a substantial interest in the
6 denial involved.

7 (h) QUALIFIED EXTERNAL REVIEW ENTITIES.—

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

10 (A) LIMITATION ON PLAN OR ISSUER SE-
11 LECTION.—The appropriate Secretary shall im-
12 plement procedures—

13 (i) to assure that the selection process
14 among qualified external review entities
15 will not create any incentives for external
16 review entities to make a decision in a bi-
17 ased manner; and

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

21 No such selection process under the procedures
22 implemented by the appropriate Secretary may
23 give either the patient or the plan or issuer any
24 ability to determine or influence the selection of

1 a qualified external review entity to review the
2 case of any participant, beneficiary, or enrollee.

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

13 (2) CONTRACT WITH QUALIFIED EXTERNAL RE-
14 VIEW ENTITY.—Except as provided in paragraph
15 (1)(B), the external review process of a plan or
16 issuer under this section shall be conducted under a
17 contract between the plan or issuer and 1 or more
18 qualified external review entities (as defined in para-
19 graph (4)(A)).

20 (3) TERMS AND CONDITIONS OF CONTRACT.—
21 The terms and conditions of a contract under para-
22 graph (2) shall—

23 (A) be consistent with the standards the
24 appropriate Secretary shall establish to assure

1 there is no real or apparent conflict of interest
2 in the conduct of external review activities; and

3 (B) provide that the costs of the external
4 review process shall be borne by the plan or
5 issuer.

6 Subparagraph (B) shall not be construed as apply-
7 ing to the imposition of a filing fee under subsection
8 (b)(2)(A)(iv) or costs incurred by the participant,
9 beneficiary, or enrollee (or authorized representative)
10 or treating health care professional (if any) in sup-
11 port of the review, including the provision of addi-
12 tional evidence or information.

13 (4) QUALIFICATIONS.—

14 (A) IN GENERAL.—In this section, the
15 term “qualified external review entity” means,
16 in relation to a plan or issuer, an entity that is
17 initially certified (and periodically recertified)
18 under subparagraph (C) as meeting the fol-
19 lowing requirements:

20 (i) The entity has (directly or through
21 contracts or other arrangements) sufficient
22 medical, legal, and other expertise and suf-
23 ficient staffing to carry out duties of a
24 qualified external review entity under this
25 section on a timely basis, including making

1 determinations under subsection (b)(2)(A)
2 and providing for independent medical re-
3 views under subsection (d).

4 (ii) The entity is not a plan or issuer
5 or an affiliate or a subsidiary of a plan or
6 issuer, and is not an affiliate or subsidiary
7 of a professional or trade association of
8 plans or issuers or of health care providers.

9 (iii) The entity has provided assur-
10 ances that it will conduct external review
11 activities consistent with the applicable re-
12 quirements of this section and standards
13 specified in subparagraph (C), including
14 that it will not conduct any external review
15 activities in a case unless the independence
16 requirements of subparagraph (B) are met
17 with respect to the case.

18 (iv) The entity has provided assur-
19 ances that it will provide information in a
20 timely manner under subparagraph (D).

21 (v) The entity meets such other re-
22 quirements as the appropriate Secretary
23 provides by regulation.

24 (B) INDEPENDENCE REQUIREMENTS.—

1 (i) IN GENERAL.—Subject to clause
2 (ii), an entity meets the independence re-
3 quirements of this subparagraph with re-
4 spect to any case if the entity—

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

7 (II) does not have a material fa-
8 miliary, financial, or professional rela-
9 tionship with such a party; and

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

13 (ii) EXCEPTION FOR REASONABLE
14 COMPENSATION.—Nothing in clause (i)
15 shall be construed to prohibit receipt by a
16 qualified external review entity of com-
17 pensation from a plan or issuer for the
18 conduct of external review activities under
19 this section if the compensation is provided
20 consistent with clause (iii).

21 (iii) LIMITATIONS ON ENTITY COM-
22 PENSATION.—Compensation provided by a
23 plan or issuer to a qualified external review
24 entity in connection with reviews under
25 this section shall—

- 1 (I) not exceed a reasonable level;
2 and
3 (II) not be contingent on any de-
4 cision rendered by the entity or by
5 any independent medical reviewer.

6 (C) CERTIFICATION AND RECERTIFICATION
7 PROCESS.—

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

11 (I) under a process that is recog-
12 nized or approved by the appropriate
13 Secretary; or

14 (II) by a qualified private stand-
15 ard-setting organization that is ap-
16 proved by the appropriate Secretary
17 under clause (iii).

18 In taking action under subclause (I), the
19 appropriate Secretary shall give deference
20 to entities that are under contract with the
21 Federal Government or with an applicable
22 State authority to perform functions of the
23 type performed by qualified external review
24 entities.

1 (ii) PROCESS.—The appropriate Sec-
2 retary shall not recognize or approve a
3 process under clause (i)(I) unless the proc-
4 ess applies standards (as promulgated in
5 regulations) that ensure that a qualified
6 external review entity—

7 (I) will carry out (and has car-
8 ried out, in the case of recertification)
9 the responsibilities of such an entity
10 in accordance with this section, in-
11 cluding meeting applicable deadlines;

12 (II) will meet (and has met, in
13 the case of recertification) appropriate
14 indicators of fiscal integrity;

15 (III) will maintain (and has
16 maintained, in the case of recertifi-
17 cation) appropriate confidentiality
18 with respect to individually identifi-
19 able health information obtained in
20 the course of conducting external re-
21 view activities; and

22 (IV) in the case of recertification,
23 shall review the matters described in
24 clause (iv).

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

12 (iv) CONSIDERATIONS IN RECERTIFI-
13 CATIONS.—In conducting recertifications of
14 a qualified external review entity under
15 this paragraph, the appropriate Secretary
16 or organization conducting the recertifi-
17 cation shall review compliance of the entity
18 with the requirements for conducting ex-
19 ternal review activities under this section,
20 including the following:

21 (I) Provision of information
22 under subparagraph (D).

23 (II) Adherence to applicable
24 deadlines (both by the entity and by

1 independent medical reviewers it re-
2 fers cases to).

3 (III) Compliance with limitations
4 on compensation (with respect to both
5 the entity and independent medical re-
6 viewers it refers cases to).

7 (IV) Compliance with applicable
8 independence requirements.

9 (V) Compliance with the require-
10 ment of subsection (d)(1) that only
11 medically reviewable decisions shall be
12 the subject of independent medical re-
13 view and with the requirement of sub-
14 section (d)(3) that independent med-
15 ical reviewers may not require cov-
16 erage for specifically excluded bene-
17 fits.

18 (v) PERIOD OF CERTIFICATION OR RE-
19 CERTIFICATION.—A certification or recer-
20 tification provided under this paragraph
21 shall extend for a period not to exceed 2
22 years.

23 (vi) REVOCATION.—A certification or
24 recertification under this paragraph may
25 be revoked by the appropriate Secretary or

1 by the organization providing such certifi-
2 cation upon a showing of cause. The Sec-
3 retary, or organization, shall revoke a cer-
4 tification or deny a recertification with re-
5 spect to an entity if there is a showing that
6 the entity has a pattern or practice of or-
7 dering coverage for benefits that are spe-
8 cifically excluded under the plan or cov-
9 erage.

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

19 (viii) SUFFICIENT NUMBER OF ENTI-
20 TIES.—The appropriate Secretary shall
21 certify and recertify a number of external
22 review entities which is sufficient to ensure
23 the timely and efficient provision of review
24 services.

25 (D) PROVISION OF INFORMATION.—

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

18 (ii) INFORMATION TO BE IN-
19 CLUDED.—The information described in
20 this subclause with respect to an entity is
21 as follows:

22 (I) The number and types of de-
23 nials for which a request for review
24 has been received by the entity.

1 (II) The disposition by the entity
2 of such denials, including the number
3 referred to a independent medical re-
4 viewer and the reasons for such dis-
5 positions (including the application of
6 exclusions), on a plan or issuer-spe-
7 cific basis and on a health care spe-
8 cialty-specific basis.

9 (III) The length of time in mak-
10 ing determinations with respect to
11 such denials.

12 (IV) Updated information on the
13 information required to be submitted
14 as a condition of certification with re-
15 spect to the entity's performance of
16 external review activities.

17 (iii) INFORMATION TO BE PROVIDED
18 TO CERTIFYING ORGANIZATION.—

19 (I) IN GENERAL.—In the case of
20 a qualified external review entity
21 which is certified (or recertified)
22 under this subsection by a qualified
23 private standard-setting organization,
24 at the request of the organization, the
25 entity shall provide the organization

1 with the information provided to the
2 appropriate Secretary under clause
3 (i).

4 (II) ADDITIONAL INFORMA-
5 TION.—Nothing in this subparagraph
6 shall be construed as preventing such
7 an organization from requiring addi-
8 tional information as a condition of
9 certification or recertification of an
10 entity.

11 (iv) USE OF INFORMATION.—Informa-
12 tion provided under this subparagraph may
13 be used by the appropriate Secretary and
14 qualified private standard-setting organiza-
15 tions to conduct oversight of qualified ex-
16 ternal review entities, including recertifi-
17 cation of such entities, and shall be made
18 available to the public in an appropriate
19 manner.

20 (E) LIMITATION ON LIABILITY.—No quali-
21 fied external review entity having a contract
22 with a plan or issuer, and no person who is em-
23 ployed by any such entity or who furnishes pro-
24 fessional services to such entity (including as an
25 independent medical reviewer), shall be held by

1 reason of the performance of any duty, func-
2 tion, or activity required or authorized pursuant
3 to this section, to be civilly liable under any law
4 of the United States or of any State (or polit-
5 ical subdivision thereof) if there was no actual
6 malice or gross misconduct in the performance
7 of such duty, function, or activity.

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

13 (A) the information that is provided under
14 paragraph (3)(D);

15 (B) the number of denials that have been
16 upheld by independent medical reviewers and
17 the number of denials that have been reversed
18 by such reviewers; and

19 (C) the extent to which independent med-
20 ical reviewers are requiring coverage for bene-
21 fits that are specifically excluded under the plan
22 or coverage.

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

24 (a) GRANTS.—

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

10 (2) STATE ELIGIBILITY.—To be eligible to re-
11 ceive a grant under this subsection a State shall pre-
12 pare and submit to the Secretary an application at
13 such time, in such manner, and containing such in-
14 formation as the Secretary may require, including a
15 State plan that describes—

16 (A) the manner in which the State will en-
17 sure that the health care consumer assistance
18 office (established under paragraph (4)) will
19 educate and assist health care consumers in ac-
20 cessing needed care;

21 (B) the manner in which the State will co-
22 ordinate and distinguish the services provided
23 by the health care consumer assistance office
24 with the services provided by Federal, State and
25 local health-related ombudsman, information,

1 protection and advocacy, insurance, and fraud
2 and abuse programs;

3 (C) the manner in which the State will
4 provide information, outreach, and services to
5 underserved, minority populations with limited
6 English proficiency and populations residing in
7 rural areas;

8 (D) the manner in which the State will
9 oversee the health care consumer assistance of-
10 fice, its activities, product materials and evalu-
11 ate program effectiveness;

12 (E) the manner in which the State will en-
13 sure that funds made available under this sec-
14 tion will be used to supplement, and not sup-
15 plant, any other Federal, State, or local funds
16 expended to provide services for programs de-
17 scribed under this section and those described
18 in subparagraphs (C) and (D);

19 (F) the manner in which the State will en-
20 sure that health care consumer office personnel
21 have the professional background and training
22 to carry out the activities of the office; and

23 (G) the manner in which the State will en-
24 sure that consumers have direct access to con-

1 sumer assistance personnel during regular busi-
2 ness hours.

3 (3) AMOUNT OF GRANT.—

4 (A) IN GENERAL.—From amounts appro-
5 priated under subsection (b) for a fiscal year,
6 the Secretary shall award a grant to a State in
7 an amount that bears the same ratio to such
8 amounts as the number of individuals within
9 the State covered under a group health plan or
10 under health insurance coverage offered by a
11 health insurance issuer bears to the total num-
12 ber of individuals so covered in all States (as
13 determined by the Secretary). Any amounts
14 provided to a State under this subsection that
15 are not used by the State shall be remitted to
16 the Secretary and reallocated in accordance
17 with this subparagraph.

18 (B) MINIMUM AMOUNT.—In no case shall
19 the amount provided to a State under a grant
20 under this subsection for a fiscal year be less
21 than an amount equal to 0.5 percent of the
22 amount appropriated for such fiscal year to
23 carry out this section.

24 (C) NON-FEDERAL CONTRIBUTIONS.—A
25 State will provide for the collection of non-Fed-

1 eral contributions for the operation of the office
2 in an amount that is not less than 25 percent
3 of the amount of Federal funds provided to the
4 State under this section.

5 (4) PROVISION OF FUNDS FOR ESTABLISHMENT
6 OF OFFICE.—

7 (A) IN GENERAL.—From amounts pro-
8 vided under a grant under this subsection, a
9 State shall, directly or through a contract with
10 an independent, nonprofit entity with dem-
11 onstrated experience in serving the needs of
12 health care consumers, provide for the estab-
13 lishment and operation of a State health care
14 consumer assistance office.

15 (B) ELIGIBILITY OF ENTITY.—To be eligi-
16 ble to enter into a contract under subparagraph
17 (A), an entity shall demonstrate that it has the
18 technical, organizational, and professional ca-
19 pacity to deliver the services described in sub-
20 section (b) to all public and private health in-
21 surance participants, beneficiaries, enrollees, or
22 prospective enrollees.

23 (C) EXISTING STATE ENTITY.—Nothing in
24 this section shall prevent the funding of an ex-
25 isting health care consumer assistance program

1 that otherwise meets the requirements of this
2 section.

3 (b) USE OF FUNDS.—

4 (1) BY STATE.—A State shall use amounts pro-
5 vided under a grant awarded under this section to
6 carry out consumer assistance activities directly or
7 by contract with an independent, non-profit organi-
8 zation. An eligible entity may use some reasonable
9 amount of such grant to ensure the adequate train-
10 ing of personnel carrying out such activities. To re-
11 ceive amounts under this subsection, an eligible enti-
12 ty shall provide consumer assistance services,
13 including—

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

16 (B) the dissemination of appropriate edu-
17 cational materials on available health insurance
18 products and on how best to access health care
19 and the rights and responsibilities of health
20 care consumers;

21 (C) the provision of education on effective
22 methods to promptly and efficiently resolve
23 questions, problems, and grievances;

1 (D) the coordination of educational and
2 outreach efforts with health plans, health care
3 providers, payers, and governmental agencies;

4 (E) referrals to appropriate private and
5 public entities to resolve questions, problems
6 and grievances; and

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

16 (2) CONFIDENTIALITY AND ACCESS TO INFOR-
17 MATION.—

18 (A) STATE ENTITY.—With respect to a
19 State that directly establishes a health care con-
20 sumer assistance office, such office shall estab-
21 lish and implement procedures and protocols in
22 accordance with applicable Federal and State
23 laws.

24 (B) CONTRACT ENTITY.—With respect to a
25 State that, through contract, establishes a

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

1 care providers, group health plans, or health in-
2 surance issuers with a written authorization (in
3 accordance with section 164.508 of title 45,
4 Code of Federal Regulations) to allow the office
5 to obtain medical information relevant to the
6 matter before the office.

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

19 (4) DESIGNATION OF RESPONSIBILITIES.—

20 (A) WITHIN EXISTING STATE ENTITY.—If
21 the health care consumer assistance office of a
22 State is located within an existing State regu-
23 latory agency or office of an elected State offi-
24 cial, the State shall ensure that—

1 (i) there is a separate delineation of
2 the funding, activities, and responsibilities
3 of the office as compared to the other
4 funding, activities, and responsibilities of
5 the agency; and

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

18 (B) CONTRACT ENTITY.—In the case of an
19 entity that enters into a contract with a State
20 under subsection (a)(3), the entity shall provide
21 assurances that the entity has no conflict of in-
22 terest in carrying out the activities of the office
23 and that the entity is independent of group
24 health plans, health insurance issuers, pro-
25 viders, payers, and regulators of health care.

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

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

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

16 (d) AUTHORIZATION OF APPROPRIATIONS.—There
17 are authorized to be appropriated such sums as may be
18 necessary to carry out this section.

19 **Subtitle B—Access to Care**

20 **SEC. 111. CONSUMER CHOICE OPTION.**

21 (a) IN GENERAL.—If—

22 (1) a health insurance issuer providing health
23 insurance coverage in connection with a group health
24 plan offers to enrollees health insurance coverage
25 which provides for coverage of services (including

1 physician pathology services) only if such services
2 are furnished through health care professionals and
3 providers who are members of a network of health
4 care professionals and providers who have entered
5 into a contract with the issuer to provide such serv-
6 ices, or

7 (2) a group health plan offers to participants or
8 beneficiaries health benefits which provide for cov-
9 erage of services only if such services are furnished
10 through health care professionals and providers who
11 are members of a network of health care profes-
12 sionals and providers who have entered into a con-
13 tract with the plan to provide such services,

14 then the issuer or plan shall also offer or arrange to be
15 offered to such enrollees, participants, or beneficiaries (at
16 the time of enrollment and during an annual open season
17 as provided under subsection (c)) the option of health in-
18 surance coverage or health benefits which provide for cov-
19 erage of such services which are not furnished through
20 health care professionals and providers who are members
21 of such a network unless such enrollees, participants, or
22 beneficiaries are offered such non-network coverage
23 through another group health plan or through another
24 health insurance issuer in the group market.

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

10 (c) **OPEN SEASON.**—An enrollee, participant, or ben-
11 efiary, may change to the offering provided under this
12 section only during a time period determined by the health
13 insurance issuer or group health plan. Such time period
14 shall occur at least annually.

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

16 (a) **PRIMARY CARE.**—If a group health plan, or a
17 health insurance issuer that offers health insurance cov-
18 erage, requires or provides for designation by a partici-
19 pant, beneficiary, or enrollee of a participating primary
20 care provider, then the plan or issuer shall permit each
21 participant, beneficiary, and enrollee to designate any par-
22 ticipating primary care provider who is available to accept
23 such individual.

24 (b) **SPECIALISTS.**—

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

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

14 (3) CONSTRUCTION.—Nothing in this sub-
15 section shall be construed as affecting the applica-
16 tion of section 114 (relating to access to specialty
17 care).

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

19 (a) COVERAGE OF EMERGENCY SERVICES.—

20 (1) IN GENERAL.—If a group health plan, or
21 health insurance coverage offered by a health insur-
22 ance issuer, provides or covers any benefits with re-
23 spect to services in an emergency department of a
24 hospital, the plan or issuer shall cover emergency
25 services (as defined in paragraph (2)(B))—

1 (A) without the need for any prior author-
2 ization determination;

3 (B) whether the health care provider fur-
4 nishing such services is a participating provider
5 with respect to such services;

6 (C) in a manner so that, if such services
7 are provided to a participant, beneficiary, or
8 enrollee—

9 (i) by a nonparticipating health care
10 provider with or without prior authoriza-
11 tion, or

12 (ii) by a participating health care pro-
13 vider without prior authorization,

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

19 (D) without regard to any other term or
20 condition of such coverage (other than exclusion
21 or coordination of benefits, or an affiliation or
22 waiting period, permitted under section 2701 of
23 the Public Health Service Act, section 701 of
24 the Employee Retirement Income Security Act
25 of 1974, or section 9801 of the Internal Rev-

1 enue Code of 1986, and other than applicable
2 cost-sharing).

3 (2) DEFINITIONS.—In this section:

4 (A) EMERGENCY MEDICAL CONDITION.—

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

15 (B) EMERGENCY SERVICES.—The term
16 “emergency services” means, with respect to an
17 emergency medical condition—

18 (i) a medical screening examination
19 (as required under section 1867 of the So-
20 cial Security Act) that is within the capa-
21 bility of the emergency department of a
22 hospital, including ancillary services rou-
23 tinely available to the emergency depart-
24 ment to evaluate such emergency medical
25 condition, and

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

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

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

19 (c) COVERAGE OF EMERGENCY AMBULANCE SERV-
20 ICES.—

21 (1) IN GENERAL.—If a group health plan, or
22 health insurance coverage provided by a health in-
23 surance issuer, provides any benefits with respect to
24 ambulance services and emergency services, the plan
25 or issuer shall cover emergency ambulance services

1 (as defined in paragraph (2)) furnished under the
2 plan or coverage under the same terms and condi-
3 tions under subparagraphs (A) through (D) of sub-
4 section (a)(1) under which coverage is provided for
5 emergency services.

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

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

24 (a) TIMELY ACCESS.—

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

9 (2) RULE OF CONSTRUCTION.—Nothing in
10 paragraph (1) shall be construed—

11 (A) to require the coverage under a group
12 health plan or health insurance coverage of ben-
13 efits or services;

14 (B) to prohibit a plan or issuer from in-
15 cluding providers in the network only to the ex-
16 tent necessary to meet the needs of the plan’s
17 or issuer’s participants, beneficiaries, or enroll-
18 ees; or

19 (C) to override any State licensure or
20 scope-of-practice law.

21 (3) ACCESS TO CERTAIN PROVIDERS.—

22 (A) IN GENERAL.—With respect to spe-
23 cialty care under this section, if a participating
24 specialist is not available and qualified to pro-
25 vide such care to the participant, beneficiary, or

1 enrollee, the plan or issuer shall provide for cov-
2 erage of such care by a nonparticipating spe-
3 cialist.

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

13 (b) REFERRALS.—

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

19 (A) shall be for an appropriate duration of
20 time or number of referrals, including an au-
21 thorization for a standing referral where appro-
22 priate; and

23 (B) may not be refused solely because the
24 authorization involves services of a nonpartici-

1 pating specialist (described in subsection
2 (a)(3)).

3 (2) REFERRALS FOR ONGOING SPECIAL CONDI-
4 TIONS.—

5 (A) IN GENERAL.—Subject to subsection
6 (a)(1), a group health plan and a health insur-
7 ance issuer shall permit a participant, bene-
8 ficiary, or enrollee who has an ongoing special
9 condition (as defined in subparagraph (B)) to
10 receive a referral to a specialist for the treat-
11 ment of such condition and such specialist may
12 authorize such referrals, procedures, tests, and
13 other medical services with respect to such con-
14 dition, or coordinate the care for such condi-
15 tion, subject to the terms of a treatment plan
16 (if any) referred to in subsection (c) with re-
17 spect to the condition.

18 (B) ONGOING SPECIAL CONDITION DE-
19 FINED.—In this subsection, the term “ongoing
20 special condition” means a condition or disease
21 that—

22 (i) is life-threatening, degenerative,
23 potentially disabling, or congenital; and

24 (ii) requires specialized medical care
25 over a prolonged period of time.

1 (c) TREATMENT PLANS.—

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

5 (A) pursuant to a treatment plan, but only
6 if the treatment plan—

7 (i) is developed by the specialist, in
8 consultation with the case manager or pri-
9 mary care provider, and the participant,
10 beneficiary, or enrollee, and

11 (ii) is approved by the plan or issuer
12 in a timely manner, if the plan or issuer
13 requires such approval; and

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

17 (2) NOTIFICATION.—Nothing in paragraph (1)
18 shall be construed as prohibiting a plan or issuer
19 from requiring the specialist to provide the plan or
20 issuer with regular updates on the specialty care
21 provided, as well as all other reasonably necessary
22 medical information.

23 (d) SPECIALIST DEFINED.—For purposes of this sec-
24 tion, the term “specialist” means, with respect to the con-
25 dition of the participant, beneficiary, or enrollee, a health

1 care professional, facility, or center that has adequate ex-
2 pertise through appropriate training and experience (in-
3 cluding, in the case of a child, appropriate pediatric exper-
4 tise) to provide high quality care in treating the condition.

5 **SEC. 115. PATIENT ACCESS TO OBSTETRICAL AND GYNECO-**
6 **LOGICAL CARE.**

7 (a) GENERAL RIGHTS.—

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

18 (2) OBSTETRICAL AND GYNECOLOGICAL
19 CARE.—A group health plan and a health insurance
20 issuer described in subsection (b) shall treat the pro-
21 vision of obstetrical and gynecological care, and the
22 ordering of related obstetrical and gynecological
23 items and services, pursuant to the direct access de-
24 scribed under paragraph (1), by a participating
25 health care professional who specializes in obstetrics

1 or gynecology as the authorization of the primary
2 care provider.

3 (b) APPLICATION OF SECTION.—A group health plan,
4 or health insurance issuer offering health insurance cov-
5 erage, described in this subsection is a group health plan
6 or coverage that—

7 (1) provides coverage for obstetric or
8 gynecologic care; and

9 (2) requires the designation by a participant,
10 beneficiary, or enrollee of a participating primary
11 care provider.

12 (c) CONSTRUCTION.—Nothing in subsection (a) shall
13 be construed to—

14 (1) waive any exclusions of coverage under the
15 terms and conditions of the plan or health insurance
16 coverage with respect to coverage of obstetrical or
17 gynecological care; or

18 (2) preclude the group health plan or health in-
19 surance issuer involved from requiring that the ob-
20 stetrical or gynecological provider notify the primary
21 care health care professional or the plan or issuer of
22 treatment decisions.

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

24 (a) PEDIATRIC CARE.—In the case of a person who
25 has a child who is a participant, beneficiary, or enrollee

1 under a group health plan, or health insurance coverage
2 offered by a health insurance issuer, if the plan or issuer
3 requires or provides for the designation of a participating
4 primary care provider for the child, the plan or issuer shall
5 permit such person to designate a physician (allopathic or
6 osteopathic) who specializes in pediatrics as the child's pri-
7 mary care provider if such provider participates in the net-
8 work of the plan or issuer.

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

13 **SEC. 117. CONTINUITY OF CARE.**

14 (a) TERMINATION OF PROVIDER.—

15 (1) IN GENERAL.—If—

16 (A) a contract between a group health
17 plan, or a health insurance issuer offering
18 health insurance coverage, and a treating health
19 care provider is terminated (as defined in para-
20 graph (e)(4)), or

21 (B) benefits or coverage provided by a
22 health care provider are terminated because of
23 a change in the terms of provider participation
24 in such plan or coverage,

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

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

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

20 (A) notify the continuing care patient in-
21 volved, or arrange to have the patient notified
22 pursuant to subsection (d)(2), on a timely basis
23 of the termination described in paragraph (1)
24 (or paragraph (2), if applicable) and the right

1 to elect continued transitional care from the
2 provider under this section;

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

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

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

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

21 (B) is undergoing a course of institutional
22 or inpatient care from the provider at the time
23 of such notice;

1 (C) is scheduled to undergo non-elective
2 surgery from the provider at the time of such
3 notice;

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

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

13 (b) TRANSITIONAL PERIODS.—

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

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

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

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

8 (3) SCHEDULED NON-ELECTIVE SURGERY.—

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

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

20 (5) TERMINAL ILLNESS.—The transitional pe-
21 riod under this subsection for a continuing care pa-
22 tient described in subsection (a)(4)(E) shall extend
23 for the remainder of the patient's life for care that
24 is directly related to the treatment of the terminal
25 illness or its medical manifestations.

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

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

20 (2) The treating health care provider agrees to
21 adhere to the quality assurance standards of the
22 plan or issuer responsible for payment under para-
23 graph (1) and to provide to such plan or issuer nec-
24 essary medical information related to the care pro-
25 vided.

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

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

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

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

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

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

22 (e) DEFINITIONS.—In this section:

23 (1) CONTRACT.—The term “contract” includes,
24 with respect to a plan or issuer and a treating
25 health care provider, a contract between such plan

1 or issuer and an organized network of providers that
2 includes the treating health care provider, and (in
3 the case of such a contract) the contract between the
4 treating health care provider and the organized net-
5 work.

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

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

13 (B) any entity that is engaged in the deliv-
14 ery of health care services in a State and that,
15 if it is required by State law or regulation to be
16 licensed or certified by the State to engage in
17 the delivery of such services in the State, is so
18 licensed.

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

23 (A) in the case of an acute illness, a condi-
24 tion that is serious enough to require special-

1 ized medical treatment to avoid the reasonable
2 possibility of death or permanent harm; or

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

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

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

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

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

20 (2) provide for disclosure of the formulary to
21 providers; and

22 (3) in accordance with the applicable quality as-
23 surance and utilization review standards of the plan
24 or issuer, provide for exceptions from the formulary
25 limitation when a non-formulary alternative is medi-

1 cally necessary and appropriate and, in the case of
2 such an exception, apply the same cost-sharing re-
3 quirements that would have applied in the case of a
4 drug covered under the formulary.

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

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

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

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

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

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

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

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

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

18 (a) COVERAGE.—

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

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

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

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

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

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

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

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

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

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

16 (2) Either—

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

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

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

4 (c) PAYMENT.—

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

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

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

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

21 (d) APPROVED CLINICAL TRIAL DEFINED.—

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

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

4 (i) the National Institutes of Health;

5 (ii) a cooperative group or center of
6 the National Institutes of Health, includ-
7 ing a qualified nongovernmental research
8 entity to which the National Cancer Insti-
9 tute has awarded a center support grant;

10 (iii) either of the following if the con-
11 ditions described in paragraph (2) are
12 met—

13 (I) the Department of Veterans
14 Affairs;

15 (II) the Department of Defense;

16 or

17 (B) approved by the Food and Drug Ad-
18 ministration.

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

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

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

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

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

15 (a) INPATIENT CARE.—

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

24 (A) a mastectomy;

25 (B) a lumpectomy; or

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

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

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

15 (c) SECONDARY CONSULTATIONS.—

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

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

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

20 (d) PROHIBITION ON PENALTIES OR INCENTIVES.—

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

23 (1) penalize or otherwise reduce or limit the re-
24 imbursement of a provider or specialist because the
25 provider or specialist provided care to a participant,

1 beneficiary, or enrollee in accordance with this sec-
2 tion;

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

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

16 **Subtitle C—Access to Information**

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

18 (a) REQUIREMENT.—

19 (1) DISCLOSURE.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

10 (b) CONSTRUCTION.—Subsection (a) shall not be
11 construed—

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

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

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

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

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

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

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

21 **SEC. 134. PAYMENT OF CLAIMS.**

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

1 issuer, in a manner that is no less protective than the pro-
2 visions of section 1842(c)(2) of the Social Security Act
3 (42 U.S.C. 1395u(c)(2)).

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

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

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

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

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

1 tation body, or appropriate management per-
2 sonnel of the plan or issuer; or

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

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

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

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

7 (B) the professional reasonably believes the
8 information to be true;

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

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

21 (3) EXCEPTION AND SPECIAL RULE.—

22 (A) GENERAL EXCEPTION.—Paragraph (1)
23 does not protect disclosures that would violate
24 Federal or State law or diminish or impair the
25 rights of any person to the continued protection

1 of confidentiality of communications provided
2 by such law.

3 (B) NOTICE OF INTERNAL PROCEDURES.—

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

13 (C) INTERNAL PROCEDURE EXCEPTION.—

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

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

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

23 (iii) the disclosure is in response to an
24 inquiry made in an investigation or pro-
25 ceeding of an appropriate public regulatory

1 agency and the information disclosed is
2 limited to the scope of the investigation or
3 proceeding.

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

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

19 (6) CONSTRUCTIONS.—

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

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

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

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

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

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

6 **Subtitle E—Definitions**

7 **SEC. 151. DEFINITIONS.**

8 (a) INCORPORATION OF GENERAL DEFINITIONS.—
9 Except as otherwise provided, the provisions of section
10 2791 of the Public Health Service Act shall apply for pur-
11 poses of this title in the same manner as they apply for
12 purposes of title XXVII of such Act.

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

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

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

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

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

12 (2) ENROLLEE.—The term “enrollee” means,
13 with respect to health insurance coverage offered by
14 a health insurance issuer, an individual enrolled with
15 the issuer to receive such coverage.

16 (3) GROUP HEALTH PLAN.—The term “group
17 health plan” has the meaning given such term in
18 section 733(a) of the Employee Retirement Income
19 Security Act of 1974, except that such term includes
20 a employee welfare benefit plan treated as a group
21 health plan under section 732(d) of such Act or de-
22 fined as such a plan under section 607(1) of such
23 Act.

24 (4) HEALTH CARE PROFESSIONAL.—The term
25 “health care professional” means an individual who

1 is licensed, accredited, or certified under State law
2 to provide specified health care services and who is
3 operating within the scope of such licensure, accredi-
4 tation, or certification.

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

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

19 (7) NONPARTICIPATING.—The term “non-
20 participating” means, with respect to a health care
21 provider that provides health care items and services
22 to a participant, beneficiary, or enrollee under group
23 health plan or health insurance coverage, a health
24 care provider that is not a participating health care
25 provider with respect to such items and services.

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

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

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

19 **SEC. 152. PREEMPTION; STATE FLEXIBILITY; CONSTRUC-**
20 **TION.**

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

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

1 or continues in effect any standard or requirement
2 solely relating to health insurance issuers (in connec-
3 tion with group health insurance coverage or other-
4 wise) except to the extent that such standard or re-
5 quirement prevents the application of a requirement
6 of this title.

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

13 (3) CONSTRUCTION.—In applying this section,
14 a State law that provides for equal access to, and
15 availability of, all categories of licensed health care
16 providers and services shall not be treated as pre-
17 venting the application of any requirement of this
18 title.

19 (b) APPLICATION OF SUBSTANTIALLY COMPLIANT
20 STATE LAWS.—

21 (1) IN GENERAL.—In the case of a State law
22 that imposes, with respect to health insurance cov-
23 erage offered by a health insurance issuer and with
24 respect to a group health plan that is a non-Federal
25 governmental plan, a requirement that substantially

1 complies (within the meaning of subsection (c)) with
2 a patient protection requirement (as defined in para-
3 graph (3)) and does not prevent the application of
4 other requirements under this Act (except in the
5 case of other substantially compliant requirements),
6 in applying the requirements of this title under sec-
7 tion 2707 and 2753 (as applicable) of the Public
8 Health Service Act (as added by title II), subject to
9 subsection (a)(2)—

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

12 (B) the State law shall apply instead of the
13 patient protection requirement otherwise appli-
14 cable with respect to health insurance coverage
15 and non-Federal governmental plans.

16 (2) LIMITATION.—In the case of a group health
17 plan covered under title I of the Employee Retirement
18 Income Security Act of 1974, paragraph (1)
19 shall be construed to apply only with respect to the
20 health insurance coverage (if any) offered in connec-
21 tion with the plan.

22 (3) DEFINITIONS.—In this section:

23 (A) PATIENT PROTECTION REQUIRE-
24 MENT.—The term “patient protection require-
25 ment” means a requirement under this title,

1 and includes (as a single requirement) a group
2 or related set of requirements under a section
3 or similar unit under this title.

4 (B) SUBSTANTIALLY COMPLIANT.—The
5 terms “substantially compliant”, substantially
6 complies”, or “substantial compliance” with re-
7 spect to a State law, mean that the State law
8 has the same or similar features as the patient
9 protection requirements and has a similar ef-
10 fect.

11 (c) DETERMINATIONS OF SUBSTANTIAL COMPLI-
12 ANCE.—

13 (1) CERTIFICATION BY STATES.—A State may
14 submit to the Secretary a certification that a State
15 law provides for patient protections that are at least
16 substantially compliant with one or more patient
17 protection requirements. Such certification shall be
18 accompanied by such information as may be re-
19 quired to permit the Secretary to make the deter-
20 mination described in paragraph (2)(A).

21 (2) REVIEW.—

22 (A) IN GENERAL.—The Secretary shall
23 promptly review a certification submitted under
24 paragraph (1) with respect to a State law to de-
25 termine if the State law substantially complies

1 with the patient protection requirement (or re-
2 quirements) to which the law relates.

3 (B) APPROVAL DEADLINES.—

4 (i) INITIAL REVIEW.—Such a certifi-
5 cation is considered approved unless the
6 Secretary notifies the State in writing,
7 within 90 days after the date of receipt of
8 the certification, that the certification is
9 disapproved (and the reasons for dis-
10 approval) or that specified additional infor-
11 mation is needed to make the determina-
12 tion described in subparagraph (A).

13 (ii) ADDITIONAL INFORMATION.—

14 With respect to a State that has been noti-
15 fied by the Secretary under clause (i) that
16 specified additional information is needed
17 to make the determination described in
18 subparagraph (A), the Secretary shall
19 make the determination within 60 days
20 after the date on which such specified ad-
21 ditional information is received by the Sec-
22 retary.

23 (3) APPROVAL.—

1 (A) IN GENERAL.—The Secretary shall ap-
2 prove a certification under paragraph (1)
3 unless—

4 (i) the State fails to provide sufficient
5 information to enable the Secretary to
6 make a determination under paragraph
7 (2)(A); or

8 (ii) the Secretary determines that the
9 State law involved does not provide for pa-
10 tient protections that substantially comply
11 with the patient protection requirement (or
12 requirements) to which the law relates.

13 (B) STATE CHALLENGE.—A State that has
14 a certification disapproved by the Secretary
15 under subparagraph (A) may challenge such
16 disapproval in the appropriate United States
17 district court.

18 (C) DEFERENCE TO STATES.—With re-
19 spect to a certification submitted under para-
20 graph (1), the Secretary shall give deference to
21 the State’s interpretation of the State law in-
22 volved with respect to the patient protection in-
23 volved.

24 (D) PUBLIC NOTIFICATION.—The Sec-
25 retary shall—

1 (i) provide a State with a notice of the
2 determination to approve or disapprove a
3 certification under this paragraph;

4 (ii) promptly publish in the Federal
5 Register a notice that a State has sub-
6 mitted a certification under paragraph (1);

7 (iii) promptly publish in the Federal
8 Register the notice described in clause (i)
9 with respect to the State; and

10 (iv) annually publish the status of all
11 States with respect to certifications.

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

19 (5) PETITIONS.—

20 (A) PETITION PROCESS.—Effective on the
21 date on which the provisions of this Act become
22 effective, as provided for in section 601, a
23 group health plan, health insurance issuer, par-
24 ticipant, beneficiary, or enrollee may submit a
25 petition to the Secretary for an advisory opinion

1 as to whether or not a standard or requirement
2 under a State law applicable to the plan, issuer,
3 participant, beneficiary, or enrollee that is not
4 the subject of a certification under this sub-
5 section, is superseded under subsection (a)(1)
6 because such standard or requirement prevents
7 the application of a requirement of this title.

8 (B) OPINION.—The Secretary shall issue
9 an advisory opinion with respect to a petition
10 submitted under subparagraph (A) within the
11 60-day period beginning on the date on which
12 such petition is submitted.

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

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

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

1 **SEC. 153. EXCLUSIONS.**

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

9 (b) **EXCLUSION FROM ACCESS TO CARE MANAGED**
10 **CARE PROVISIONS FOR FEE-FOR-SERVICE COVERAGE.**—

11 (1) **IN GENERAL.**—The provisions of sections
12 111 through 117 shall not apply to a group health
13 plan or health insurance coverage if the only cov-
14 erage offered under the plan or coverage is fee-for-
15 service coverage (as defined in paragraph (2)).

16 (2) **FEE-FOR-SERVICE COVERAGE DEFINED.**—
17 For purposes of this subsection, the term “fee-for-
18 service coverage” means coverage under a group
19 health plan or health insurance coverage that—

20 (A) reimburses hospitals, health profes-
21 sionals, and other providers on a fee-for-service
22 basis without placing the provider at financial
23 risk;

24 (B) does not vary reimbursement for such
25 a provider based on an agreement to contract

1 terms and conditions or the utilization of health
2 care items or services relating to such provider;

3 (C) allows access to any provider that is
4 lawfully authorized to provide the covered serv-
5 ices and that agrees to accept the terms and
6 conditions of payment established under the
7 plan or by the issuer; and

8 (D) for which the plan or issuer does not
9 require prior authorization before providing for
10 any health care services.

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

12 (a) IN GENERAL.—The requirements of this title and
13 the provisions of sections 502(a)(1)(C), 502(n), and
14 514(d) of the Employee Retirement Income Security Act
15 of 1974 (added by section 402) shall not apply to excepted
16 benefits (as defined in section 733(c) of such Act), other
17 than benefits described in section 733(c)(2)(A) of such
18 Act, in the same manner as the provisions of part 7 of
19 subtitle B of title I of such Act do not apply to such bene-
20 fits under subsections (b) and (c) of section 732 of such
21 Act.

22 (b) COVERAGE OF CERTAIN LIMITED SCOPE
23 PLANS.—Only for purposes of applying the requirements
24 of this title under sections 2707 and 2753 of the Public
25 Health Service Act, section 714 of the Employee Retire-

1 ment Income Security Act of 1974, and section 9813 of
2 the Internal Revenue Code of 1986, the following sections
3 shall be deemed not to apply:

4 (1) Section 2791(c)(2)(A) of the Public Health
5 Service Act.

6 (2) Section 733(c)(2)(A) of the Employee Re-
7 tirement Income Security Act of 1974.

8 (3) Section 9832(c)(2)(A) of the Internal Rev-
9 enue Code of 1986.

10 **SEC. 155. REGULATIONS.**

11 The Secretaries of Health and Human Services,
12 Labor, and the Treasury shall issue such regulations as
13 may be necessary or appropriate to carry out this title.
14 Such regulations shall be issued consistent with section
15 104 of Health Insurance Portability and Accountability
16 Act of 1996. Such Secretaries may promulgate any in-
17 terim final rules as the Secretaries determine are appro-
18 priate to carry out this title.

19 **SEC. 156. INCORPORATION INTO PLAN OR COVERAGE DOC-
20 UMENTS.**

21 The requirements of this title with respect to a group
22 health plan or health insurance coverage are, subject to
23 section 154, deemed to be incorporated into, and made
24 a part of, such plan or the policy, certificate, or contract
25 providing such coverage and are enforceable under law as

1 if directly included in the documentation of such plan or
2 such policy, certificate, or contract.

3 **SEC. 157. PRESERVATION OF PROTECTIONS.**

4 (a) IN GENERAL.—The rights under this Act (includ-
5 ing the right to maintain a civil action and any other
6 rights under the amendments made by this Act) may not
7 be waived, deferred, or lost pursuant to any agreement
8 not authorized under this Act.

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

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

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

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

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

13 “Each group health plan shall comply with patient
14 protection requirements under title I of the 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 **TITLE III—APPLICATION OF PA-**
8 **TIENT PROTECTION STAND-**
9 **ARDS TO FEDERAL HEALTH**
10 **INSURANCE PROGRAMS**

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

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

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

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

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

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

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

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

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

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

13 “(a) IN GENERAL.—Subject to subsection (b), a
14 group health plan (and a health insurance issuer offering
15 group health insurance coverage in connection with such
16 a plan) shall comply with the requirements of title I of
17 the 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 in connection with health insurance cov-
20 erage, any reference in this subsection to a require-
21 ment in a section or other provision in the Bipar-
22 tisan Patient Protection Act with respect to a health
23 insurance issuer is deemed to include a reference to
24 a requirement under a State law that substantially
25 complies (as determined under section 152(c) of

1 such Act) with the requirement in such section or
2 other provisions.

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

10 “(c) ENFORCEMENT OF CERTAIN REQUIREMENTS.—

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

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

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

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

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

1 (c) CONFORMING AMENDMENTS.—(1) Section 732(a)
2 of such Act (29 U.S.C. 1185(a)) is amended by striking
3 “section 711” and inserting “sections 711 and 714”.

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

“Sec. 714. Patient protection standards.”.

7 (3) Section 502(b)(3) of such Act (29 U.S.C.
8 1132(b)(3)) is amended by inserting “(other than section
9 135(b))” after “part 7”.

10 **SEC. 402. AVAILABILITY OF CIVIL REMEDIES.**

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

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

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

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

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

1 for benefits of a participant or beneficiary
2 under section 102 of the Bipartisan Patient
3 Protection Act (relating to procedures for initial
4 claims for benefits and prior authorization de-
5 terminations) or upon review of a denial of such
6 a claim under section 103 of such Act (relating
7 to internal appeal of a denial of a claim for ben-
8 efits), fails to exercise ordinary care in making
9 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 (relating to
22 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 AND RELATED RULES.—For
7 purposes of this subsection.—

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.

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.

4 “(E) TREATMENT OF EXCEPTED BENE-
5 FITS.—Under section 154(a) of the Bipartisan
6 Patient Protection Act, the provisions of this
7 subsection and subsection (a)(1)(C) do not
8 apply to certain excepted benefits.

9 “(5) EXCLUSION OF EMPLOYERS AND OTHER
10 PLAN SPONSORS.—

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

19 “(B) CERTAIN CAUSES OF ACTION PER-
20 MITTED.—Notwithstanding subparagraph (A),
21 a cause of action may arise against an employer
22 or other plan sponsor (or against an employee
23 of such an employer or sponsor acting within
24 the scope of employment) under paragraph
25 (1)(A), to the extent there was direct participa-

1 tion by the employer or other plan sponsor (or
2 employee) in the decision of the plan under sec-
3 tion 102 of the Bipartisan Patient Protection
4 Act upon consideration of a claim for benefits
5 or under section 103 of such Act upon review
6 of a denial of a claim for benefits.

7 “(C) DIRECT PARTICIPATION.—

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

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

24 “(I) any participation by the em-
25 ployer or other plan sponsor (or em-

1 ployee) in the selection of the group
2 health plan or health insurance cov-
3 erage involved or the third party ad-
4 ministrator or other agent;

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

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

21 “(IV) any participation by the
22 employer or other plan sponsor (or
23 employee) in the design of any benefit
24 under the plan, including the amount

1 of copayment and limits connected
2 with such benefit.

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

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

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

1 “(D) APPLICATION TO CERTAIN PLANS.—

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

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

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

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

24 “(6) EXCLUSION OF PHYSICIANS AND OTHER
25 HEALTH CARE PROFESSIONALS.—

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

11 “(B) DEFINITIONS.—For purposes of sub-
12 paragraph (A)—

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

20 “(ii) NON-MEDICALLY REVIEWABLE
21 DUTY.—The term ‘non-medically review-
22 able duty’ means a duty the discharge of
23 which does not include the making of a
24 medically reviewable decision.

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

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

17 “(9) REQUIREMENT OF EXHAUSTION.—

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

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

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

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

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

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

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

18 “(10) STATUTORY DAMAGES.—

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

23 “(B) ASSESSMENT OF CIVIL PENALTIES.—
24 In addition to the remedies provided for in
25 paragraph (1) (relating to the failure to provide

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

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

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

22 “(B) DETERMINATION BY DISTRICT
23 COURT.—The last Federal district court in
24 which the action was pending upon the final
25 disposition, including all appeals, of the action

1 shall have jurisdiction to review the attorney's
2 fee to ensure that the fee is a reasonable one.

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

6 “(A) the date on which the plaintiff first
7 knew, or reasonably should have known, of the
8 personal injury or death resulting from the fail-
9 ure described in paragraph (1), or

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

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

23 “(14) PURCHASE OF INSURANCE TO COVER LI-
24 ABILITY.—Nothing in section 410 shall be construed
25 to preclude the purchase by a group health plan of

1 insurance to cover any liability or losses arising
2 under a cause of action under subsection (a)(1)(C)
3 and this subsection.

4 “(15) EXCLUSION OF DIRECTED RECORD-
5 KEEPERS.—

6 “(A) IN GENERAL.—Subject to subpara-
7 graph (C), paragraph (1) shall not apply with
8 respect to a directed recordkeeper in connection
9 with a group health plan.

10 “(B) DIRECTED RECORDKEEPER.—For
11 purposes of this paragraph, the term ‘directed
12 recordkeeper’ means, in connection with a
13 group health plan, a person engaged in directed
14 recordkeeping activities pursuant to the specific
15 instructions of the plan or the employer or
16 other plan sponsor, including the distribution of
17 enrollment information and distribution of dis-
18 closure materials under this Act or title I of the
19 Bipartisan Patient Protection Act and whose
20 duties do not include making decisions on
21 claims for benefits.

22 “(C) LIMITATION.—Subparagraph (A)
23 does not apply in connection with any directed
24 recordkeeper to the extent that the directed rec-
25 ordkeeper fails to follow the specific instruction

1 of the plan or the employer or other plan spon-
2 sor.

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

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

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

19 “(A) IN GENERAL.—Notwithstanding the
20 direct participation (as defined in paragraph
21 (5)(C)(i)) of an employer or plan sponsor, in
22 any case in which there is (or is deemed under
23 subparagraph (B) to be) a designated decision-
24 maker under subparagraph (B) that meets the

1 requirements of subsection (o)(1) for an em-
2 ployer or other plan sponsor—

3 “(i) all liability of such employer or
4 plan sponsor involved (and any employee of
5 such employer or sponsor acting within the
6 scope of employment) under this sub-
7 section in connection with any participant
8 or beneficiary shall be transferred to, and
9 assumed by, the designated decisionmaker,
10 and

11 “(ii) with respect to such liability, the
12 designated decisionmaker shall be sub-
13 stituted for the employer or sponsor (or
14 employee) in the action and may not raise
15 any defense that the employer or sponsor
16 (or employee) could not raise if such a de-
17 cisionmaker were not so deemed.

18 “(B) AUTOMATIC DESIGNATION.—A health
19 insurance issuer shall be deemed to be a des-
20 ignated decisionmaker for purposes of subpara-
21 graph (A) with respect to the participants and
22 beneficiaries of an employer or plan sponsor,
23 whether or not the employer or plan sponsor
24 makes such a designation, and shall be deemed
25 to have assumed unconditionally all liability of

1 the employer or plan sponsor under such des-
2 gnation in accordance with subsection (o), un-
3 less the employer or plan sponsor affirmatively
4 enters into a contract to prevent the service of
5 the designated decisionmaker.

6 “(C) TREATMENT OF CERTAIN TRUST
7 FUNDS.—For purposes of this paragraph, the
8 terms ‘employer’ and ‘plan sponsor’, in connec-
9 tion with the assumption by a designated deci-
10 sionmaker of the liability of employer or other
11 plan sponsor pursuant to this paragraph, shall
12 be construed to include a trust fund maintained
13 pursuant to section 302 of the Labor Manage-
14 ment Relations Act, 1947 (29 U.S.C. 186) or
15 the Railway Labor Act (45 U.S.C. 151 et seq.).

16 “(19) PREVIOUSLY PROVIDED SERVICES.—

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

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

3 “(i) prohibit a cause of action under
4 paragraph (1) where the nonpayment in-
5 volved results in the participant or bene-
6 ficiary being unable to receive further
7 items or services that are directly related
8 to the item or service involved in the denial
9 referred to in subparagraph (A) or that
10 are part of a continuing treatment or se-
11 ries of procedures; or

12 “(ii) limit liability that otherwise
13 would arise from the provision of the item
14 or services or the performance of a medical
15 procedure.

16 “(20) EXEMPTION FROM PERSONAL LIABILITY
17 FOR INDIVIDUAL MEMBERS OF BOARDS OF DIREC-
18 TORS, JOINT BOARDS OF TRUSTEES, ETC.—Any indi-
19 vidual who is—

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

22 “(B) a member of an association, com-
23 mittee, employee organization, joint board of
24 trustees, or other similar group of representa-
25 tives of the entities that are the plan sponsor

1 of plan maintained by two or more employers
2 and one or more employee organizations;
3 shall not be personally liable under this subsection
4 for conduct that is within the scope of employment
5 or of plan-related duties of the individuals unless the
6 individual acts in a fraudulent manner for personal
7 enrichment.

8 “(o) REQUIREMENTS FOR DESIGNATED DECISION-
9 MAKERS OF GROUP HEALTH PLANS.—

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

14 “(A) such designation is in such form as
15 may be prescribed in regulations of the Sec-
16 retary,

17 “(B) the designated decisionmaker—

18 “(i) meets the requirements of para-
19 graph (2),

20 “(ii) assumes unconditionally all liabil-
21 ity of the employer or plan sponsor in-
22 volved (and any employee of such employer
23 or sponsor acting within the scope of em-
24 ployment) either arising under subsection
25 (n) or arising in a cause of action per-

1 mitted under section 514(d) in connection
2 with actions (and failures to act) of the
3 employer or plan sponsor (or employee) oc-
4 curring during the period in which the des-
5 ignation under subsection (n)(18) or sec-
6 tion 514(d)(9) is in effect relating to such
7 participant and beneficiary,

8 “(iii) agrees to be substituted for the
9 employer or plan sponsor (or employee) in
10 the action and not to raise any defense
11 with respect to such liability that the em-
12 ployer or plan sponsor (or employee) may
13 not raise, and

14 “(iv) where paragraph (2)(B) applies,
15 assumes unconditionally the exclusive au-
16 thority under the group health plan to
17 make medically reviewable decisions under
18 the plan with respect to such participant
19 or beneficiary, and

20 “(C) the designated decisionmaker and the
21 participants and beneficiaries for whom the de-
22 cisionmaker has assumed liability are identified
23 in the written instrument required under sec-
24 tion 402(a) and as required under section

1 121(b)(19) of the Bipartisan Patient Protection
2 Act.

3 Any liability assumed by a designated decisionmaker
4 pursuant to this subsection shall be in addition to
5 any liability that it may otherwise have under appli-
6 cable law.

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

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

1 constitutes a multiyear arrangement, in con-
2 junction with the renewal of the arrangement.

3 “(B) SPECIAL QUALIFICATION IN THE
4 CASE OF CERTAIN REVIEWABLE DECISIONS.—In
5 the case of a group health plan that provides
6 benefits consisting of medical care to a partici-
7 pant or beneficiary only through health insur-
8 ance coverage offered by a single health insur-
9 ance issuer, such issuer is the only entity that
10 may be qualified under this paragraph to serve
11 as a designated decisionmaker with respect to
12 such participant or beneficiary, and shall serve
13 as the designated decisionmaker unless the em-
14 ployer or other plan sponsor acts affirmatively
15 to prevent such service.

16 “(3) REQUIREMENTS RELATING TO FINANCIAL
17 OBLIGATIONS.—For purposes of paragraph (2)(A),
18 the requirements relating to the financial obligation
19 of an entity for liability shall include—

20 “(A) coverage of such entity under an in-
21 surance policy or other arrangement, secured
22 and maintained by such entity, to effectively in-
23 sure such entity against losses arising from pro-
24 fessional liability claims, including those arising

1 from its service as a designated decisionmaker
2 under this part; or

3 “(B) evidence of minimum capital and sur-
4 plus levels that are maintained by such entity
5 to cover any losses as a result of liability arising
6 from its service as a designated decisionmaker
7 under this part.

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

22 “(4) LIMITATION ON APPOINTMENT OF TREAT-
23 ING PHYSICIANS.—A treating physician who directly
24 delivered the care, treatment, or provided the patient
25 service that is the subject of a cause of action by a

1 participant or beneficiary under subsection (n) or
2 section 514(d) may not be designated as a des-
3 ignated decisionmaker under this subsection with re-
4 spect to such participant or beneficiary.”.

5 (2) CONFORMING AMENDMENT.—Section
6 502(a)(1) of such Act (29 U.S.C. 1132(a)(1)) is
7 amended—

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

10 (B) in subparagraph (B), by striking
11 “plan;” and inserting “plan, or”; and

12 (C) by adding at the end the following new
13 subparagraph:

14 “(C) for the relief provided for in sub-
15 section (n) of this section.”.

16 (b) RULES RELATING TO ERISA PREEMPTION.—
17 Section 514 of the Employee Retirement Income Security
18 Act of 1974 (29 U.S.C. 1144) is amended—

19 (1) by redesignating subsection (d) as sub-
20 section (f); and

21 (2) by inserting after subsection (c) the fol-
22 lowing new subsections:

23 “(d) PREEMPTION NOT TO APPLY TO CAUSES OF
24 ACTION UNDER STATE LAW INVOLVING MEDICALLY RE-
25 VIEWABLE DECISION.—

1 “(1) NON-PREEMPTION OF CERTAIN CAUSES OF
2 ACTION.—

3 “(A) IN GENERAL.—Except as provided in
4 this subsection, nothing in this title (including
5 section 502) shall be construed to supersede or
6 otherwise alter, amend, modify, invalidate, or
7 impair any cause of action under State law of
8 a participant or beneficiary under a group
9 health plan (or the estate of such a participant
10 or beneficiary) against the plan, the plan spon-
11 sor, any health insurance issuer offering health
12 insurance coverage in connection with the plan,
13 or any managed care entity in connection with
14 the plan to recover damages resulting from per-
15 sonal injury or for wrongful death if such cause
16 of action arises by reason of a medically review-
17 able decision.

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

1 “(C) LIMITATION ON PUNITIVE DAM-
2 AGES.—

3 “(i) IN GENERAL.—Except as pro-
4 vided in clauses (ii) and (iii), with respect
5 to a cause of action described in subpara-
6 graph (A) brought with respect to a partici-
7 pant or beneficiary, State law is super-
8 seded insofar as it provides any punitive,
9 exemplary, or similar damages if, as of the
10 time of the personal injury or death, all
11 the requirements of the following sections
12 of the Bipartisan Patient Protection Act
13 were satisfied with respect to the partici-
14 pant or beneficiary:

15 “(I) Section 102 (relating to pro-
16 cedures for initial claims for benefits
17 and prior authorization determina-
18 tions).

19 “(II) Section 103 of such Act
20 (relating to internal appeals of claims
21 denials).

22 “(III) Section 104 of such Act
23 (relating to independent external ap-
24 peals procedures).

1 “(ii) EXCEPTION FOR CERTAIN AC-
2 TIONS FOR WRONGFUL DEATH.—Clause (i)
3 shall not apply with respect to an action
4 for wrongful death if the applicable State
5 law provides (or has been construed to pro-
6 vide) for damages in such an action which
7 are only punitive or exemplary in nature.

8 “(iii) EXCEPTION FOR WILLFUL OR
9 WANTON DISREGARD FOR THE RIGHTS OR
10 SAFETY OF OTHERS.—Clause (i) shall not
11 apply with respect to any cause of action
12 described in subparagraph (A) if, in such
13 action, the plaintiff establishes by clear
14 and convincing evidence that conduct car-
15 ried out by the defendant with willful or
16 wanton disregard for the rights or safety
17 of others was a proximate cause of the per-
18 sonal injury or wrongful death that is the
19 subject of the action.

20 “(2) DEFINITIONS AND RELATED RULES.—For
21 purposes of this subsection and subsection (e)—

22 “(A) TREATMENT OF EXCEPTED BENE-
23 FITS.—Under section 154(a) of the Bipartisan
24 Patient Protection Act, the provisions of this

1 subsection do not apply to certain excepted ben-
2 efits.

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

7 “(C) CLAIM FOR BENEFIT; DENIAL.—The
8 terms ‘claim for benefits’ and ‘denial of a claim
9 for benefits’ shall have the meaning provided
10 such terms under section 102(e) of the Bipar-
11 tisan Patient Protection Act.

12 “(D) MANAGED CARE ENTITY.—

13 “(i) IN GENERAL.—The term ‘man-
14 aged care entity’ means, in connection with
15 a group health plan and subject to clause
16 (ii), any entity that is involved in deter-
17 mining the manner in which or the extent
18 to which items or services (or reimburse-
19 ment therefor) are to be provided as bene-
20 fits under the plan.

21 “(ii) TREATMENT OF TREATING PHY-
22 SICIANS, OTHER TREATING HEALTH CARE
23 PROFESSIONALS, AND TREATING HOS-
24 PITALS.—Such term does not include a
25 treating physician or other treating health

1 care professional (as defined in section
2 502(n)(6)(B)(i)) of the participant or ben-
3 eficiary and also does not include a treat-
4 ing hospital insofar as it is acting solely in
5 the capacity of providing treatment or care
6 to the participant or beneficiary. Nothing
7 in the preceding sentence shall be con-
8 strued to preempt vicarious liability of any
9 plan, plan sponsor, health insurance issuer,
10 or managed care entity.

11 “(3) 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)
16 does not apply with respect to—

17 “(i) any cause of action against an
18 employer or other plan sponsor maintain-
19 ing the plan (or against an employee of
20 such an employer or sponsor acting within
21 the scope of employment), or

22 “(ii) a right of recovery, indemnity, or
23 contribution by a person against an em-
24 ployer or other plan sponsor (or such an
25 employee) for damages assessed against

1 the person pursuant to a cause of action to
2 which paragraph (1) applies.

3 “(B) CERTAIN CAUSES OF ACTION PER-
4 MITTED.—Notwithstanding subparagraph (A),
5 paragraph (1) applies with respect to any cause
6 of action that is brought by a participant or
7 beneficiary under a group health plan (or the
8 estate of such a participant or beneficiary) to
9 recover damages resulting from personal injury
10 or for wrongful death against any employer or
11 other plan sponsor maintaining the plan (or
12 against an employee of such an employer or
13 sponsor acting within the scope of employment)
14 if such cause of action arises by reason of a
15 medically reviewable decision, to the extent that
16 there was direct participation by the employer
17 or other plan sponsor (or employee) in the deci-
18 sion.

19 “(C) DIRECT PARTICIPATION.—

20 “(i) DIRECT PARTICIPATION IN DECI-
21 SIONS.—For purposes of subparagraph
22 (B), the term ‘direct participation’ means,
23 in connection with a decision described in
24 subparagraph (B), the actual making of
25 such decision or the actual exercise of con-

1 troll in making such decision or in the con-
2 duct constituting the failure.

3 “(ii) RULES OF CONSTRUCTION.—For
4 purposes of clause (i), the employer or plan
5 sponsor (or employee) shall not be con-
6 strued to be engaged in direct participation
7 because of any form of decisionmaking or
8 other conduct that is merely collateral or
9 precedent to the decision described in sub-
10 paragraph (B) on a particular claim for
11 benefits of a particular participant or bene-
12 ficiary, including (but not limited to)—

13 “(I) any participation by the em-
14 ployer or other plan sponsor (or em-
15 ployee) in the selection of the group
16 health plan or health insurance cov-
17 erage involved or the third party ad-
18 ministrators or other agent;

19 “(II) any engagement by the em-
20 ployer or other plan sponsor (or em-
21 ployee) in any cost-benefit analysis
22 undertaken in connection with the se-
23 lection of, or continued maintenance
24 of, the plan or coverage involved;

1 “(III) any participation by the
2 employer or other plan sponsor (or
3 employee) in the process of creating,
4 continuing, modifying, or terminating
5 the plan or any benefit under the
6 plan, if such process was not substan-
7 tially focused solely on the particular
8 situation of the participant or bene-
9 ficiary referred to in paragraph
10 (1)(A); and

11 “(IV) any participation by the
12 employer or other plan sponsor (or
13 employee) in the design of any benefit
14 under the plan, including the amount
15 of copayment and limits connected
16 with such benefit.

17 “(iv) IRRELEVANCE OF CERTAIN COL-
18 LATERAL EFFORTS MADE BY EMPLOYER
19 OR PLAN SPONSOR.—For purposes of this
20 subparagraph, an employer or plan sponsor
21 shall not be treated as engaged in direct
22 participation in a decision with respect to
23 any claim for benefits or denial thereof in
24 the case of any particular participant or
25 beneficiary solely by reason of—

1 “(I) any efforts that may have
2 been made by the employer or plan
3 sponsor to advocate for authorization
4 of coverage for that or any other par-
5 ticipant or beneficiary (or any group
6 of participants or beneficiaries), or

7 “(II) any provision that may
8 have been made by the employer or
9 plan sponsor for benefits which are
10 not covered under the terms and con-
11 ditions of the plan for that or any
12 other participant or beneficiary (or
13 any group of participants or bene-
14 ficiaries).

15 “(4) REQUIREMENT OF EXHAUSTION.—

16 “(A) IN GENERAL.—Except as provided in
17 subparagraph (D), a cause of action may not be
18 brought under paragraph (1) in connection with
19 any denial of a claim for benefits of any indi-
20 vidual until all administrative processes under
21 sections 102, 103, and 104 of the Bipartisan
22 Patient Protection Act (if applicable) have been
23 exhausted.

24 “(B) LATE MANIFESTATION OF INJURY.—

1 “(i) IN GENERAL.—A participant or
2 beneficiary shall not be precluded from
3 pursuing a review under section 104 of the
4 Bipartisan Patient Protection Act regard-
5 ing an injury that such participant or ben-
6 eficiary has experienced if the external re-
7 view entity first determines that the injury
8 of such participant or beneficiary is a late
9 manifestation of an earlier injury.

10 “(ii) DEFINITION.—In this subpara-
11 graph, the term ‘late manifestation of an
12 earlier injury’ means an injury sustained
13 by the participant or beneficiary which was
14 not known, and should not have been
15 known, by such participant or beneficiary
16 by the latest date that the requirements of
17 subparagraph (A) should have been met
18 regarding the claim for benefits which was
19 denied.

20 “(C) EXCEPTION FOR NEEDED CARE.—A
21 participant or beneficiary may seek relief exclu-
22 sively in Federal court under subsection
23 502(a)(1)(B) prior to the exhaustion of admin-
24 istrative remedies under sections 102, 103, or
25 104 of the Bipartisan Patient Protection Act

1 (as required under subparagraph (A)) if it is
2 demonstrated to the court that the exhaustion
3 of such remedies would cause irreparable harm
4 to the health of the participant or beneficiary.
5 Notwithstanding the awarding of relief under
6 subsection 502(a)(1)(B) pursuant to this sub-
7 paragraph, no relief shall be available as a re-
8 sult of, or arising under, paragraph (1)(A) un-
9 less the requirements of subparagraph (A) are
10 met.

11 “(D) FAILURE TO REVIEW.—

12 “(i) IN GENERAL.—If the external re-
13 view entity fails to make a determination
14 within the time required under section
15 104(e)(1)(A)(i), a participant or bene-
16 ficiary may bring an action under section
17 514(d) after 10 additional days after the
18 date on which such time period has expired
19 and the filing of such action shall not af-
20 fect the duty of the independent medical
21 reviewer (or reviewers) to make a deter-
22 mination pursuant to section
23 104(e)(1)(A)(i).

24 “(ii) EXPEDITED DETERMINATION.—

25 If the external review entity fails to make

1 a determination within the time required
2 under section 104(e)(1)(A)(ii), a partici-
3 pant or beneficiary may bring an action
4 under this subsection and the filing of such
5 an action shall not affect the duty of the
6 independent medical reviewer (or review-
7 ers) to make a determination pursuant to
8 section 104(e)(1)(A)(ii).

9 “(E) RECEIPT OF BENEFITS DURING AP-
10 PEALS PROCESS.—Receipt by the participant or
11 beneficiary of the benefits involved in the claim
12 for benefits during the pendency of any admin-
13 istrative processes referred to in subparagraph
14 (A) or of any action commenced under this
15 subsection—

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

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

22 “(F) ADMISSIBLE.—Any determination
23 made by a reviewer in an administrative pro-
24 ceeding under section 104 of the Bipartisan Pa-
25 tient Protection Act shall be admissible in any

1 Federal or State court proceeding and shall be
2 presented to the trier of fact.

3 “(5) TOLLING PROVISION.—The statute of limi-
4 tations for any cause of action arising under section
5 502(n) relating to a denial of a claim for benefits
6 that is the subject of an action brought in State
7 court shall be tolled until such time as the State
8 court makes a final disposition, including all ap-
9 peals, of whether such claim should properly be
10 within the jurisdiction of the State court. The tolling
11 period shall be determined by the applicable Federal
12 or State law, whichever period is greater.

13 “(6) EXCLUSION OF DIRECTED RECORD-
14 KEEPERS.—

15 “(A) IN GENERAL.—Subject to subpara-
16 graph (C), paragraph (1) shall not apply with
17 respect to a directed recordkeeper in connection
18 with a group health plan.

19 “(B) DIRECTED RECORDKEEPER.—For
20 purposes of this paragraph, the term ‘directed
21 recordkeeper’ means, in connection with a
22 group health plan, a person engaged in directed
23 recordkeeping activities pursuant to the specific
24 instructions of the plan or the employer or
25 other plan sponsor, including the distribution of

1 enrollment information and distribution of dis-
2 closure materials under this Act or title I of the
3 Bipartisan Patient Protection Act and whose
4 duties do not include making decisions on
5 claims for benefits.

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

12 “(7) CONSTRUCTION.—Nothing in this sub-
13 section shall be construed as—

14 “(A) saving from preemption a cause of
15 action under State law for the failure to provide
16 a benefit for an item or service which is specifi-
17 cally excluded under the group health plan in-
18 volved, except to the extent that—

19 “(i) the application or interpretation
20 of the exclusion involves a determination
21 described in section 104(d)(2) of the Bi-
22 partisan Patient Protection Act, or

23 “(ii) the provision of the benefit for
24 the item or service is required under Fed-

1 eral law or under applicable State law con-
2 sistent with subsection (b)(2)(B);

3 “(B) preempting a State law which re-
4 quires an affidavit or certificate of merit in a
5 civil action;

6 “(C) affecting a cause of action or remedy
7 under State law in connection with the provi-
8 sion or arrangement of excepted benefits (as de-
9 fined in section 733(c)), other than those de-
10 scribed in section 733(c)(2)(A); or

11 “(D) affecting a cause of action under
12 State law other than a cause of action described
13 in paragraph (1)(A).

14 “(8) PURCHASE OF INSURANCE TO COVER LI-
15 ABILITY.—Nothing in section 410 shall be construed
16 to preclude the purchase by a group health plan of
17 insurance to cover any liability or losses arising
18 under a cause of action described in paragraph
19 (1)(A).

20 “(9) RELIEF FROM LIABILITY FOR EMPLOYER
21 OR OTHER PLAN SPONSOR BY MEANS OF DES-
22 IGNATED DECISIONMAKER.—

23 “(A) IN GENERAL.—Paragraph (1) shall
24 not apply with respect to any cause of action
25 described in paragraph (1)(A) under State law

1 insofar as such cause of action provides for li-
2 ability with respect to a participant or bene-
3 ficiary of an employer or plan sponsor (or an
4 employee of such employer or sponsor acting
5 within the scope of employment), if with respect
6 to the employer or plan sponsor there is (or is
7 deemed under subparagraph (B) to be) a des-
8 ignated decisionmaker that meets the require-
9 ments of section 502(o)(1) with respect to such
10 participant or beneficiary. Such paragraph (1)
11 shall apply with respect to any cause of action
12 described in paragraph (1)(A) under State law
13 against the designated decisionmaker of such
14 employer or other plan sponsor with respect to
15 the participant or beneficiary.

16 “(B) AUTOMATIC DESIGNATION.—A health
17 insurance issuer shall be deemed to be a des-
18 ignated decisionmaker for purposes of subpara-
19 graph (A) with respect to the participants and
20 beneficiaries of an employer or plan sponsor,
21 whether or not the employer or plan sponsor
22 makes such a designation, and shall be deemed
23 to have assumed unconditionally all liability of
24 the employer or plan sponsor under such des-
25 ignation in accordance with subsection (o), un-

1 less the employer or plan sponsor affirmatively
2 enters into a contract to prevent the service of
3 the designated decisionmaker.

4 “(C) TREATMENT OF CERTAIN TRUST
5 FUNDS.—For purposes of this paragraph, the
6 terms ‘employer’ and ‘plan sponsor’, in connec-
7 tion with the assumption by a designated deci-
8 sionmaker of the liability of employer or other
9 plan sponsor pursuant to this paragraph, shall
10 be construed to include a trust fund maintained
11 pursuant to section 302 of the Labor Manage-
12 ment Relations Act, 1947 (29 U.S.C. 186) or
13 the Railway Labor Act (45 U.S.C. 151 et seq.).

14 “(10) PREVIOUSLY PROVIDED SERVICES.—

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

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

1 “(i) prohibit a cause of action under
2 paragraph (1) where the nonpayment in-
3 volved results in the participant or bene-
4 ficiary being unable to receive further
5 items or services that are directly related
6 to the item or service involved in the denial
7 referred to in subparagraph (A) or that
8 are part of a continuing treatment or se-
9 ries of procedures;

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

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

17 “(11) EXEMPTION FROM PERSONAL LIABILITY
18 FOR INDIVIDUAL MEMBERS OF BOARDS OF DIREC-
19 TORS, JOINT BOARDS OF TRUSTEES, ETC.—Any indi-
20 vidual who is—

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

23 “(B) a member of an association, com-
24 mittee, employee organization, joint board of
25 trustees, or other similar group of representa-

1 tives of the entities that are the plan sponsor
2 of plan maintained by two or more employers
3 and one or more employee organizations;
4 shall not be personally liable under this subsection
5 for conduct that is within the scope of employment
6 or of plan-related duties of the individuals unless the
7 individual acts in a fraudulent manner for personal
8 enrichment.

9 “(12) CHOICE OF LAW.—A cause of action
10 brought under paragraph (1) shall be governed by
11 the law (including choice of law rules) of the State
12 in which the plaintiff resides.

13 “(13) LIMITATION ON ATTORNEYS’ FEES.—

14 “(A) IN GENERAL.—Notwithstanding any
15 other provision of law, or any arrangement,
16 agreement, or contract regarding an attorney’s
17 fee, the amount of an attorney’s contingency fee
18 allowable for a cause of action brought under
19 paragraph (1) shall not exceed $\frac{1}{3}$ of the total
20 amount of the plaintiff’s recovery (not including
21 the reimbursement of actual out-of-pocket ex-
22 penses of the attorney).

23 “(B) DETERMINATION BY COURT.—The
24 last court in which the action was pending upon
25 the final disposition, including all appeals, of

1 the action may review the attorney’s fee to en-
2 sure that the fee is a reasonable one.

3 “(C) NO PREEMPTION OF STATE LAW.—
4 Subparagraph (A) shall not apply with respect
5 to a cause of action under paragraph (1) that
6 is brought in a State that has a law or frame-
7 work of laws with respect to the amount of an
8 attorney’s contingency fee that may be incurred
9 for the representation of a participant or bene-
10 ficiary (or the estate of such participant or ben-
11 eficiary) who brings such a cause of action.

12 “(e) RULES OF CONSTRUCTION RELATING TO
13 HEALTH CARE.—Nothing in this title shall be construed
14 as—

15 “(1) affecting any State law relating to the
16 practice of medicine or the provision of, or the fail-
17 ure to provide, medical care, or affecting any action
18 (whether the liability is direct or vicarious) based
19 upon such a State law,

20 “(2) superseding any State law permitted under
21 section 152(b)(1)(A) of the Bipartisan Patient Pro-
22 tection Act, or

23 “(3) affecting any applicable State law with re-
24 spect to limitations on monetary damages.

1 “(f) NO RIGHT OF ACTION FOR RECOVERY, INDEM-
2 NITY, OR CONTRIBUTION BY ISSUERS AGAINST TREATING
3 HEALTH CARE PROFESSIONALS AND TREATING HOS-
4 PITALS.—In the case of any care provided, or any treat-
5 ment decision made, by the treating health care profes-
6 sional or the treating hospital of a participant or bene-
7 ficiary under a group health plan which consists of medical
8 care provided under such plan, any cause of action under
9 State law against the treating health care professional or
10 the treating hospital by the plan or a health insurance
11 issuer providing health insurance coverage in connection
12 with the plan for recovery, indemnity, or contribution in
13 connection with such care (or any medically reviewable de-
14 cision made in connection with such care) or such treat-
15 ment decision is superseded.”.

16 (c) EFFECTIVE DATE.—The amendments made by
17 this section shall apply to acts and omissions (from which
18 a cause of action arises) occurring on or after the applica-
19 ble effective under section 601.

20 **SEC. 403. LIMITATION ON CERTAIN CLASS ACTION LITIGA-**
21 **TION.**

22 Section 502 of the Employee Retirement Income Se-
23 curity Act of 1974 (29 U.S.C. 1132), as amended by sec-
24 tion 402, is further amended by adding at the end the
25 following:

1 “(p) LIMITATION ON CLASS ACTION LITIGATION.—

2 “(1) IN GENERAL.—Any claim or cause of ac-
3 tion that is maintained under this section in connec-
4 tion with a group health plan, or health insurance
5 coverage issued in connection with a group health
6 plan, as a class action, derivative action, or as an ac-
7 tion on behalf of any group of 2 or more claimants,
8 may be maintained only if the class, the derivative
9 claimant, or the group of claimants is limited to the
10 participants or beneficiaries of a group health plan
11 established by only 1 plan sponsor. No action main-
12 tained by such class, such derivative claimant, or
13 such group of claimants may be joined in the same
14 proceeding with any action maintained by another
15 class, derivative claimant, or group of claimants or
16 consolidated for any purpose with any other pro-
17 ceeding. In this paragraph, the terms ‘group health
18 plan’ and ‘health insurance coverage’ have the mean-
19 ings given such terms in section 733.

20 “(2) EFFECTIVE DATE.—This subsection shall
21 apply to all civil actions that are filed on or after
22 January 1, 2002.”.

23 **SEC. 404. LIMITATIONS ON ACTIONS.**

24 Section 502 of the Employee Retirement Income Se-
25 curity Act of 1974 (29 U.S.C. 1132) (as amended by sec-

1 tion 402(a)) is amended further by adding at the end the
2 following new subsection:

3 “(q) LIMITATIONS ON ACTIONS RELATING TO GROUP
4 HEALTH PLANS.—

5 “(1) IN GENERAL.—Except as provided in para-
6 graph (2), no action may be brought under sub-
7 section (a)(1)(B), (a)(2), or (a)(3) by a participant
8 or beneficiary seeking relief based on the application
9 of any provision in section 101, subtitle B, or sub-
10 title D of title I of the Bipartisan Patient Protection
11 Act (as incorporated under section 714).

12 “(2) CERTAIN ACTIONS ALLOWABLE.—An ac-
13 tion may be brought under subsection (a)(1)(B),
14 (a)(2), or (a)(3) by a participant or beneficiary seek-
15 ing relief based on the application of section 101,
16 113, 114, 115, 116, 117, 118(a)(3), 119, or 120 of
17 the Bipartisan Patient Protection Act (as incor-
18 porated under section 714) to the individual cir-
19 cumstances of that participant or beneficiary, except
20 that—

21 “(A) such an action may not be brought or
22 maintained as a class action; and

23 “(B) in such an action, relief may only
24 provide for the provision of (or payment of)
25 benefits, items, or services denied to the indi-

1 vidual participant or beneficiary involved (and
2 for attorney’s fees and the costs of the action,
3 at the discretion of the court) and shall not pro-
4 vide for any other relief to the participant or
5 beneficiary or for any relief to any other person.

6 “(3) OTHER PROVISIONS UNAFFECTED.—Noth-
7 ing in this subsection shall be construed as affecting
8 subsections (a)(1)(C) and (n) or section 514(d).

9 “(4) ENFORCEMENT BY SECRETARY UNAF-
10 FECTED.—Nothing in this subsection shall be con-
11 strued as affecting any action brought by the Sec-
12 retary.”.

13 **SEC. 405. COOPERATION BETWEEN FEDERAL AND STATE**
14 **AUTHORITIES.**

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

19 **“SEC. 735. COOPERATION BETWEEN FEDERAL AND STATE**
20 **AUTHORITIES.**

21 “(a) AGREEMENT WITH STATES.—A State may enter
22 into an agreement with the Secretary for the delegation
23 to the State of some or all of the Secretary’s authority
24 under this title to enforce the requirements applicable
25 under title I of the Bipartisan Patient Protection Act with

1 respect to health insurance coverage offered by a health
2 insurance issuer and with respect to a group health plan
3 that is a non-Federal governmental plan.

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

10 **SEC. 406. SENSE OF THE SENATE CONCERNING THE IMPOR-**
11 **TANCE OF CERTAIN UNPAID SERVICES.**

12 It is the sense of the Senate that the court should
13 consider the loss of a nonwage earning spouse or parent
14 as an economic loss for the purposes of this section. Fur-
15 thermore, the court should define the compensation for the
16 loss not as minimum services, but, rather, in terms that
17 fully compensate for the true and whole replacement cost
18 to the family.

1 **TITLE V—AMENDMENTS TO THE**
2 **INTERNAL REVENUE CODE**
3 **OF 1986**

4 **Subtitle A—Application of Patient**
5 **Protection Provisions**

6 **SEC. 501. APPLICATION TO GROUP HEALTH PLANS UNDER**
7 **THE INTERNAL REVENUE CODE OF 1986.**

8 Subchapter B of chapter 100 of the Internal Revenue
9 Code of 1986 is amended—

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

“Sec. 9813. Standard relating to patients’ bill of rights.”;

13 and

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

16 **“SEC. 9813. STANDARD RELATING TO PATIENTS’ BILL OF**
17 **RIGHTS.**

18 “A group health plan shall comply with the require-
19 ments of title I of the Bipartisan Patient Protection Act
20 (as in effect as of the date of the enactment of such Act),
21 and such requirements shall be deemed to be incorporated
22 into this section.”.

1 **SEC. 502. CONFORMING ENFORCEMENT FOR WOMEN'S**
2 **HEALTH AND CANCER RIGHTS.**

3 Subchapter B of chapter 100 of the Internal Revenue
4 Code of 1986, as amended by section 501, is further
5 amended—

6 (1) in the table of sections, by inserting after
7 the item relating to section 9813 the following new
8 item:

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

9 and

10 (2) by inserting after section 9813 the fol-
11 lowing:

12 **“SEC. 9814. STANDARD RELATING TO WOMEN'S HEALTH**
13 **AND CANCER RIGHTS.**

14 “The provisions of section 713 of the Employee Re-
15 tirement Income Security Act of 1974 (as in effect as of
16 the date of the enactment of this section) shall apply to
17 group health plans as if included in this subchapter.”.

18 **Subtitle B—Health Care Coverage**
19 **Access Tax Incentives**

20 **SEC. 511. EXPANDED AVAILABILITY OF ARCHER MSAS.**

21 (a) EXTENSION OF PROGRAM.—Paragraphs (2) and
22 (3)(B) of section 220(i) of the Internal Revenue Code of
23 1986 (defining cut-off year) are each amended by striking
24 “2002” each place it appears and inserting “2004”.

1 (b) INCREASE IN NUMBER OF PERMITTED ACCOUNT
2 PARTICIPANTS.—

3 (1) IN GENERAL.—Subsection (j) of section 220
4 of such Code is amended by redesignating para-
5 graphs (3), (4), and (5) as paragraphs (4), (5), and
6 (6) and by inserting after paragraph (2) the fol-
7 lowing new paragraph:

8 “(3) DETERMINATION OF WHETHER LIMIT EX-
9 CEDED FOR YEARS AFTER 2001.—

10 “(A) IN GENERAL.—The numerical limita-
11 tion for any year after 2001 is exceeded if the
12 sum of—

13 “(i) the number of Archer MSA re-
14 turns filed on or before April 15 of such
15 calendar year for taxable years ending with
16 or within the preceding calendar year, plus

17 “(ii) the Secretary’s estimate (deter-
18 mined on the basis of the returns described
19 in clause (i)) of the number of Archer
20 MSA returns for such taxable years which
21 will be filed after such date, exceeds
22 1,000,000. For purposes of the preceding
23 sentence, the term ‘Archer MSA return’
24 means any return on which any exclusion

1 is claimed under section 106(b) or any de-
2 duction is claimed under this section.

3 “(B) ALTERNATIVE COMPUTATION OF LIM-
4 ITATION.—The numerical limitation for any
5 year after 2001 is also exceeded if the sum of—

6 “(i) 90 percent of the sum determined
7 under subparagraph (A) for such calendar
8 year, plus

9 “(ii) the product of 2.5 and the num-
10 ber of medical savings accounts established
11 during the portion of such year preceding
12 July 1 (based on the reports required
13 under paragraph (5)) for taxable years be-
14 ginning in such year,

15 exceeds 1,000,000”.

16 (2) CONFORMING AMENDMENTS.—

17 (A) Clause (ii) of section 220(j)(2)(B) of
18 such Code is amended by striking “paragraph
19 (4)” and inserting “paragraph (5)”.

20 (B) Subparagraph (A) of section 220(j)(4)
21 of such Code is amended by striking “and
22 2001” and inserting “2001, 2002, and 2003”.

23 (c) INCREASE IN SIZE OF ELIGIBLE EMPLOYERS.—
24 Subparagraph (A) of section 220(c)(4) of such Code is

1 amended by striking “50 or fewer employees” and insert-
2 ing “100 or fewer employees”.

3 (d) EFFECTIVE DATE.—The amendments made by
4 this section shall take effect on the date of the enactment
5 of this Act.

6 (e) GAO STUDY.—Not later than 1 year after the
7 date of the enactment of this Act, the Comptroller General
8 of the United States shall prepare and submit a report
9 to the Committee on Ways and Means of the House of
10 Representatives and the Committee on Finance of the
11 Senate on the impact of Archer MSAs on the cost of con-
12 ventional insurance (especially in those areas where there
13 are higher numbers of such accounts) and on adverse se-
14 lection and health care costs.

15 **SEC. 512. DEDUCTION FOR 100 PERCENT OF HEALTH IN-**
16 **SURANCE COSTS OF SELF-EMPLOYED INDI-**
17 **VIDUALS.**

18 (a) IN GENERAL.—Paragraph (1) of section 162(l)
19 of the Internal Revenue Code of 1986 is amended to read
20 as follows:

21 “(1) ALLOWANCE OF DEDUCTION.—In the case
22 of an individual who is an employee within the
23 meaning of section 401(c)(1), there shall be allowed
24 as a deduction under this section an amount equal
25 to 100 percent of the amount paid during the tax-

1 “(1) in the case of insurance purchased as a
2 member of a qualified health benefit purchasing coa-
3 lition (as defined in section 9841), 30 percent, and

4 “(2) in the case of insurance not described in
5 paragraph (1), 20 percent.

6 “(c) LIMITATIONS.—

7 “(1) PER EMPLOYEE DOLLAR LIMITATION.—

8 The amount of expenses taken into account under
9 subsection (a) with respect to any employee for any
10 taxable year shall not exceed—

11 “(A) \$2,000 in the case of self-only cov-
12 erage, and

13 “(B) \$5,000 in the case of family coverage.

14 In the case of an employee who is covered by a new
15 health plan of the employer for only a portion of
16 such taxable year, the limitation under the preceding
17 sentence shall be an amount which bears the same
18 ratio to such limitation (determined without regard
19 to this sentence) as such portion bears to the entire
20 taxable year.

21 “(2) PERIOD OF COVERAGE.—Expenses may be
22 taken into account under subsection (a) only with
23 respect to coverage for the 4-year period beginning
24 on the date the employer establishes a new health
25 plan.

1 “(d) DEFINITIONS.—For purposes of this section—

2 “(1) HEALTH INSURANCE COVERAGE.—The
3 term ‘health insurance coverage’ has the meaning
4 given such term by section 9832(b)(1).

5 “(2) NEW HEALTH PLAN.—

6 “(A) IN GENERAL.—The term ‘new health
7 plan’ means any arrangement of the employer
8 which provides health insurance coverage to em-
9 ployees if—

10 “(i) such employer (and any prede-
11 cessor employer) did not establish or main-
12 tain such arrangement (or any similar ar-
13 rangement) at any time during the 2 tax-
14 able years ending prior to the taxable year
15 in which the credit under this section is
16 first allowed, and

17 “(ii) such arrangement provides
18 health insurance coverage to at least 70
19 percent of the qualified employees of such
20 employer.

21 “(B) QUALIFIED EMPLOYEE.—

22 “(i) IN GENERAL.—The term ‘quali-
23 fied employee’ means any employee of an
24 employer if the annual rate of such em-

1 employee's compensation (as defined in sec-
2 tion 414(s)) exceeds \$10,000.

3 “(ii) TREATMENT OF CERTAIN EM-
4 PLOYEES.—The term ‘employee’ shall in-
5 clude a leased employee within the mean-
6 ing of section 414(n).

7 “(3) SMALL EMPLOYER.—The term ‘small em-
8 ployer’ has the meaning given to such term by sec-
9 tion 4980D(d)(2); except that only qualified employ-
10 ees shall be taken into account.

11 “(e) SPECIAL RULES.—

12 “(1) CERTAIN RULES MADE APPLICABLE.—For
13 purposes of this section, rules similar to the rules of
14 section 52 shall apply.

15 “(2) AMOUNTS PAID UNDER SALARY REDUC-
16 TION ARRANGEMENTS.—No amount paid or incurred
17 pursuant to a salary reduction arrangement shall be
18 taken into account under subsection (a).

19 “(f) TERMINATION.—This section shall not apply to
20 expenses paid or incurred by an employer with respect to
21 any arrangement established on or after January 1,
22 2010.”.

23 (b) CREDIT TO BE PART OF GENERAL BUSINESS
24 CREDIT.—Section 38(b) of such Code (relating to current
25 year business credit) is amended by striking “plus” at the

1 end of paragraph (12), by striking the period at the end
2 of paragraph (13) and inserting “, plus”, and by adding
3 at the end the following:

4 “(14) in the case of a small employer (as de-
5 fined in section 45E(d)(3)), the health insurance
6 credit determined under section 45E(a).”.

7 (c) NO CARRYBACKS.—Subsection (d) of section 39
8 of such Code (relating to carryback and carryforward of
9 unused credits) is amended by adding at the end the fol-
10 lowing:

11 “(10) NO CARRYBACK OF SECTION 45E CREDIT
12 BEFORE EFFECTIVE DATE.—No portion of the un-
13 used business credit for any taxable year which is
14 attributable to the employee health insurance ex-
15 penses credit determined under section 45E may be
16 carried back to a taxable year ending before the date
17 of the enactment of section 45E.”.

18 (d) DENIAL OF DOUBLE BENEFIT.—Section 280C of
19 such Code is amended by adding at the end the following
20 new subsection:

21 “(d) CREDIT FOR SMALL BUSINESS HEALTH INSUR-
22 ANCE EXPENSES.—

23 “(1) IN GENERAL.—No deduction shall be al-
24 lowed for that portion of the expenses (otherwise al-
25 lowable as a deduction) taken into account in deter-

1 mining the credit under section 45E for the taxable
2 year which is equal to the amount of the credit de-
3 termined for such taxable year under section
4 45E(a).

5 “(2) CONTROLLED GROUPS.—Persons treated
6 as a single employer under subsection (a) or (b) of
7 section 52 shall be treated as 1 person for purposes
8 of this section.”.

9 (e) CLERICAL AMENDMENT.—The table of sections
10 for subpart D of part IV of subchapter A of chapter 1
11 of such Code is amended by adding at the end the fol-
12 lowing:

“Sec. 45E. Small business health insurance expenses.”.

13 (f) EFFECTIVE DATE.—The amendments made by
14 this section shall apply to amounts paid or incurred in tax-
15 able years beginning after December 31, 2001, for ar-
16 rangements established after the date of the enactment
17 of this Act.

18 **SEC. 514. CERTAIN GRANTS BY PRIVATE FOUNDATIONS TO**
19 **QUALIFIED HEALTH BENEFIT PURCHASING**
20 **COALITIONS.**

21 (a) IN GENERAL.—Section 4942 of the Internal Rev-
22 enue Code of 1986 (relating to taxes on failure to dis-
23 tribute income) is amended by adding at the end the fol-
24 lowing:

1 “(k) CERTAIN QUALIFIED HEALTH BENEFIT PUR-
2 CHASING COALITION DISTRIBUTIONS.—

3 “(1) IN GENERAL.—For purposes of subsection
4 (g), sections 170, 501, 507, 509, and 2522, and this
5 chapter, a qualified health benefit purchasing coalition
6 distribution by a private foundation shall be
7 considered to be a distribution for a charitable pur-
8 pose.

9 “(2) QUALIFIED HEALTH BENEFIT PUR-
10 CHASING COALITION DISTRIBUTION.—For purposes
11 of paragraph (1)—

12 “(A) IN GENERAL.—The term ‘qualified
13 health benefit purchasing coalition distribution’
14 means any amount paid or incurred by a pri-
15 vate foundation to or on behalf of a qualified
16 health benefit purchasing coalition (as defined
17 in section 9841) for purposes of payment or re-
18 imbursement of amounts paid or incurred in
19 connection with the establishment and mainte-
20 nance of such coalition.

21 “(B) EXCLUSIONS.—Such term shall not
22 include any amount used by a qualified health
23 benefit purchasing coalition (as so defined)—

24 “(i) for the purchase of real property,

1 “(ii) as payment to, or for the benefit
2 of, members (or employees or affiliates of
3 such members) of such coalition, or

4 “(iii) for any expense paid or incurred
5 more than 48 months after the date of es-
6 tablishment of such coalition.

7 “(3) TERMINATION.—This subsection shall not
8 apply—

9 “(A) to qualified health benefit purchasing
10 coalition distributions paid or incurred after
11 December 31, 2009, and

12 “(B) with respect to start-up costs of a co-
13 alition which are paid or incurred after Decem-
14 ber 31, 2010.”.

15 (b) QUALIFIED HEALTH BENEFIT PURCHASING CO-
16 ALITION.—

17 (1) IN GENERAL.—Chapter 100 of such Code
18 (relating to group health plan requirements) is
19 amended by adding at the end the following new
20 subchapter:

21 **“Subchapter D—Qualified Health Benefit**
22 **Purchasing Coalition**

 “Sec. 9841. Qualified health benefit purchasing coalition.

1 **“SEC. 9841. QUALIFIED HEALTH BENEFIT PURCHASING CO-**
2 **ALITION.**

3 “(a) IN GENERAL.—A qualified health benefit pur-
4 chasing coalition is a private not-for-profit corporation
5 which—

6 “(1) sells health insurance through State li-
7 censed health insurance issuers in the State in which
8 the employers to which such coalition is providing
9 insurance are located, and

10 “(2) establishes to the Secretary, under State
11 certification procedures or other procedures as the
12 Secretary may provide by regulation, that such coali-
13 tion meets the requirements of this section.

14 “(b) BOARD OF DIRECTORS.—

15 “(1) IN GENERAL.—Each purchasing coalition
16 under this section shall be governed by a Board of
17 Directors.

18 “(2) ELECTION.—The Secretary shall establish
19 procedures governing election of such Board.

20 “(3) MEMBERSHIP.—The Board of Directors
21 shall—

22 “(A) be composed of representatives of the
23 members of the coalition, in equal number, in-
24 cluding small employers and employee rep-
25 resentatives of such employers, but

1 “(B) not include other interested parties,
2 such as service providers, health insurers, or in-
3 surance agents or brokers which may have a
4 conflict of interest with the purposes of the coa-
5 lition.

6 “(c) MEMBERSHIP OF COALITION.—

7 “(1) IN GENERAL.—A purchasing coalition
8 shall accept all small employers residing within the
9 area served by the coalition as members if such em-
10 ployers request such membership.

11 “(2) OTHER MEMBERS.—The coalition, at the
12 discretion of its Board of Directors, may be open to
13 individuals and large employers.

14 “(3) VOTING.—Members of a purchasing coali-
15 tion shall have voting rights consistent with the rules
16 established by the State.

17 “(d) DUTIES OF PURCHASING COALITIONS.—Each
18 purchasing coalition shall—

19 “(1) enter into agreements with small employ-
20 ers (and, at the discretion of its Board, with individ-
21 uals and other employers) to provide health insur-
22 ance benefits to employees and retirees of such em-
23 ployers,

1 “(2) where feasible, enter into agreements with
2 3 or more unaffiliated, qualified licensed health
3 plans, to offer benefits to members,

4 “(3) offer to members at least 1 open enroll-
5 ment period of at least 30 days per calendar year,

6 “(4) serve a significant geographical area and
7 market to all eligible members in that area, and

8 “(5) carry out other functions provided for
9 under this section.

10 “(e) LIMITATION ON ACTIVITIES.—A purchasing coa-
11 lition shall not—

12 “(1) perform any activity (including certifi-
13 cation or enforcement) relating to compliance or li-
14 censing of health plans,

15 “(2) assume insurance or financial risk in rela-
16 tion to any health plan, or

17 “(3) perform other activities identified by the
18 State as being inconsistent with the performance of
19 its duties under this section.

20 “(f) ADDITIONAL REQUIREMENTS FOR PURCHASING
21 COALITIONS.—As provided by the Secretary in regula-
22 tions, a purchasing coalition shall be subject to require-
23 ments similar to the requirements of a group health plan
24 under this chapter.

25 “(g) RELATION TO OTHER LAWS.—

1 “(1) PREEMPTION OF STATE FICTITIOUS
2 GROUP LAWS.—Requirements (commonly referred to
3 as fictitious group laws) relating to grouping and
4 similar requirements for health insurance coverage
5 are preempted to the extent such requirements im-
6 pede the establishment and operation of qualified
7 health benefit purchasing coalitions.

8 “(2) ALLOWING SAVINGS TO BE PASSED
9 THROUGH.—Any State law that prohibits health in-
10 surance issuers from reducing premiums on health
11 insurance coverage sold through a qualified health
12 benefit purchasing coalition to reflect administrative
13 savings is preempted. This paragraph shall not be
14 construed to preempt State laws that impose restric-
15 tions on premiums based on health status, claims
16 history, industry, age, gender, or other underwriting
17 factors.

18 “(3) NO WAIVER OF HIPAA REQUIREMENTS.—
19 Nothing in this section shall be construed to change
20 the obligation of health insurance issuers to comply
21 with the requirements of title XXVII of the Public
22 Health Service Act with respect to health insurance
23 coverage offered to small employers in the small
24 group market through a qualified health benefit pur-
25 chasing coalition.

1 “(h) DEFINITION OF SMALL EMPLOYER.—For pur-
2 poses of this section—

3 “(1) IN GENERAL.—The term ‘small employer’
4 means, with respect to any calendar year, any em-
5 ployer if such employer employed an average of at
6 least 2 and not more than 50 qualified employees on
7 business days during either of the 2 preceding cal-
8 endar years. For purposes of the preceding sentence,
9 a preceding calendar year may be taken into account
10 only if the employer was in existence throughout
11 such year.

12 “(2) EMPLOYERS NOT IN EXISTENCE IN PRE-
13 CEDING YEAR.—In the case of an employer which
14 was not in existence throughout the 1st preceding
15 calendar year, the determination under paragraph
16 (1) shall be based on the average number of quali-
17 fied employees that it is reasonably expected such
18 employer will employ on business days in the current
19 calendar year.”.

20 “(2) CONFORMING AMENDMENT.—The table of
21 subchapters for chapter 100 of such Code is amend-
22 ed by adding at the end the following item:

 “Subchapter D. Qualified health benefit purchasing coalition.”.

23 “(c) EFFECTIVE DATE.—The amendment made by
24 subsection (a) shall apply to taxable years beginning after
25 December 31, 2001.

1 **SEC. 515. STATE GRANT PROGRAM FOR MARKET INNOVA-**
2 **TION.**

3 (a) IN GENERAL.—The Secretary of Health and
4 Human Services (in this section referred to as the “Sec-
5 retary”) shall establish a program (in this section referred
6 to as the “program”) to award demonstration grants
7 under this section to States to allow States to demonstrate
8 the effectiveness of innovative ways to increase access to
9 health insurance through market reforms and other inno-
10 vative means. Such innovative means may include (and are
11 not limited to) any of the following:

12 (1) Alternative group purchasing or pooling ar-
13 rangements, such as purchasing cooperatives for
14 small businesses, reinsurance pools, or high risk
15 pools.

16 (2) Individual or small group market reforms.

17 (3) Consumer education and outreach.

18 (4) Subsidies to individuals, employers, or both,
19 in obtaining health insurance.

20 (b) SCOPE; DURATION.—The program shall be lim-
21 ited to not more than 10 States and to a total period of
22 5 years, beginning on the date the first demonstration
23 grant is made.

24 (c) CONDITIONS FOR DEMONSTRATION GRANTS.—

25 (1) IN GENERAL.—The Secretary may not pro-
26 vide for a demonstration grant to a State under the

1 program unless the Secretary finds that under the
2 proposed demonstration grant—

3 (A) the State will provide for demonstrated
4 increase of access for some portion of the exist-
5 ing uninsured population through a market in-
6 novation (other than merely through a financial
7 expansion of a program initiated before the
8 date of the enactment of this Act);

9 (B) the State will comply with applicable
10 Federal laws;

11 (C) the State will not discriminate among
12 participants on the basis of any health status-
13 related factor (as defined in section 2791(d)(9)
14 of the Public Health Service Act), except to the
15 extent a State wishes to focus on populations
16 that otherwise would not obtain health insur-
17 ance because of such factors; and

18 (D) the State will provide for such evalua-
19 tion, in coordination with the evaluation re-
20 quired under subsection (d), as the Secretary
21 may specify.

22 (2) APPLICATION.—The Secretary shall not
23 provide a demonstration grant under the program to
24 a State unless—

1 (A) the State submits to the Secretary
2 such an application, in such a form and man-
3 ner, as the Secretary specifies;

4 (B) the application includes information
5 regarding how the demonstration grant will ad-
6 dress issues such as governance, targeted popu-
7 lation, expected cost, and the continuation after
8 the completion of the demonstration grant pe-
9 riod; and

10 (C) the Secretary determines that the dem-
11 onstration grant will be used consistent with
12 this section.

13 (3) FOCUS.—A demonstration grant proposal
14 under section need not cover all uninsured individ-
15 uals in a State or all health care benefits with re-
16 spect to such individuals.

17 (d) EVALUATION.—The Secretary shall enter into a
18 contract with an appropriate entity outside the Depart-
19 ment of Health and Human Services to conduct an overall
20 evaluation of the program at the end of the program pe-
21 riod. Such evaluation shall include an analysis of improve-
22 ments in access, costs, quality of care, or choice of cov-
23 erage, under different demonstration grants.

24 (e) OPTION TO PROVIDE FOR INITIAL PLANNING
25 GRANTS.—Notwithstanding the previous provisions of this

1 section, under the program the Secretary may provide for
2 a portion of the amounts appropriated under subsection
3 (f) (not to exceed \$5,000,000) to be made available to any
4 State for initial planning grants to permit States to de-
5 velop demonstration grant proposals under the previous
6 provisions of this section.

7 (f) AUTHORIZATION OF APPROPRIATIONS.—There
8 are authorized to be appropriated \$100,000,000 for each
9 fiscal year to carry out this section. Amounts appropriated
10 under this subsection shall remain available until ex-
11 pended.

12 (g) STATE DEFINED.—For purposes of this section,
13 the term “State” has the meaning given such term for
14 purposes of title XIX of the Social Security Act.

15 **TITLE VI—EFFECTIVE DATES;**
16 **COORDINATION IN IMPLE-**
17 **MENTATION**

18 **SEC. 601. EFFECTIVE DATES.**

19 (a) GROUP HEALTH COVERAGE.—

20 (1) IN GENERAL.—Subject to paragraph (2)
21 and subsection (d), the amendments made by sec-
22 tions 201(a), 401, 403, 501, and 502 (and title I in-
23 sofar as it relates to such sections) shall apply with
24 respect to group health plans, and health insurance
25 coverage offered in connection with group health

1 plans, for plan years beginning on or after October
2 1, 2002 (in this section referred to as the “general
3 effective date”).

4 (2) TREATMENT OF COLLECTIVE BARGAINING
5 AGREEMENTS.—In the case of a group health plan
6 maintained pursuant to one or more collective bar-
7 gaining agreements between employee representa-
8 tives and one or more employers ratified before the
9 date of the enactment of this Act, the amendments
10 made by sections 201(a), 401, 403, 501, and 502
11 (and title I insofar as it relates to such sections)
12 shall not apply to plan years beginning before the
13 later of—

14 (A) the date on which the last collective
15 bargaining agreements relating to the plan ter-
16 minates (excluding any extension thereof agreed
17 to after the date of the enactment of this Act);
18 or

19 (B) the general effective date;
20 but shall apply not later than 1 year after the gen-
21 eral effective date. For purposes of subparagraph
22 (A), any plan amendment made pursuant to a collec-
23 tive bargaining agreement relating to the plan which
24 amends the plan solely to conform to any require-

1 ment added by this Act shall not be treated as a ter-
2 mination of such collective bargaining agreement.

3 (b) INDIVIDUAL HEALTH INSURANCE COVERAGE.—

4 Subject to subsection (d), the amendments made by sec-
5 tion 202 shall apply with respect to individual health in-
6 surance coverage offered, sold, issued, renewed, in effect,
7 or operated in the individual market on or after the gen-
8 eral effective date.

9 (c) TREATMENT OF RELIGIOUS NONMEDICAL PRO-
10 VIDERS.—

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

13 (A) restrict or limit the right of group
14 health plans, and of health insurance issuers of-
15 fering health insurance coverage, to include as
16 providers religious nonmedical providers;

17 (B) require such plans or issuers to—

18 (i) utilize medically based eligibility
19 standards or criteria in deciding provider
20 status of religious nonmedical providers;

21 (ii) use medical professionals or cri-
22 teria to decide patient access to religious
23 nonmedical providers;

24 (iii) utilize medical professionals or
25 criteria in making decisions in internal or

1 external appeals regarding coverage for
2 care by religious nonmedical providers; or
3 (iv) compel a participant or bene-
4 ficiary to undergo a medical examination
5 or test as a condition of receiving health
6 insurance coverage for treatment by a reli-
7 gious nonmedical provider; or

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

14 (2) RELIGIOUS NONMEDICAL PROVIDER.—For
15 purposes of this subsection, the term “religious non-
16 medical provider” means a provider who provides no
17 medical care but who provides only religious non-
18 medical treatment or religious nonmedical nursing
19 care.

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

23 (1) subsection (a) with respect to a group
24 health plan that is maintained as of the general ef-
25 fective date, not later than 30 days before the begin-

1 ning of the first plan year to which title I applies
2 in connection with the plan under such subsection;
3 or

4 (2) subsection (b) with respect to a individual
5 health insurance coverage that is in effect as of the
6 general effective date, not later than 30 days before
7 the first date as of which title I applies to the cov-
8 erage under such subsection.

9 **SEC. 602. COORDINATION IN IMPLEMENTATION.**

10 The Secretary of Labor and the Secretary of Health
11 and Human Services shall ensure, through the execution
12 of an interagency memorandum of understanding among
13 such Secretaries, that—

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

20 (2) coordination of policies relating to enforcing
21 the same requirements through such Secretaries in
22 order to have a coordinated enforcement strategy
23 that avoids duplication of enforcement efforts and
24 assigns priorities in enforcement.

1 **SEC. 603. SEVERABILITY.**

2 If any provision of this Act, an amendment made by
3 this Act, or the application of such provision or amend-
4 ment to any person or circumstance is held to be unconsti-
5 tutional, the remainder of this Act, the amendments made
6 by this Act, and the application of the provisions of such
7 to any person or circumstance shall not be affected there-
8 by.

9 **TITLE VII—MISCELLANEOUS**
10 **PROVISIONS**

11 **SEC. 701. NO IMPACT ON SOCIAL SECURITY TRUST FUND.**

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

16 (b) TRANSFERS.—

17 (1) ESTIMATE OF SECRETARY.—The Secretary
18 of the Treasury shall annually estimate the impact
19 that the enactment of this Act has on the income
20 and balances of the trust funds established under
21 section 201 of the Social Security Act (42 U.S.C.
22 401).

23 (2) TRANSFER OF FUNDS.—If, under para-
24 graph (1), the Secretary of the Treasury estimates
25 that the enactment of this Act has a negative impact
26 on the income and balances of the trust funds estab-

1 lished under section 201 of the Social Security Act
2 (42 U.S.C. 401), the Secretary shall transfer, not
3 less frequently than quarterly, from the general reve-
4 nues of the Federal Government an amount suffi-
5 cient so as to ensure that the income and balances
6 of such trust funds are not reduced as a result of
7 the enactment of such Act.

8 **SEC. 702. CUSTOMS USER FEES.**

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

14 **SEC. 703. FISCAL YEAR 2002 MEDICARE PAYMENTS.**

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

22 **SEC. 704. SENSE OF SENATE WITH RESPECT TO PARTICIPA-**
23 **TION IN CLINICAL TRIALS AND ACCESS TO**
24 **SPECIALTY CARE.**

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

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

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

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

9 (4) Breast cancer is the second leading cause of
10 cancer death among all women and the leading
11 cause of cancer death among women between ages
12 40 and 55.

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

15 (6) 1,500 children are expected to die from can-
16 cer this year.

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

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

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

1 (10) 31,500 men will die from prostate cancer
2 this year. It is the second leading cause of cancer in
3 men.

4 (11) While information obtained from clinical
5 trials is essential to finding cures for diseases, it is
6 still research which carries the risk of fatal results.
7 Future efforts should be taken to protect the health
8 and safety of adults and children who enroll in clin-
9 ical trials.

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

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

19 (1) men and women battling life-threatening,
20 deadly diseases, including advanced breast or ovar-
21 ian cancer, should have the opportunity to partici-
22 pate in a federally approved or funded clinical trial
23 recommended by their physician;

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

4 (A) that individual—

5 (i) has a life-threatening or serious ill-
6 ness for which no standard treatment is ef-
7 fective;

8 (ii) is eligible to participate in a feder-
9 ally approved or funded clinical trial ac-
10 cording to the trial protocol with respect to
11 treatment of the illness;

12 (B) that individual's participation in the
13 trial offers meaningful potential for significant
14 clinical benefit for the individual; and

15 (C) either—

16 (i) the referring physician is a partici-
17 pating health care professional and has
18 concluded that the individual's participa-
19 tion in the trial would be appropriate,
20 based upon the individual meeting the con-
21 ditions described in subparagraph (A); or

22 (ii) the participant, beneficiary, or en-
23 rollee provides medical and scientific infor-
24 mation establishing that the individual's
25 participation in the trial would be appro-

1 priate, based upon the individual meeting
2 the conditions described in subparagraph
3 (A);

4 (3) a child with a life-threatening illness, in-
5 cluding cancer, should be allowed to participate in a
6 federally approved or funded clinical trial if that
7 participation meets the requirements of paragraph
8 (2);

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

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

19 **SEC. 705. SENSE OF THE SENATE REGARDING FAIR REVIEW**
20 **PROCESS.**

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

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

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

4 (3) It is incompatible with a fair and inde-
5 pendent appeals process to allow a health mainte-
6 nance organization to select the review organization
7 that is entrusted with providing a neutral and unbi-
8 ased medical review.

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

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

17 (1) every patient who is denied care by a health
18 maintenance organization or other health insurance
19 company should be entitled to a fair, speedy, impar-
20 tial appeal to a review organization that has not
21 been selected by the health plan;

22 (2) the States should be empowered to maintain
23 and develop the appropriate process for selection of
24 the independent external review entity;

1 (3) a child battling a rare cancer whose health
2 maintenance organization has denied a covered
3 treatment recommended by its physician should be
4 entitled to a fair and impartial external appeal to a
5 review organization that has not been chosen by the
6 organization or plan that has denied the care; and

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

11 **SEC. 706. ANNUAL REVIEW.**

12 (a) IN GENERAL.—Not later than 24 months after
13 the general effective date referred to in section 601(a)(1),
14 and annually thereafter for each of the succeeding 4 cal-
15 endar years (or until a repeal is effective under subsection
16 (b)), the Secretary of Health and Human Services shall
17 request that the Institute of Medicine of the National
18 Academy of Sciences prepare and submit to the appro-
19 priate committees of Congress a report concerning the im-
20 pact of this Act, and the amendments made by this Act,
21 on the number of individuals in the United States with
22 health insurance coverage.

23 (b) LIMITATION WITH RESPECT TO CERTAIN
24 PLANS.—If the Secretary, in any report submitted under
25 subsection (a), determines that more than 1,000,000 indi-

1 individuals in the United States have lost their health insur-
2 ance coverage as a result of the enactment of this Act,
3 as compared to the number of individuals with health in-
4 surance coverage in the 12-month period preceding the
5 date of enactment of this Act, section 402 of this Act shall
6 be repealed effective on the date that is 12 month after
7 the date on which the report is submitted, and the submis-
8 sion of any further reports under subsection (a) shall not
9 be required.

10 (c) FUNDING.—From funds appropriated to the De-
11 partment of Health and Human Services for fiscal years
12 2003 and 2004, the Secretary of Health and Human Serv-
13 ices shall provide for such funding as the Secretary deter-
14 mines necessary for the conduct of the study of the Na-
15 tional Academy of Sciences under this section.

16 **SEC. 707. DEFINITION OF BORN-ALIVE INFANT.**

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

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

22 “(a) In determining the meaning of any Act of Con-
23 gress, or of any ruling, regulation, or interpretation of the
24 various administrative bureaus and agencies of the United
25 States, the words ‘person’, ‘human being’, ‘child’, and ‘in-

1 individual', shall include every infant member of the species
2 homo sapiens who is born alive at any stage of develop-
3 ment.

4 “(b) As used in this section, the term ‘born alive’,
5 with respect to a member of the species homo sapiens,
6 means the complete expulsion or extraction from his or
7 her mother of that member, at any stage of development,
8 who after such expulsion or extraction breathes or has a
9 beating heart, pulsation of the umbilical cord, or definite
10 movement of voluntary muscles, regardless of whether the
11 umbilical cord has been cut, and regardless of whether the
12 expulsion or extraction occurs as a result of natural or
13 induced labor, caesarean section, or induced abortion.

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

19 (b) CLERICAL AMENDMENT.—The table of sections
20 at the beginning of chapter 1 of title 1, United States
21 Code, is amended by adding at the end the following new
22 item:

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

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