

107TH CONGRESS
1ST SESSION

S. 1052

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

IN THE SENATE OF THE UNITED STATES

JUNE 14, 2001

Mr. MCCAIN (for himself, Mr. EDWARDS, and Mr. KENNEDY) introduced the following bill; which was read the first time

A BILL

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

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

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

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

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.

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. Coverage of limited scope plans.
- Sec. 155. Regulations.
- Sec. 156. Incorporation into plan or coverage documents.

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

- Sec. 201. Application to group health plans and group health insurance coverage.
- Sec. 202. Application to individual health insurance coverage.

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

- Sec. 301. Application of patient protection standards to group health plans and group health insurance coverage under the Employee Retirement Income Security Act of 1974.
- Sec. 302. Availability of civil remedies.
- Sec. 303. Limitations on actions.

TITLE IV—EFFECTIVE DATES; COORDINATION IN
IMPLEMENTATION

- Sec. 401. Effective dates.
Sec. 402. Coordination in implementation.
Sec. 403. Severability.

TITLE V—MISCELLANEOUS PROVISIONS

- Sec. 501. No impact on Social Security Trust Fund.
Sec. 502. Customs user fees.
Sec. 503. Fiscal year 2002 medicare payments.

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

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

7 (a) COMPLIANCE WITH REQUIREMENTS.—

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

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

1 are conducted in accordance with a utilization review
2 program that meets the requirements of this section.

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

12 (b) WRITTEN POLICIES AND CRITERIA.—

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

17 (2) USE OF WRITTEN CRITERIA.—

18 (A) IN GENERAL.—Such a program shall
19 utilize written clinical review criteria developed
20 with input from a range of appropriate actively
21 practicing health care professionals, as deter-
22 mined by the plan, pursuant to the program.
23 Such criteria shall include written clinical re-
24 view criteria that are based on valid clinical evi-
25 dence where available and that are directed spe-

1 cifically at meeting the needs of at-risk popu-
2 lations and covered individuals with chronic
3 conditions or severe illnesses, including gender-
4 specific criteria and pediatric-specific criteria
5 where available and appropriate.

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

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

21 (c) CONDUCT OF PROGRAM ACTIVITIES.—

22 (1) ADMINISTRATION BY HEALTH CARE PRO-
23 FESSIONALS.—A utilization review program shall be
24 administered by qualified health care professionals
25 who shall oversee review decisions.

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

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

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

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

22 (3) ACCESSIBILITY OF REVIEW.—Such a pro-
23 gram shall provide that appropriate personnel per-
24 forming utilization review activities under the pro-
25 gram, including the utilization review administrator,

1 are reasonably accessible by toll-free telephone dur-
2 ing normal business hours to discuss patient care
3 and allow response to telephone requests, and that
4 appropriate provision is made to receive and respond
5 promptly to calls received during other hours.

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

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

16 (a) PROCEDURES OF INITIAL CLAIMS FOR BENE-
17 FITS.—

18 (1) IN GENERAL.—A group health plan, or
19 health insurance issuer offering health insurance
20 coverage, shall—

21 (A) make a determination on an initial
22 claim for benefits by a participant, beneficiary,
23 or enrollee (or authorized representative) re-
24 garding payment or coverage for items or serv-
25 ices under the terms and conditions of the plan

1 or coverage involved, including any cost-sharing
2 amount that the participant, beneficiary, or en-
3 rollee is required to pay with respect to such
4 claim for benefits; and

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

16 (2) ACCESS TO INFORMATION.—

17 (A) TIMELY PROVISION OF NECESSARY IN-
18 FORMATION.—With respect to an initial claim
19 for benefits, the participant, beneficiary, or en-
20 rollee (or authorized representative) and the
21 treating health care professional (if any) shall
22 provide the plan or issuer with access to infor-
23 mation requested by the plan or issuer that is
24 necessary to make a determination relating to
25 the claim. Such access shall be provided not

1 later than 5 days after the date on which the
2 request for information is received, or, in a case
3 described in subparagraph (B) or (C) of sub-
4 section (b)(1), by such earlier time as may be
5 necessary to comply with the applicable timeline
6 under such subparagraph.

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

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

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

10 (b) TIMELINE FOR MAKING DETERMINATIONS.—

11 (1) PRIOR AUTHORIZATION DETERMINATION.—

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

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

23 (C) ONGOING CARE.—

24 (i) CONCURRENT REVIEW.—

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

18 (II) CONTENTS OF NOTICE.—
19 Such notice shall include, with respect
20 to ongoing health care items and serv-
21 ices, the number of ongoing services
22 approved, the new total of approved
23 services, the date of onset of services,
24 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, or health insurance issuer offer-
10 ing 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, or
5 health insurance issuer offering health insur-
6 ance coverage, shall ensure that a participant,
7 beneficiary, or enrollee (or authorized represent-
8 ative) has a period of not less than 180 days
9 beginning on the date of a denial of a claim for
10 benefits under section 102 in which to appeal
11 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 partic-
15 ipant, 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 ac-
11 cess 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 be
14 provided not later than 5 days after the date on
15 which the request for information is received,
16 or, in a case described in subparagraph (B) or
17 (C) of paragraph (3), by such earlier time as
18 may be necessary to comply with the applicable
19 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.—A group health plan, or
10 health insurance issuer offering health insur-
11 ance coverage, shall make a determination on
12 an appeal of a denial of a claim for benefits
13 under this subsection in accordance with the
14 medical exigencies of the case and as soon as
15 possible, but in no case later than 14 days from
16 the date on which the plan or issuer receives in-
17 formation that is reasonably necessary to enable
18 the plan or issuer to make a determination on
19 the appeal and in no case later than 28 days
20 after the date the request for the appeal is re-
21 ceived.

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

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

20 (C) ONGOING CARE DETERMINATIONS.—

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

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

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

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

1 peal and in no case later than 60 days after the
2 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) REVIEW OF MEDICAL DECISIONS BY PHYSI-
9 CIANS.—A review of an appeal of a denial of a claim
10 for benefits that is based on a lack of medical neces-
11 sity and appropriateness, or based on an experi-
12 mental or investigational treatment, or requires an
13 evaluation of medical facts, shall be made by a phy-
14 sician (allopathic or osteopathic) with appropriate
15 expertise (including, in the case of a child, appro-
16 priate pediatric expertise) who was not involved in
17 the initial determination.

18 (d) NOTICE OF DETERMINATION.—

19 (1) IN GENERAL.—Written notice of a deter-
20 mination made under an internal appeal of a denial
21 of a claim for benefits shall be issued to the partici-
22 pant, beneficiary, or enrollee (or authorized rep-
23 resentative) and the treating health care professional
24 in accordance with the medical exigencies of the case
25 and as soon as possible, but in no case later than

1 2 days after the date of completion of the review (or,
2 in the case described in subparagraph (B) or (C) of
3 subsection (b)(3), within the 72-hour or applicable
4 period referred to in such subparagraph).

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

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

22 (A) the specific reasons for the determina-
23 tion (including a summary of the clinical or sci-
24 entific evidence used in making the determina-
25 tion);

1 (B) the procedures for obtaining additional
2 information concerning the determination; and

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

6 **SEC. 104. INDEPENDENT EXTERNAL APPEALS PROCE-**
7 **DURES.**

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

14 (b) **INITIATION OF THE INDEPENDENT EXTERNAL**
15 **REVIEW PROCESS.**—

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

1 sion and that the beneficiary must file an appeal
2 with an external review entity within 180 days if the
3 participant or beneficiary desires to file such an ap-
4 peal.

5 (2) FILING OF REQUEST.—

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

10 (i) except as provided in subparagraph

11 (B)(i), require that a request for review be
12 in writing;

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

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

23 (iv) except as provided in subpara-
24 graph (B)(ii), require payment of a filing

1 fee to the plan or issuer of a sum that does
2 not exceed \$25; and

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

12 (B) REQUIREMENTS AND EXCEPTION RE-
13 LATING TO GENERAL RULE.—

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

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

11 (ii) EXCEPTION TO FILING FEE RE-
12 QUIREMENT.—

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

22 (II) FEE NOT REQUIRED.—Pay-
23 ment of a filing fee shall not be re-
24 quired under subparagraph (A)(iv) if
25 the plan or issuer waives the internal

1 appeals process under section
2 103(a)(4).

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

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

16 (c) REFERRAL TO QUALIFIED EXTERNAL REVIEW
17 ENTITY UPON REQUEST.—

18 (1) IN GENERAL.—Upon the filing of a request
19 for independent external review with the group
20 health plan, or health insurance issuer offering
21 health insurance coverage, the plan or issuer shall
22 immediately refer such request, and forward the
23 plan or issuer's initial decision (including the infor-
24 mation described in section 103(d)(3)(A)), to a

1 qualified external review entity selected in accord-
2 ance with this section.

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

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

20 (A) IN GENERAL.—With respect to a re-
21 quest referred to a qualified external review en-
22 tity under paragraph (1) relating to a denial of
23 a claim for benefits, the entity shall refer such
24 request for the conduct of an independent med-
25 ical review unless the entity determines that—

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

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

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

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

23 Upon making a determination that any of clauses (i)
24 through (iv) applies with respect to the request, the entity
25 shall determine that the denial of a claim for benefits in-

1 volved is not eligible for independent medical review under
2 subsection (d), and shall provide notice in accordance with
3 subparagraph (C).

4 (B) PROCESS FOR MAKING DETERMINA-
5 TIONS.—

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

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

18 (C) NOTICES AND GENERAL TIMELINES
19 FOR DETERMINATION.—

20 (i) NOTICE IN CASE OF DENIAL OF
21 REFERRAL.—If the entity under this para-
22 graph does not make a referral to an inde-
23 pendent medical reviewer, the entity shall
24 provide notice to the plan or issuer, the
25 participant, beneficiary, or enrollee (or au-

1 thorized representative) filing the request,
2 and the treating health care professional
3 (if any) that the denial is not subject to
4 independent medical review. Such notice—

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

9 (II) shall include the reasons for
10 the determination;

11 (III) include any relevant terms
12 and conditions of the plan or cov-
13 erage; and

14 (IV) include a description of any
15 further recourse available to the indi-
16 vidual.

17 (ii) GENERAL TIMELINE FOR DETER-
18 MINATIONS.—Upon receipt of information
19 under paragraph (2), the qualified external
20 review entity, and if required the inde-
21 pendent medical reviewer, shall make a de-
22 termination within the overall timeline that
23 is applicable to the case under review as
24 described in subsection (e), except that if
25 the entity determines that a referral to an

1 independent medical reviewer is not re-
2 quired, the entity shall provide notice of
3 such determination to the participant, ben-
4 eficiary, or enrollee (or authorized rep-
5 resentative) within such timeline and with-
6 in 2 days of the date of such determina-
7 tion.

8 (d) INDEPENDENT MEDICAL REVIEW.—

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

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

23 (A) DENIALS BASED ON MEDICAL NECES-
24 SITY AND APPROPRIATENESS.—A determination
25 that the item or service is not covered because

1 it is not medically necessary and appropriate or
2 based on the application of substantially equiva-
3 lent terms.

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

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

18 (3) INDEPENDENT MEDICAL REVIEW DETER-
19 MINATION.—

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

1 (B) STANDARD FOR DETERMINATION.—

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

14 (C) NO COVERAGE FOR EXCLUDED BENE-
15 FITS.—Nothing in this subsection shall be con-
16 strued to permit an independent medical re-
17 viewer to require that a group health plan, or
18 health insurance issuer offering health insur-
19 ance coverage, provide coverage for items or
20 services for which benefits are specifically ex-
21 cluded or expressly limited under the plan or
22 coverage in the plain language of the plan docu-
23 ment (and which are disclosed under section
24 121(b)(1)(C)) except to the extent that the ap-
25 plication or interpretation of the exclusion or

1 limitation involves a determination described in
2 paragraph (2).

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 subtitle, 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 as soon in ac-
10 cordance with the medical exigencies of the
11 case and as soon as possible, but in no
12 case later than 72 hours after the time the
13 request for external review is received by
14 the qualified external review entity.

15 (iii) ONGOING CARE DETERMINA-
16 TION.—Notwithstanding clause (i), in the
17 case of a review described in such sub-
18 clause that involves a termination or reduc-
19 tion of care, the notice of the determina-
20 tion shall be completed not later than 24
21 hours after the time the request for exter-
22 nal review is received by the qualified ex-
23 ternal review entity and before the end of
24 the approved 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 in 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 typically treats the condi-

1 tion, makes the diagnosis, or provides the
2 type of treatment under review; or

3 (ii) by a health care professional
4 (other than a physician), a reviewer shall
5 be a practicing physician (allopathic or os-
6 teopathic) or, if determined appropriate by
7 the qualified external review entity, a prac-
8 ticing health care professional (other than
9 such a physician), of the same or similar
10 specialty as the health care professional
11 who typically treats the condition, makes
12 the diagnosis, or provides the type of treat-
13 ment under review.

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

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

23 (6) LIMITATIONS ON REVIEWER COMPENSA-
24 TION.—Compensation provided by a qualified exter-
25 nal review entity to an independent medical reviewer

1 in connection with a review under this section
2 shall—

3 (A) not exceed a reasonable level; and

4 (B) not be contingent on the decision ren-
5 dered by the reviewer.

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

11 (A) The plan, plan sponsor, or issuer in-
12 volved, or any fiduciary, officer, director, or em-
13 ployee of such plan, plan sponsor, or issuer.

14 (B) The participant, beneficiary, or en-
15 rollee (or authorized representative).

16 (C) The health care professional that pro-
17 vides the items or services involved in the de-
18 nial.

19 (D) The institution at which the items or
20 services (or treatment) involved in the denial
21 are provided.

22 (E) The manufacturer of any drug or
23 other item that is included in the items or serv-
24 ices involved in the denial.

1 (F) Any other party determined under any
 2 regulations to have a substantial interest in the
 3 denial involved.

4 (h) QUALIFIED EXTERNAL REVIEW ENTITIES.—

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

7 (A) LIMITATION ON PLAN OR ISSUER SE-
 8 LECTION.—The appropriate Secretary shall im-
 9 plement procedures—

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

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

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

24 (B) STATE AUTHORITY WITH RESPECT TO
 25 QUALIFIED EXTERNAL REVIEW ENTITIES FOR

1 HEALTH INSURANCE ISSUERS.—With respect to
2 health insurance issuers offering health insur-
3 ance coverage in a State, the State may provide
4 for external review activities to be conducted by
5 a qualified external appeal entity that is des-
6 ignated by the State or that is selected by the
7 State in a manner determined by the State to
8 assure an unbiased determination.

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

16 (3) TERMS AND CONDITIONS OF CONTRACT.—
17 The terms and conditions of a contract under para-
18 graph (2) shall—

19 (A) be consistent with the standards the
20 appropriate Secretary shall establish to assure
21 there is no real or apparent conflict of interest
22 in the conduct of external review activities; and

23 (B) provide that the costs of the external
24 review process shall be borne by the plan or
25 issuer.

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

8 (4) QUALIFICATIONS.—

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

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

24 (ii) The entity is not a plan or issuer
25 or an affiliate or a subsidiary of a plan or

1 issuer, and is not an affiliate or subsidiary
2 of a professional or trade association of
3 plans or issuers or of health care providers.

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

13 (iv) The entity has provided assur-
14 ances that it will provide information in a
15 timely manner under subparagraph (D).

16 (v) The entity meets such other re-
17 quirements as the appropriate Secretary
18 provides by regulation.

19 (B) INDEPENDENCE REQUIREMENTS.—

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

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

1 (II) does not have a material fa-
2 miliary, financial, or professional rela-
3 tionship with such a party; and

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

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

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

20 (I) not exceed a reasonable level;
21 and

22 (II) not be contingent on any de-
23 cision rendered by the entity or by
24 any independent medical reviewer.

1 (C) CERTIFICATION AND RECERTIFICATION
2 PROCESS.—

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

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

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

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

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

1 (I) will carry out (and has car-
2 ried out, in the case of recertification)
3 the responsibilities of such an entity
4 in accordance with this section, in-
5 cluding meeting applicable deadlines;

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

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

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

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

1 review entities that meet at least the
2 standards required for the certification (or
3 recertification) of external review entities
4 under clause (ii).

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

14 (I) Provision of information
15 under subparagraph (D).

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

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

24 (IV) Compliance with applicable
25 independence requirements.

1 (v) PERIOD OF CERTIFICATION OR RE-
2 CERTIFICATION.—A certification or recer-
3 tification provided under this paragraph
4 shall extend for a period not to exceed 2
5 years.

6 (vi) REVOCATION.—A certification or
7 recertification under this paragraph may
8 be revoked by the appropriate Secretary or
9 by the organization providing such certifi-
10 cation upon a showing of cause.

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

17 (D) PROVISION OF INFORMATION.—

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

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

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

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

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

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

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

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

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

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

1 certification or recertification of an
2 entity.

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

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

1 **Subtitle B—Access to Care**

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

3 (a) IN GENERAL.—If—

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

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

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

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

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

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

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

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

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

4 (b) SPECIALISTS.—

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

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

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

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

23 (a) COVERAGE OF EMERGENCY SERVICES.—

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

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

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

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

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

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

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

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

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

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

7 (2) DEFINITIONS.—In this section:

8 (A) EMERGENCY MEDICAL CONDITION.—

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

19 (B) EMERGENCY SERVICES.—The term

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

22 (i) a medical screening examination

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

1 hospital, including ancillary services rou-
2 tinely available to the emergency depart-
3 ment to evaluate such emergency medical
4 condition, and

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

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

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

23 (c) COVERAGE OF EMERGENCY AMBULANCE SERV-
24 ICES.—

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

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

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

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

4 (a) **TIMELY ACCESS.**—

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

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

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

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

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

25 (3) **ACCESS TO CERTAIN PROVIDERS.**—

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

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

17 (b) REFERRALS.—

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

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

1 thorization for a standing referral where appro-
2 priate; and

3 (B) may not be refused solely because the
4 authorization involves services of a nonpartici-
5 pating specialist (described in subsection
6 (a)(3)).

7 (2) REFERRALS FOR ONGOING SPECIAL CONDI-
8 TIONS.—

9 (A) IN GENERAL.—Subject to subsection
10 (a)(1), a group health plan or health insurance
11 issuer shall permit a participant, beneficiary, or
12 enrollee who has an ongoing special condition
13 (as defined in subparagraph (B)) to receive a
14 referral to a specialist for the treatment of such
15 condition and such specialist may authorize
16 such referrals, procedures, tests, and other
17 medical services with respect to such condition,
18 or coordinate the care for such condition, sub-
19 ject to the terms of a treatment plan (if any)
20 referred to in subsection (c) with respect to the
21 condition.

22 (B) ONGOING SPECIAL CONDITION DE-
23 FINED.—In this subsection, the term “ongoing
24 special condition” means a condition or disease
25 that—

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

5 (c) TREATMENT PLANS.—

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

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

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

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

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

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

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

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

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

12 (a) GENERAL RIGHTS.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

19 (a) TERMINATION OF PROVIDER.—

20 (1) IN GENERAL.—If—

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

1 (B) benefits or coverage provided by a
2 health care provider are terminated because of
3 a change in the terms of provider participation
4 in such plan or coverage,
5 the plan or issuer shall meet the requirements of
6 paragraph (3) with respect to each continuing care
7 patient.

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

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

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

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

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

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

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

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

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

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

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

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

16 (b) TRANSITIONAL PERIODS.—

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

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

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

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

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

10 (3) SCHEDULED NON-ELECTIVE SURGERY.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

24 (e) DEFINITIONS.—In this section:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

19 (a) COVERAGE.—

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

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

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

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

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

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

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

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

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

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

16 (2) Either—

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

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

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

4 (c) PAYMENT.—

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

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

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

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

20 (d) APPROVED CLINICAL TRIAL DEFINED.—

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

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;

7 (iii) either of the following if the con-
8 ditions described in paragraph (2) are
9 met—

10 (I) the Department of Veterans
11 Affairs;

12 (II) the Department of Defense;

13 or

14 (B) approved by the Food and Drug Ad-
15 ministration.

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

22 (A) to be comparable to the system of peer
23 review of studies and investigations used by the
24 National Institutes of Health; and

1 (B) assures unbiased review of the highest
2 scientific standards by qualified individuals who
3 have no interest in the outcome of the review.

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

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

12 (a) INPATIENT CARE.—

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

21 (A) a mastectomy;

22 (B) a lumpectomy; or

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

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

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

13 (c) SECONDARY CONSULTATIONS.—

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

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

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

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

21 (1) penalize or otherwise reduce or limit the re-
22 imbursement of a provider or specialist because the
23 provider or specialist provided care to a participant,
24 beneficiary, or enrollee in accordance with this sec-
25 tion;

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

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

14 **Subtitle C—Access to Information**

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

16 (a) REQUIREMENT.—

17 (1) DISCLOSURE.—

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

23 (i) of the information described in
24 subsection (b) at the time of the initial en-

1 rollment of the participant, beneficiary, or
2 enrollee under the plan or coverage;

3 (ii) of such information on an annual
4 basis—

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

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

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

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

22 (i) jointly to each participant, bene-
23 ficiary, and enrollee who reside at the same
24 address; or

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

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

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

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

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

23 (B) specific preventive services covered
24 under the plan or coverage if such services are
25 covered;

1 (C) any specific exclusions or express limi-
2 tations of benefits described in section
3 104(b)(3)(C);

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

9 (E) any definition of medical necessity
10 used in making coverage determinations by the
11 plan, issuer, or claims administrator.

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

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

19 (B) any maximum out-of-pocket expense
20 for which the participant, beneficiary, or en-
21 rollee may be liable;

22 (C) any cost-sharing requirements for out-
23 of-network benefits or services received from
24 nonparticipating providers; and

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

6 (3) SERVICE AREA.—A description of the plan
7 or issuer’s service area, including the provision of
8 any out-of-area coverage.

9 (4) PARTICIPATING PROVIDERS.—A directory of
10 participating providers (to the extent a plan or
11 issuer provides coverage through a network of pro-
12 viders) that includes, at a minimum, the name, ad-
13 dress, and telephone number of each participating
14 provider, and information about how to inquire
15 whether a participating provider is currently accept-
16 ing new patients.

17 (5) CHOICE OF PRIMARY CARE PROVIDER.—A
18 description of any requirements and procedures to
19 be used by participants, beneficiaries, and enrollees
20 in selecting, accessing, or changing their primary
21 care provider, including providers both within and
22 outside of the network (if the plan or issuer permits
23 out-of-network services), and the right to select a pe-
24 diatrician as a primary care provider under section

1 116 for a participant, beneficiary, or enrollee who is
2 a child if such section applies.

3 (6) PREAUTHORIZATION REQUIREMENTS.—A
4 description of the requirements and procedures to be
5 used to obtain preauthorization for health services,
6 if such preauthorization is required.

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

13 (8) SPECIALTY CARE.—A description of the re-
14 quirements and procedures to be used by partici-
15 pants, beneficiaries, and enrollees in accessing spe-
16 cialty care and obtaining referrals to participating
17 and nonparticipating specialists, including any limi-
18 tations on choice of health care professionals re-
19 ferred to in section 112(b)(2) and the right to timely
20 access to specialists care under section 114 if such
21 section applies.

22 (9) CLINICAL TRIALS.—A description of the cir-
23 cumstances and conditions under which participation
24 in clinical trials is covered under the terms and con-
25 ditions of the plan or coverage, and the right to ob-

1 tain coverage for approved clinical trials under sec-
2 tion 119 if such section applies.

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

13 (11) EMERGENCY SERVICES.—A summary of
14 the rules and procedures for accessing emergency
15 services, including the right of a participant, bene-
16 ficiary, or enrollee to obtain emergency services
17 under the prudent layperson standard under section
18 113, if such section applies, and any educational in-
19 formation that the plan or issuer may provide re-
20 garding the appropriate use of emergency services.

21 (12) CLAIMS AND APPEALS.—A description of
22 the plan or issuer's rules and procedures pertaining
23 to claims and appeals, a description of the rights
24 (including deadlines for exercising rights) of partici-
25 pants, beneficiaries, and enrollees under subtitle A

1 in obtaining covered benefits, filing a claim for bene-
2 fits, and appealing coverage decisions internally and
3 externally (including telephone numbers and mailing
4 addresses of the appropriate authority), and a de-
5 scription of any additional legal rights and remedies
6 available under section 502 of the Employee Retire-
7 ment Income Security Act of 1974 and applicable
8 State law.

9 (13) ADVANCE DIRECTIVES AND ORGAN DONA-
10 TION.—A description of procedures for advance di-
11 rectives and organ donation decisions if the plan or
12 issuer maintains such procedures.

13 (14) INFORMATION ON PLANS AND ISSUERS.—
14 The name, mailing address, and telephone number
15 or numbers of the plan administrator and the issuer
16 to be used by participants, beneficiaries, and enroll-
17 ees seeking information about plan or coverage bene-
18 fits and services, payment of a claim, or authoriza-
19 tion for services and treatment. Notice of whether
20 the benefits under the plan or coverage are provided
21 under a contract or policy of insurance issued by an
22 issuer, or whether benefits are provided directly by
23 the plan sponsor who bears the insurance risk.

24 (15) TRANSLATION SERVICES.—A summary de-
25 scription of any translation or interpretation services

1 (including the availability of printed information in
2 languages other than English, audio tapes, or infor-
3 mation in Braille) that are available for non-English
4 speakers and participants, beneficiaries, and enroll-
5 ees with communication disabilities and a description
6 of how to access these items or services.

7 (16) ACCREDITATION INFORMATION.—Any in-
8 formation that is made public by accrediting organi-
9 zations in the process of accreditation if the plan or
10 issuer is accredited, or any additional quality indica-
11 tors (such as the results of enrollee satisfaction sur-
12 veys) that the plan or issuer makes public or makes
13 available to participants, beneficiaries, and enrollees.

14 (17) NOTICE OF REQUIREMENTS.—A descrip-
15 tion of any rights of participants, beneficiaries, and
16 enrollees that are established by the Bipartisan Pa-
17 tient Protection Act (excluding those described in
18 paragraphs (1) through (16)) if such sections apply.
19 The description required under this paragraph may
20 be combined with the notices of the type described
21 in sections 711(d), 713(b), or 606(a)(1) of the Em-
22 ployee Retirement Income Security Act of 1974 and
23 with any other notice provision that the appropriate
24 Secretary determines may be combined, so long as
25 such combination does not result in any reduction

1 in the information that would otherwise be provided
2 to the recipient.

3 (18) AVAILABILITY OF ADDITIONAL INFORMA-
4 TION.—A statement that the information described
5 in subsection (c), and instructions on obtaining such
6 information (including telephone numbers and, if
7 available, Internet websites), shall be made available
8 upon request.

9 (c) ADDITIONAL INFORMATION.—The informational
10 materials to be provided upon the request of a participant,
11 beneficiary, or enrollee shall include for each option avail-
12 able under a group health plan or health insurance cov-
13 erage the following:

14 (1) STATUS OF PROVIDERS.—The State licen-
15 sure status of the plan or issuer’s participating
16 health care professionals and participating health
17 care facilities, and, if available, the education, train-
18 ing, specialty qualifications or certifications of such
19 professionals.

20 (2) COMPENSATION METHODS.—A summary
21 description by category of the applicable methods
22 (such as capitation, fee-for-service, salary, bundled
23 payments, per diem, or a combination thereof) used
24 for compensating prospective or treating health care
25 professionals (including primary care providers and

1 specialists) and facilities in connection with the pro-
2 vision of health care under the plan or coverage.

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

7 (4) UTILIZATION REVIEW ACTIVITIES.—A de-
8 scription of procedures used and requirements (in-
9 cluding circumstances, timeframes, and appeals
10 rights) under any utilization review program under
11 sections 101 and 102, including any drug formulary
12 program under section 118.

13 (5) EXTERNAL APPEALS INFORMATION.—Ag-
14 gregate information on the number and outcomes of
15 external medical reviews, relative to the sample size
16 (such as the number of covered lives) under the plan
17 or under the coverage of the issuer.

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

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

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

6 (2) complying with the provisions of this section
7 by providing information in brochures, through the
8 Internet or other electronic media, or through other
9 similar means, so long as—

10 (A) the disclosure of such information in
11 such form is in accordance with requirements
12 as the appropriate Secretary may impose, and

13 (B) in connection with any such disclosure
14 of information through the Internet or other
15 electronic media—

16 (i) the recipient has affirmatively con-
17 sented to the disclosure of such informa-
18 tion in such form,

19 (ii) the recipient is capable of access-
20 ing the information so disclosed on the re-
21 cipient's individual workstation or at the
22 recipient's home,

23 (iii) the recipient retains an ongoing
24 right to receive paper disclosure of such in-
25 formation and receives, in advance of any

1 attempt at disclosure of such information
2 to him or her through the Internet or
3 other electronic media, notice in printed
4 form of such ongoing right and of the
5 proper software required to view informa-
6 tion so disclosed, and

7 (iv) the plan administrator appro-
8 priately ensures that the intended recipient
9 is receiving the information so disclosed
10 and provides the information in printed
11 form if the information is not received.

12 **Subtitle D—Protecting the Doctor-**
13 **Patient Relationship**

14 **SEC. 131. PROHIBITION OF INTERFERENCE WITH CERTAIN**
15 **MEDICAL COMMUNICATIONS.**

16 (a) GENERAL RULE.—The provisions of any contract
17 or agreement, or the operation of any contract or agree-
18 ment, between a group health plan or health insurance
19 issuer in relation to health insurance coverage (including
20 any partnership, association, or other organization that
21 enters into or administers such a contract or agreement)
22 and a health care provider (or group of health care pro-
23 viders) shall not prohibit or otherwise restrict a health
24 care professional from advising such a participant, bene-
25 ficiary, or enrollee who is a patient of the professional

1 about the health status of the individual or medical care
2 or treatment for the individual's condition or disease, re-
3 gardless of whether benefits for such care or treatment
4 are provided under the plan or coverage, if the professional
5 is acting within the lawful scope of practice.

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

9 **SEC. 132. PROHIBITION OF DISCRIMINATION AGAINST PRO-**
10 **VIDERS BASED ON LICENSURE.**

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

18 (b) CONSTRUCTION.—Subsection (a) shall not be
19 construed—

20 (1) as requiring the coverage under a group
21 health plan or health insurance coverage of a par-
22 ticular benefit or service or to prohibit a plan or
23 issuer from including providers only to the extent
24 necessary to meet the needs of the plan's or issuer's
25 participants, beneficiaries, or enrollees or from es-

1 tablishing any measure designed to maintain quality
2 and control costs consistent with the responsibilities
3 of the plan or issuer;

4 (2) to override any State licensure or scope-of-
5 practice law; or

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

10 **SEC. 133. PROHIBITION AGAINST IMPROPER INCENTIVE**
11 **ARRANGEMENTS.**

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

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

1 and a participant, beneficiary, or enrollee with the plan
2 or organization, respectively.

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

6 **SEC. 134. PAYMENT OF CLAIMS.**

7 A group health plan, and a health insurance issuer
8 offering group health insurance coverage, shall provide for
9 prompt payment of claims submitted for health care serv-
10 ices or supplies furnished to a participant, beneficiary, or
11 enrollee with respect to benefits covered by the plan or
12 issuer, in a manner consistent with the provisions of sec-
13 tion 1842(c)(2) of the Social Security Act (42 U.S.C.
14 1395u(c)(2)).

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

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

1 (b) PROTECTION FOR QUALITY ADVOCACY BY
2 HEALTH CARE PROFESSIONALS.—

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

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

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

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

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

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

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

18 (B) the professional reasonably believes the
19 information to be true;

20 (C) the information evidences either a vio-
21 lation of a law, rule, or regulation, of an appli-
22 cable accreditation standard, or of a generally
23 recognized professional or clinical standard or
24 that a patient is in imminent hazard of loss of
25 life or serious injury; and

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

7 (3) EXCEPTION AND SPECIAL RULE.—

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

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

1 (C) INTERNAL PROCEDURE EXCEPTION.—

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

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

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

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

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

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

8 (6) CONSTRUCTIONS.—

9 (A) DETERMINATIONS OF COVERAGE.—

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

15 (B) ENFORCEMENT OF PEER REVIEW PRO-

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

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

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

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

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

21 **Subtitle E—Definitions**

22 **SEC. 151. DEFINITIONS.**

23 (a) INCORPORATION OF GENERAL DEFINITIONS.—
 24 Except as otherwise provided, the provisions of section
 25 2791 of the Public Health Service Act shall apply for pur-

1 poses of this title in the same manner as they apply for
2 purposes of title XXVII of such Act.

3 (b) SECRETARY.—Except as otherwise provided, the
4 term “Secretary” means the Secretary of Health and
5 Human Services, in consultation with the Secretary of
6 Labor and the term “appropriate Secretary” means the
7 Secretary of Health and Human Services in relation to
8 carrying out this title under sections 2706 and 2751 of
9 the Public Health Service Act and the Secretary of Labor
10 in relation to carrying out this title under section 713 of
11 the Employee Retirement Income Security Act of 1974.

12 (c) ADDITIONAL DEFINITIONS.—For purposes of this
13 title:

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

16 (A) in the case of a group health plan, the
17 Secretary of Health and Human Services and
18 the Secretary of Labor; and

19 (B) in the case of a health insurance issuer
20 with respect to a specific provision of this title,
21 the applicable State authority (as defined in
22 section 2791(d) of the Public Health Service
23 Act), or the Secretary of Health and Human
24 Services, if such Secretary is enforcing such

1 provision under section 2722(a)(2) or
2 2761(a)(2) of the Public Health Service Act.

3 (2) ENROLLEE.—The term “enrollee” means,
4 with respect to health insurance coverage offered by
5 a health insurance issuer, an individual enrolled with
6 the issuer to receive such coverage.

7 (3) GROUP HEALTH PLAN.—The term “group
8 health plan” has the meaning given such term in
9 section 733(a) of the Employee Retirement Income
10 Security Act of 1974, except that such term includes
11 a employee welfare benefit plan treated as a group
12 health plan under section 732(d) of such Act or de-
13 fined as such a plan under section 607(1) of such
14 Act.

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

21 (5) HEALTH CARE PROVIDER.—The term
22 “health care provider” includes a physician or other
23 health care professional, as well as an institutional
24 or other facility or agency that provides health care
25 services and that is licensed, accredited, or certified

1 to provide health care items and services under ap-
2 plicable State law.

3 (6) NETWORK.—The term “network” means,
4 with respect to a group health plan or health insur-
5 ance issuer offering health insurance coverage, the
6 participating health care professionals and providers
7 through whom the plan or issuer provides health
8 care items and services to participants, beneficiaries,
9 or enrollees.

10 (7) NONPARTICIPATING.—The term “non-
11 participating” means, with respect to a health care
12 provider that provides health care items and services
13 to a participant, beneficiary, or enrollee under group
14 health plan or health insurance coverage, a health
15 care provider that is not a participating health care
16 provider with respect to such items and services.

17 (8) PARTICIPATING.—The term “participating”
18 means, with respect to a health care provider that
19 provides health care items and services to a partici-
20 pant, beneficiary, or enrollee under group health
21 plan or health insurance coverage offered by a
22 health insurance issuer, a health care provider that
23 furnishes such items and services under a contract
24 or other arrangement with the plan or issuer.

1 (9) **PRIOR AUTHORIZATION.**—The term “prior
2 authorization” means the process of obtaining prior
3 approval from a health insurance issuer or group
4 health plan for the provision or coverage of medical
5 services.

6 (10) **TERMS AND CONDITIONS.**—The term
7 “terms and conditions” includes, with respect to a
8 group health plan or health insurance coverage, re-
9 quirements imposed under this title with respect to
10 the plan or coverage.

11 **SEC. 152. PREEMPTION; STATE FLEXIBILITY; CONSTRUC-**
12 **TION.**

13 (a) **CONTINUED APPLICABILITY OF STATE LAW**
14 **WITH RESPECT TO HEALTH INSURANCE ISSUERS.**—

15 (1) **IN GENERAL.**—Subject to paragraph (2),
16 this title shall not be construed to supersede any
17 provision of State law which establishes, implements,
18 or continues in effect any standard or requirement
19 solely relating to health insurance issuers (in connec-
20 tion with group health insurance coverage or other-
21 wise) except to the extent that such standard or re-
22 quirement prevents the application of a requirement
23 of this title.

24 (2) **CONTINUED PREEMPTION WITH RESPECT**
25 **TO GROUP HEALTH PLANS.**—Nothing in this title

1 shall be construed to affect or modify the provisions
2 of section 514 of the Employee Retirement Income
3 Security Act of 1974 with respect to group health
4 plans.

5 (3) CONSTRUCTION.—In applying this section,
6 a State law that provides for equal access to, and
7 availability of, all categories of licensed health care
8 providers and services shall not be treated as pre-
9 venting the application of any requirement of this
10 title.

11 (b) APPLICATION OF SUBSTANTIALLY EQUIVALENT
12 STATE LAWS.—

13 (1) IN GENERAL.—In the case of a State law
14 that imposes, with respect to health insurance cov-
15 erage offered by a health insurance issuer and with
16 respect to a group health plan that is a non-Federal
17 governmental plan, a requirement that is substan-
18 tially equivalent (within the meaning of subsection
19 (c)) to a patient protection requirement (as defined
20 in paragraph (3)) and does not prevent the applica-
21 tion of other requirements under this Act (except in
22 the case of other substantially equivalent require-
23 ments), in applying the requirements of this title
24 under section 2707 and 2753 (as applicable) of the

1 Public Health Service Act (as added by title II),
2 subject to subsection (a)(2)—

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

5 (B) the State law shall apply instead of the
6 patient protection requirement otherwise appli-
7 cable with respect to health insurance coverage
8 and non-Federal governmental plans.

9 (2) LIMITATION.—In the case of a group health
10 plan covered under title I of the Employee Retirement
11 Income Security Act of 1974, paragraph (1)
12 shall be construed to apply only with respect to the
13 health insurance coverage (if any) offered in connec-
14 tion with the plan.

15 (3) PATIENT PROTECTION REQUIREMENT DE-
16 FINED.—For purposes of this section, the term “pa-
17 tient protection requirement” means a requirement
18 under this title, and includes (as a single require-
19 ment) a group or related set of requirements under
20 a section or similar unit under this title.

21 (c) DETERMINATIONS OF SUBSTANTIAL EQUIVA-
22 LENCE.—

23 (1) CERTIFICATION BY STATES.—A State may
24 submit to the Secretary a certification that a State
25 law provides for patient protections that are at least

1 substantially equivalent to one or more patient pro-
2 tection requirements. Such certification shall be ac-
3 companied by such information as may be required
4 to permit the Secretary to make the determination
5 described in paragraph (2)(A).

6 (2) REVIEW.—

7 (A) IN GENERAL.—The Secretary shall
8 promptly review a certification submitted under
9 paragraph (1) with respect to a State law to de-
10 termine if the State law provides for at least
11 substantially equivalent and effective patient
12 protections to the patient protection require-
13 ment (or requirements) to which the law re-
14 lates.

15 (B) APPROVAL DEADLINES.—

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

1 (ii) ADDITIONAL INFORMATION.—

2 With respect to a State that has been noti-
3 fied by the Secretary under clause (i) that
4 specified additional information is needed
5 to make the determination described in
6 subparagraph (A), the Secretary shall
7 make the determination within 60 days
8 after the date on which such specified ad-
9 ditional information is received by the Sec-
10 retary.

11 (3) APPROVAL.—

12 (A) IN GENERAL.—The Secretary shall ap-
13 prove a certification under paragraph (1)
14 unless—

15 (i) the State fails to provide sufficient
16 information to enable the Secretary to
17 make a determination under paragraph
18 (2)(A); or

19 (ii) the Secretary determines that the
20 State law involved does not provide for pa-
21 tient protections that are at least substan-
22 tially equivalent to and as effective as the
23 patient protection requirement (or require-
24 ments) to which the law relates.

1 (B) STATE CHALLENGE.—A State that has
2 a certification disapproved by the Secretary
3 under subparagraph (A) may challenge such
4 disapproval in the appropriate United States
5 district court.

6 (4) CONSTRUCTION.—Nothing in this sub-
7 section shall be construed as preventing the certifi-
8 cation (and approval of certification) of a State law
9 under this subsection solely because it provides for
10 greater protections for patients than those protec-
11 tions otherwise required to establish substantial
12 equivalence.

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. COVERAGE OF LIMITED SCOPE PLANS.**

12 Only for purposes of applying the requirements of
13 this title under sections 2707 and 2753 of the Public
14 Health Service Act and section 714 of the Employee Re-
15 tirement Income Security Act of 1974, section
16 2791(c)(2)(A), and section 733(c)(2)(A) of the Employee
17 Retirement Income Security Act of 1974 shall be deemed
18 not to apply.

19 **SEC. 155. REGULATIONS.**

20 The Secretaries of Health and Human Services and
21 Labor shall issue such regulations as may be necessary
22 or appropriate to carry out this title. Such regulations
23 shall be issued consistent with section 104 of Health In-
24 surance Portability and Accountability Act of 1996. Such
25 Secretaries may promulgate any interim final rules as the

1 Secretaries determine are appropriate to carry out this
2 title.

3 **SEC. 156. INCORPORATION INTO PLAN OR COVERAGE DOC-**
4 **UMENTS.**

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

12 **TITLE II—APPLICATION OF**
13 **QUALITY CARE STANDARDS**
14 **TO GROUP HEALTH PLANS**
15 **AND HEALTH INSURANCE**
16 **COVERAGE UNDER THE PUB-**
17 **LIC HEALTH SERVICE ACT**

18 **SEC. 201. APPLICATION TO GROUP HEALTH PLANS AND**
19 **GROUP HEALTH INSURANCE COVERAGE.**

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

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

24 “Each group health plan shall comply with patient
25 protection requirements under title I of the Bipartisan Pa-

1 tient Protection Act, and each health insurance issuer
2 shall comply with patient protection requirements under
3 such title with respect to group health insurance coverage
4 it offers, and such requirements shall be deemed to be in-
5 corporated into this subsection.”.

6 (b) CONFORMING AMENDMENT.—Section
7 2721(b)(2)(A) of such Act (42 U.S.C. 300gg–21(b)(2)(A))
8 is amended by inserting “(other than section 2707)” after
9 “requirements of such subparts”.

10 **SEC. 202. APPLICATION TO INDIVIDUAL HEALTH INSUR-**
11 **ANCE COVERAGE.**

12 Part B of title XXVII of the Public Health Service
13 Act is amended by inserting after section 2752 the fol-
14 lowing new section:

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

16 “Each health insurance issuer shall comply with pa-
17 tient protection requirements under title I of the Bipar-
18 tisan Patient Protection Act with respect to individual
19 health insurance coverage it offers, and such requirements
20 shall be deemed to be incorporated into this subsection.”.

1 **TITLE III—AMENDMENTS TO**
2 **THE EMPLOYEE RETIREMENT**
3 **INCOME SECURITY ACT OF**
4 **1974**

5 **SEC. 301. APPLICATION OF PATIENT PROTECTION STAND-**
6 **ARDS TO GROUP HEALTH PLANS AND GROUP**
7 **HEALTH INSURANCE COVERAGE UNDER THE**
8 **EMPLOYEE RETIREMENT INCOME SECURITY**
9 **ACT OF 1974.**

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

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

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

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

24 “(1) SATISFACTION OF CERTAIN REQUIRE-
25 MENTS THROUGH INSURANCE.—For purposes of

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

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

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

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

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

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

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

23 “(G) Section 117 (relating to continuity of
24 care), but only insofar as a replacement issuer
25 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 EQUIVA-
18 LENT STATE LAWS.—For purposes of applying this
19 subsection, any reference in this subsection to a re-
20 quirement in a section or other provision in the Bi-
21 partisan Patient Protection Act with respect to a
22 health insurance issuer is deemed to include a ref-
23 erence to a requirement under a State law that is
24 substantially equivalent (as determined under section

1 152(c) of such Act) to the requirement in such sec-
2 tion or other provisions.

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

10 “(c) ENFORCEMENT OF CERTAIN REQUIREMENTS.—

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

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

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

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

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

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

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

“Sec. 714. Patient protection standards.”.

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

10 **SEC. 302. AVAILABILITY OF CIVIL REMEDIES.**

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

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

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—

1 “(i) upon consideration of a claim for
2 benefits of a participant or beneficiary
3 under section 102 of the Bipartisan Pa-
4 tient Protection Act of 2001 (relating to
5 procedures for initial claims for benefits
6 and prior authorization determinations) or
7 upon review of a denial of such a claim
8 under section 103 of such Act (relating to
9 internal appeal of a denial of a claim for
10 benefits), fails to exercise ordinary care in
11 making a decision—

12 “(I) regarding whether an item
13 or service is covered under the terms
14 and conditions of the plan or cov-
15 erage,

16 “(II) regarding whether an indi-
17 vidual is a participant or beneficiary
18 who is enrolled under the terms and
19 conditions of the plan or coverage (in-
20 cluding the applicability of any wait-
21 ing period under the plan or cov-
22 erage), or

23 “(III) as to the application of
24 cost-sharing requirements or the ap-
25 plication of a specific exclusion or ex-

1 press limitation on the amount, dura-
2 tion, or scope of coverage of items or
3 services under the terms and condi-
4 tions of the plan or coverage, or

5 “(ii) otherwise fails to exercise ordi-
6 nary care in the performance of a duty
7 under the terms and conditions of the plan
8 with respect to a participant or beneficiary,
9 and

10 “(B) such failure is a proximate cause of
11 personal injury to, or the death of, the partici-
12 pant or beneficiary,

13 such person shall be liable to the participant or ben-
14 eficiary (or the estate of such participant or bene-
15 ficiary) for economic and noneconomic damages (but
16 not exemplary or punitive damages) in connection
17 with such personal injury or death.

18 “(2) CAUSE OF ACTION MUST NOT INVOLVE
19 MEDICALLY REVIEWABLE DECISION.—

20 “(A) IN GENERAL.—A cause of action is
21 established under paragraph (1)(A) only if the
22 decision referred to in clause (i) or the failure
23 described in clause (ii) does not include a medi-
24 cally reviewable decision.

1 “(B) MEDICALLY REVIEWABLE DECI-
2 SION.—For purposes of this subsection, the
3 term ‘medically reviewable decision’ means a de-
4 nial of a claim for benefits under the plan
5 which is described in section 104(d)(2) of the
6 Bipartisan Patient Protection Act of 2001 (re-
7 lating to medically reviewable decisions).

8 “(3) LIMITATION REGARDING CERTAIN TYPES
9 OF ACTIONS SAVED FROM PREEMPTION OF STATE
10 LAW.—A cause of action is not established under
11 paragraph (1)(A) in connection with a failure de-
12 scribed in paragraph (1)(A) to the extent that a
13 cause of action under State law (as defined in sec-
14 tion 514(c)) for such failure would not be preempted
15 under section 514.

16 “(4) DEFINITIONS.—For purposes of this sub-
17 section.—

18 “(A) ORDINARY CARE.—The term ‘ordi-
19 nary care’ means—

20 “(i) with respect to a determination
21 on a claim for benefits, that degree of care,
22 skill, and diligence that a reasonable and
23 prudent individual would exercise in mak-
24 ing a fair determination on a claim for

1 benefits of like kind to the claim involved;
2 and

3 “(ii) with respect to the performance
4 of a duty, that degree of care, skill, and
5 diligence that a reasonable and prudent in-
6 dividual would exercise in performing the
7 duty or a duty of like character.

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

12 “(C) CLAIM FOR BENEFITS; DENIAL.—The
13 terms ‘claim for benefits’ and ‘denial of a claim
14 for benefits’ have the meanings provided such
15 terms in section 102(e) of the Bipartisan Pa-
16 tient Protection Act of 2001.

17 “(D) TERMS AND CONDITIONS.—The term
18 ‘terms and conditions’ includes, with respect to
19 a group health plan or health insurance cov-
20 erage, requirements imposed under title I of the
21 Bipartisan Patient Protection Act of 2001 or
22 under part 6 or 7.

23 “(E) GROUP HEALTH PLAN AND OTHER
24 RELATED TERMS.—The provisions of sections
25 732(d) and 733 apply for purposes of this sub-

1 section in the same manner as they apply for
2 purposes of part 7, except that the term ‘group
3 health plan’ includes a group health plan (as
4 defined in section 607(1)).

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

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

15 “(B) CERTAIN CAUSES OF ACTION PER-
16 MITTED.—Notwithstanding subparagraph (A),
17 a cause of action may arise against an employer
18 or other plan sponsor (or against an employee
19 of such an employer or sponsor acting within
20 the scope of employment)—

21 “(i) under clause (i) of paragraph
22 (1)(A), to the extent there was direct par-
23 ticipation by the employer or other plan
24 sponsor (or employee) in the decision of
25 the plan under section 102 of the Bipar-

1 tisan Patient Protection Act of 2001 upon
2 consideration of a claim for benefits or
3 under section 103 of such Act upon review
4 of a denial of a claim for benefits, or

5 “(ii) under clause (ii) of paragraph
6 (1)(A), to the extent there was direct par-
7 ticipation by the employer or other plan
8 sponsor (or employee) in the failure de-
9 scribed in such clause.

10 “(C) DIRECT PARTICIPATION.—

11 “(i) DIRECT PARTICIPATION IN DECI-
12 SIONS.—For purposes of subparagraph
13 (B), the term ‘direct participation’ means,
14 in connection with a decision described in
15 clause (i) of paragraph (1)(A) or a failure
16 described in clause (ii) of such paragraph,
17 the actual making of such decision or the
18 actual exercise of control in making such
19 decision or in the conduct constituting the
20 failure.

21 “(ii) RULES OF CONSTRUCTION.—For
22 purposes of clause (i), the employer or plan
23 sponsor (or employee) shall not be con-
24 strued to be engaged in direct participation
25 because of any form of decisionmaking or

1 other conduct that is merely collateral or
2 precedent to the decision described in
3 clause (i) of paragraph (1)(A) on a par-
4 ticular claim for benefits of a participant
5 or beneficiary or that is merely collateral
6 or precedent to the conduct constituting a
7 failure described in clause (ii) of paragraph
8 (1)(A) with respect to a particular partici-
9 pant or beneficiary, including (but not lim-
10 ited to)—

11 “(I) any participation by the em-
12 ployer or other plan sponsor (or em-
13 ployee) in the selection of the group
14 health plan or health insurance cov-
15 erage involved or the third party ad-
16 ministrator or other agent;

17 “(II) any engagement by the em-
18 ployer or other plan sponsor (or em-
19 ployee) in any cost-benefit analysis
20 undertaken in connection with the se-
21 lection of, or continued maintenance
22 of, the plan or coverage involved;

23 “(III) any participation by the
24 employer or other plan sponsor (or
25 employee) in the process of creating,

1 continuing, modifying, or terminating
2 the plan or any benefit under the
3 plan, if such process was not substan-
4 tially focused solely on the particular
5 situation of the participant or bene-
6 ficiary referred to in paragraph
7 (1)(A); and

8 “(IV) any participation by the
9 employer or other plan sponsor (or
10 employee) in the design of any benefit
11 under the plan, including the amount
12 of copayment and limits connected
13 with such benefit.

14 “(iv) IRRELEVANCE OF CERTAIN COL-
15 LATERAL EFFORTS MADE BY EMPLOYER
16 OR PLAN SPONSOR.—For purposes of this
17 subparagraph, an employer or plan sponsor
18 shall not be treated as engaged in direct
19 participation in a decision with respect to
20 any claim for benefits or denial thereof in
21 the case of any particular participant or
22 beneficiary solely by reason of—

23 “(I) any efforts that may have
24 been made by the employer or plan
25 sponsor to advocate for authorization

1 of coverage for that or any other par-
2 ticipant or beneficiary (or any group
3 of participants or beneficiaries), or

4 “(II) any provision that may
5 have been made by the employer or
6 plan sponsor for benefits which are
7 not covered under the terms and con-
8 ditions of the plan for that or any
9 other participant or beneficiary (or
10 any group of participants or bene-
11 ficiaries).

12 “(6) EXCLUSION OF PHYSICIANS AND OTHER
13 HEALTH CARE PROFESSIONALS.—

14 “(A) IN GENERAL.—No treating physician
15 or other treating health care professional of the
16 participant or beneficiary, and no person acting
17 under the direction of such a physician or
18 health care professional, shall be liable under
19 paragraph (1) for the performance of, or the
20 failure to perform, any non-medically reviewable
21 duty of the plan, the plan sponsor, or any
22 health insurance issuer offering health insur-
23 ance coverage in connection with the plan.

24 “(B) DEFINITIONS.—For purposes of sub-
25 paragraph (A)—

1 “(i) HEALTH CARE PROFESSIONAL.—

2 The term ‘health care professional’ means
3 an individual who is licensed, accredited, or
4 certified under State law to provide speci-
5 fied health care services and who is oper-
6 ating within the scope of such licensure,
7 accreditation, or certification.

8 “(ii) NON-MEDICALLY REVIEWABLE

9 DUTY.—The term ‘non-medically review-
10 able duty’ means a duty the discharge of
11 which does not include the making of a
12 medically reviewable decision.

13 “(7) EXCLUSION OF HOSPITALS.—No treating

14 hospital of the participant or beneficiary shall be lia-
15 ble under paragraph (1) for the performance of, or
16 the failure to perform, any non-medically reviewable
17 duty (as defined in paragraph (6)(B)(ii)) of the
18 plan, the plan sponsor, or any health insurance
19 issuer offering health insurance coverage in connec-
20 tion with the plan.

21 “(8) RULE OF CONSTRUCTION RELATING TO

22 EXCLUSION FROM LIABILITY OF PHYSICIANS,
23 HEALTH CARE PROFESSIONALS, AND HOSPITALS.—

24 Nothing in paragraph (6) or (7) shall be construed
25 to limit the liability (whether direct or vicarious) of

1 the plan, the plan sponsor, or any health insurance
2 issuer offering health insurance coverage in connec-
3 tion with the plan.

4 “(9) REQUIREMENT OF EXHAUSTION.—

5 “(A) IN GENERAL.—Except as provided in
6 this paragraph, a cause of action may not be
7 brought under paragraph (1) in connection with
8 any denial of a claim for benefits of any indi-
9 vidual until all administrative processes under
10 sections 102 and 103 of the Bipartisan Patient
11 Protection Act of 2001 (if applicable) have been
12 exhausted.

13 “(B) LATE MANIFESTATION OF INJURY.—

14 The requirements under subparagraph (A) for a
15 cause of action in connection with any denial of
16 a claim for benefits shall be deemed satisfied,
17 notwithstanding any failure to timely commence
18 review under section 103 with respect to the de-
19 nial, if the personal injury is first known (or
20 first reasonably should have been known) to the
21 individual (or the death occurs) after the latest
22 date by which the applicable requirements of
23 subparagraph (A) can be met in connection
24 with such denial.

1 “(C) OCCURRENCE OF IMMEDIATE AND IR-
2 REPARABLE HARM OR DEATH PRIOR TO COM-
3 PLETION OF PROCESS.—

4 “(i) IN GENERAL.—The requirements
5 of subparagraph (A) shall not apply in any
6 case of immediate and irreparable harm or
7 death occurring, as a result of the denial
8 of a claim for benefits, prior to the comple-
9 tion of the administrative processes re-
10 ferred to in subparagraph (A) with respect
11 to such denial.

12 “(ii) CONSTRUCTION.—Nothing in
13 clause (i) shall be construed to preclude—

14 “(I) continuation of such proc-
15 esses to their conclusion if so moved
16 by any party, and

17 “(II) consideration in such action
18 of the final decisions issued in such
19 processes.

20 “(iii) DEFINITION.—In clause (i), the
21 term ‘irreparable harm’, with respect to an
22 individual, means an injury or condition
23 that, regardless of whether the individual
24 receives the treatment that is the subject
25 of the denial, cannot be repaired in a man-

1 ner that would restore the individual to the
2 individual's pre-injured condition.

3 “(D) RECEIPT OF BENEFITS DURING AP-
4 PEALS PROCESS.—Receipt by the participant or
5 beneficiary of the benefits involved in the claim
6 for benefits during the pendency of any admin-
7 istrative processes referred to in subparagraph
8 (A) or of any action commenced under this
9 subsection—

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

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

16 The court in any action commenced under this
17 subsection shall take into account any receipt of
18 benefits during such administrative processes or
19 such action in determining the amount of the
20 damages awarded.

21 “(10) STATUTORY DAMAGES.—

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

1 “(B) ASSESSMENT OF CIVIL PENALTIES.—

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

15 “(11) LIMITATION OF ACTION.—Paragraph (1)
16 shall not apply in connection with any action com-
17 menced after 3 years after the later of—

18 “(A) the date on which the plaintiff first
19 knew, or reasonably should have known, of the
20 personal injury or death resulting from the fail-
21 ure described in paragraph (1), or

22 “(B) the date as of which the requirements
23 of paragraph (5) are first met.

24 “(12) TOLLING PROVISION.—The statute of
25 limitations for any cause of action arising under

1 State law relating to a denial of a claim for benefits
2 that is the subject of an action brought in Federal
3 court under this subsection shall be tolled until such
4 time as the Federal court makes a final disposition,
5 including all appeals, of whether such claim should
6 properly be within the jurisdiction of the Federal
7 court. The tolling period shall be determined by the
8 applicable Federal or State law, whichever period is
9 greater.

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

16 “(14) EXCLUSION OF DIRECTED RECORD-
17 KEEPERS.—

18 “(A) IN GENERAL.—Subject to subpara-
19 graph (C), paragraph (1) shall not apply with
20 respect to a directed recordkeeper in connection
21 with a group health plan.

22 “(B) DIRECTED RECORDKEEPER.—For
23 purposes of this paragraph, the term ‘directed
24 recordkeeper’ means, in connection with a
25 group health plan, a person engaged in directed

1 recordkeeping activities pursuant to the specific
2 instructions of the plan or the employer or
3 other plan sponsor, including the distribution of
4 enrollment information and distribution of dis-
5 closure materials under this Act or title I of the
6 Bipartisan Patient Protection Act of 2001 and
7 whose duties do not include making decisions
8 on claims for benefits.

9 “(C) LIMITATION.—Subparagraph (A)
10 does not apply in connection with any directed
11 recordkeeper to the extent that the directed re-
12 cordkeeper fails to follow the specific instruction
13 of the plan or the employer or other plan spon-
14 sor.

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

22 “(16) NO EFFECT ON STATE LAW.—No provi-
23 sion of State law (as defined in section 514(c)(1))
24 shall be treated as superseded or otherwise altered,
25 amended, modified, invalidated, or impaired by rea-

1 son of the provisions of subsection (a)(1)(C) and this
2 subsection.”.

3 (2) CONFORMING AMENDMENT.—Section
4 502(a)(1) of such Act (29 U.S.C. 1132(a)(1)) is
5 amended—

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

8 (B) in subparagraph (B), by striking
9 “plan;” and inserting “plan, or”; and

10 (C) by adding at the end the following new
11 subparagraph:

12 “(C) for the relief provided for in sub-
13 section (n) of this section.”.

14 (b) RULES RELATING TO ERISA PREEMPTION.—
15 Section 514 of the Employee Retirement Income Security
16 Act of 1974 (29 U.S.C. 1144) is amended—

17 (1) by redesignating subsection (d) as sub-
18 section (f); and

19 (2) by inserting after subsection (c) the fol-
20 lowing new subsections:

21 “(d) PREEMPTION NOT TO APPLY TO CAUSES OF
22 ACTION UNDER STATE LAW INVOLVING MEDICALLY RE-
23 VIEWABLE DECISION.—

24 “(1) NON-PREEMPTION OF CERTAIN CAUSES OF
25 ACTION.—

1 “(A) IN GENERAL.—Except as provided in
2 this subsection, nothing in this title (including
3 section 502) shall be construed to supersede or
4 otherwise alter, amend, modify, invalidate, or
5 impair any cause of action under State law of
6 a participant or beneficiary under a group
7 health plan (or the estate of such a participant
8 or beneficiary) to recover damages resulting
9 from personal injury or for wrongful death
10 against any person if such cause of action
11 arises by reason of a medically reviewable deci-
12 sion.

13 “(B) MEDICALLY REVIEWABLE DECI-
14 SION.—For purposes of subparagraph (A), the
15 term ‘medically reviewable decision’ means a de-
16 nial of a claim for benefits under the plan
17 which is described in section 104(d)(2) of the
18 Bipartisan Patient Protection Act of 2001 (re-
19 lating to medically reviewable decisions).

20 “(C) LIMITATION ON PUNITIVE DAM-
21 AGES.—

22 “(i) IN GENERAL.—Except as pro-
23 vided in clauses (ii) and (iii), with respect
24 to a cause of action described in subpara-
25 graph (A) brought with respect to a partic-

1 participant or beneficiary, State law is super-
2 seded insofar as it provides any punitive,
3 exemplary, or similar damages if, as of the
4 time of the personal injury or death, all
5 the requirements of the following sections
6 of the Bipartisan Patient Protection Act of
7 2001 were satisfied with respect to the
8 participant or beneficiary:

9 “(I) Section 102 (relating to pro-
10 cedures for initial claims for benefits
11 and prior authorization determina-
12 tions).

13 “(II) Section 103 of such Act
14 (relating to internal appeals of claims
15 denials).

16 “(III) Section 104 of such Act
17 (relating to independent external ap-
18 peals procedures).

19 “(ii) EXCEPTION FOR CERTAIN AC-
20 TIONS FOR WRONGFUL DEATH.—Clause (i)
21 shall not apply with respect to an action
22 for wrongful death if the applicable State
23 law provides (or has been construed to pro-
24 vide) for damages in such an action which
25 are only punitive or exemplary in nature.

1 “(iii) EXCEPTION FOR WILLFUL OR
2 WANTON DISREGARD FOR THE RIGHTS OR
3 SAFETY OF OTHERS.—Clause (i) shall not
4 apply with respect to any cause of action
5 described in subparagraph (A) if, in such
6 action, the plaintiff establishes by clear
7 and convincing evidence that conduct car-
8 ried out by the defendant with willful or
9 wanton disregard for the rights or safety
10 of others was a proximate cause of the per-
11 sonal injury or wrongful death that is the
12 subject of the action.

13 “(2) DEFINITIONS.—For purposes of this sub-
14 section and subsection (e)—

15 “(A) GROUP HEALTH PLAN AND OTHER
16 RELATED TERMS.—The provisions of sections
17 732(d) and 733 apply for purposes of this sub-
18 section in the same manner as they apply for
19 purposes of part 7, except that the term ‘group
20 health plan’ includes a group health plan (as
21 defined in section 607(1)).

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

1 “(C) CLAIM FOR BENEFIT; DENIAL.—The
2 terms ‘claim for benefits’ and ‘denial of a claim
3 for benefits’ shall have the meaning provided
4 such terms under section 102(e) of the Bipar-
5 tisan Patient Protection Act of 2001.

6 “(3) EXCLUSION OF EMPLOYERS AND OTHER
7 PLAN SPONSORS.—

8 “(A) CAUSES OF ACTION AGAINST EM-
9 PLOYERS AND PLAN SPONSORS PRECLUDED.—
10 Subject to subparagraph (B), paragraph (1)
11 does not apply with respect to—

12 “(i) any cause of action against an
13 employer or other plan sponsor maintain-
14 ing the plan (or against an employee of
15 such an employer or sponsor acting within
16 the scope of employment), or

17 “(ii) a right of recovery, indemnity, or
18 contribution by a person against an em-
19 ployer or other plan sponsor (or such an
20 employee) for damages assessed against
21 the person pursuant to a cause of action to
22 which paragraph (1) applies.

23 “(B) CERTAIN CAUSES OF ACTION PER-
24 MITTED.—Notwithstanding subparagraph (A),
25 paragraph (1) applies with respect to any cause

1 of action described in paragraph (1) maintained
2 by a participant or beneficiary against an em-
3 ployer or other plan sponsor (or against an em-
4 ployee of such an employer or sponsor acting
5 within the scope of employment)—

6 “(i) in the case of any cause of action
7 based on a decision of the plan under sec-
8 tion 102 of the Bipartisan Patient Protec-
9 tion Act of 2001 upon consideration of a
10 claim for benefits or under section 103 of
11 such Act upon review of a denial of a claim
12 for benefits, to the extent there was direct
13 participation by the employer or other plan
14 sponsor (or employee) in the decision, or

15 “(ii) in the case of any cause of action
16 based on a failure to otherwise perform a
17 duty under the terms and conditions of the
18 plan with respect to a claim for benefits of
19 a participant or beneficiary, to the extent
20 there was direct participation by the em-
21 ployer or other plan sponsor (or employee)
22 in the failure.

23 “(C) DIRECT PARTICIPATION.—

24 “(i) DIRECT PARTICIPATION IN DECI-
25 SIONS.—For purposes of subparagraph

1 (B), the term ‘direct participation’ means,
2 in connection with a decision described in
3 subparagraph (B)(i) or a failure described
4 in subparagraph (B)(ii), the actual making
5 of such decision or the actual exercise of
6 control in making such decision or in the
7 conduct constituting the failure.

8 “(ii) RULES OF CONSTRUCTION.—For
9 purposes of clause (i), the employer or plan
10 sponsor (or employee) shall not be con-
11 strued to be engaged in direct participation
12 because of any form of decisionmaking or
13 other conduct that is merely collateral or
14 precedent to the decision described in sub-
15 paragraph (B)(i) on a particular claim for
16 benefits of a particular participant or bene-
17 ficiary or that is merely collateral or prece-
18 dent to the conduct constituting a failure
19 described in subparagraph (B)(ii) with re-
20 spect to a particular participant or bene-
21 ficiary, including (but not limited to)—

22 “(I) any participation by the em-
23 ployer or other plan sponsor (or em-
24 ployee) in the selection of the group
25 health plan or health insurance cov-

1 erage involved or the third party ad-
2 ministrator or other agent;

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

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

19 “(IV) any participation by the
20 employer or other plan sponsor (or
21 employee) in the design of any benefit
22 under the plan, including the amount
23 of copayment and limits connected
24 with such benefit.

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

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

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

24 “(4) REQUIREMENT OF EXHAUSTION.—

1 “(A) IN GENERAL.—Except as provided in
2 this paragraph, paragraph (1) shall not apply
3 with respect to a cause of action described in
4 such paragraph in connection with any denial of
5 a claim for benefits of any individual until all
6 administrative processes under sections 102,
7 103, and 104 of the Bipartisan Patient Protec-
8 tion Act of 2001 (if applicable) have been ex-
9 hausted.

10 “(B) LATE MANIFESTATION OF INJURY.—
11 The requirements under subparagraph (A) for a
12 cause of action in connection with any denial of
13 a claim for benefits shall be deemed satisfied,
14 notwithstanding any failure to timely commence
15 review under section 103 or 104 with respect to
16 the denial, if the personal injury is first known
17 (or first should have been known) to the indi-
18 vidual (or the death occurs) after the latest
19 date by which the applicable requirements of
20 subparagraph (A) can be met in connection
21 with such denial.

22 “(C) OCCURRENCE OF IMMEDIATE AN IR-
23 REPARABLE HARM OR DEATH PRIOR TO COM-
24 PLETION OF PROCESS.—

1 “(i) IN GENERAL.—The requirements
2 of subparagraph (A) shall not apply in any
3 case of immediate and irreparable harm or
4 death occurring, as a result of the denial
5 of a claim for benefits, prior to the comple-
6 tion of the administrative processes re-
7 ferred to in subparagraph (A) with respect
8 to such denial.

9 “(ii) CONSTRUCTION.—Nothing in
10 clause (i) shall be construed to preclude—

11 “(I) continuation of such proc-
12 esses to their conclusion if so moved
13 by any party, and

14 “(II) consideration in such action
15 of the final decisions issued in such
16 processes.

17 “(iii) DEFINITION.—In clause (i), the
18 term ‘irreparable harm’, with respect to an
19 individual, means an injury or condition
20 that, regardless of whether the individual
21 receives the treatment that is the subject
22 of the denial, cannot be repaired in a man-
23 ner that would restore the individual to the
24 individual’s pre-injured condition.

1 “(D) RECEIPT OF BENEFITS DURING AP-
2 PEALS PROCESS.—Receipt by the participant or
3 beneficiary of the benefits involved in the claim
4 for benefits during the pendency of any admin-
5 istrative processes referred to in subparagraph
6 (A) or of any action commenced under this
7 subsection—

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

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

14 “(5) TOLLING PROVISION.—The statute of limi-
15 tations for any cause of action arising under section
16 502(n) relating to a denial of a claim for benefits
17 that is the subject of an action brought in State
18 court shall be tolled until such time as the State
19 court makes a final disposition, including all ap-
20 peals, of whether such claim should properly be
21 within the jurisdiction of the State court. The tolling
22 period shall be determined by the applicable Federal
23 or State law, whichever period is greater.

24 “(6) EXCLUSION OF DIRECTED RECORD-
25 KEEPERS.—

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

5 “(B) DIRECTED RECORDKEEPER.—For
6 purposes of this paragraph, the term ‘directed
7 recordkeeper’ means, in connection with a
8 group health plan, a person engaged in directed
9 recordkeeping activities pursuant to the specific
10 instructions of the plan or the employer or
11 other plan sponsor, including the distribution of
12 enrollment information and distribution of dis-
13 closure materials under this Act or title I of the
14 Bipartisan Patient Protection Act of 2001 and
15 whose duties do not include making decisions
16 on claims for benefits.

17 “(C) LIMITATION.—Subparagraph (A)
18 does not apply in connection with any directed
19 recordkeeper to the extent that the directed rec-
20 ordkeeper fails to follow the specific instruction
21 of the plan or the employer or other plan spon-
22 sor.

23 “(7) CONSTRUCTION.—Nothing in this sub-
24 section shall be construed as—

1 “(A) saving from preemption a cause of
2 action under State law for the failure to provide
3 a benefit for an item or service which is specifi-
4 cally excluded under the group health plan in-
5 volved, except to the extent that—

6 “(i) the application or interpretation
7 of the exclusion involves a determination
8 described in section 104(d)(2) of the Bi-
9 partisan Patient Protection Act of 2001,
10 or

11 “(ii) the provision of the benefit for
12 the item or service is required under Fed-
13 eral law or under applicable State law con-
14 sistent with subsection (b)(2)(B);

15 “(B) preempting a State law which re-
16 quires an affidavit or certificate of merit in a
17 civil action;

18 “(C) affecting a cause of action or remedy
19 under State law in connection with the provi-
20 sion or arrangement of excepted benefits (as de-
21 fined in section 733(c)), other than those de-
22 scribed in section 733(c)(2)(A); or

23 “(D) affecting a cause of action under
24 State law other than a cause of action described
25 in paragraph (1)(A).

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

7 “(e) RULES OF CONSTRUCTION RELATING TO
8 HEALTH CARE.—Nothing in this title shall be construed
9 as—

10 “(1) affecting any State law relating to the
11 practice of medicine or the provision of, or the fail-
12 ure to provide, medical care, or affecting any action
13 (whether the liability is direct or vicarious) based
14 upon such a State law,

15 “(2) superseding any State law permitted under
16 section 152(b)(1)(A) of the Bipartisan Patient Pro-
17 tection Act of 2001, or

18 “(3) affecting any applicable State law with re-
19 spect to limitations on monetary damages.”.

20 (c) EFFECTIVE DATE.—The amendments made by
21 this section shall apply to acts and omissions (from which
22 a cause of action arises) occurring on or after October 1,
23 2002.

1 **SEC. 303. LIMITATIONS ON ACTIONS.**

2 Section 502 of the Employee Retirement Income Se-
3 curity Act of 1974 (29 U.S.C. 1132) (as amended by sec-
4 tion 302(a)) is amended further by adding at the end the
5 following new subsection:

6 “(o) **LIMITATIONS ON ACTIONS RELATING TO GROUP**
7 **HEALTH PLANS.**—

8 “(1) **IN GENERAL.**—Except as provided in para-
9 graph (2), no action may be brought under sub-
10 section (a)(1)(B), (a)(2), or (a)(3) by a participant
11 or beneficiary seeking relief based on the application
12 of any provision in section 101, subtitle B, or sub-
13 title D of title I of the Bipartisan Patient Protection
14 Act (as incorporated under section 714).

15 “(2) **CERTAIN ACTIONS ALLOWABLE.**—An ac-
16 tion may be brought under subsection (a)(1)(B),
17 (a)(2), or (a)(3) by a participant or beneficiary seek-
18 ing relief based on the application of section 101,
19 113, 114, 115, 116, 117, 118(a)(3), 119, or 120 of
20 the Bipartisan Patient Protection Act (as incor-
21 porated under section 714) to the individual cir-
22 cumstances of that participant or beneficiary, except
23 that—

24 “(A) such an action may not be brought or
25 maintained as a class action; and

1 “(B) in such an action, relief may only
 2 provide for the provision of (or payment of)
 3 benefits, items, or services denied to the indi-
 4 vidual participant or beneficiary involved (and
 5 for attorney’s fees and the costs of the action,
 6 at the discretion of the court) and shall not pro-
 7 vide for any other relief to the participant or
 8 beneficiary or for any relief to any other person.

9 “(3) OTHER PROVISIONS UNAFFECTED.—Noth-
 10 ing in this subsection shall be construed as affecting
 11 subsections (a)(1)(C) and (n) or section 514(d).

12 “(4) ENFORCEMENT BY SECRETARY UNAF-
 13 FECTED.—Nothing in this subsection shall be con-
 14 strued as affecting any action brought by the Sec-
 15 retary.”.

16 **TITLE IV—EFFECTIVE DATES;**
 17 **COORDINATION IN IMPLE-**
 18 **MENTATION**

19 **SEC. 401. EFFECTIVE DATES.**

20 (a) GROUP HEALTH COVERAGE.—

21 (1) IN GENERAL.—Subject to paragraph (2)
 22 and subsection (d), the amendments made by sec-
 23 tions 201(a), 301, and 303 (and title I insofar as it
 24 relates to such sections) shall apply with respect to
 25 group health plans, and health insurance coverage

1 offered in connection with group health plans, for
2 plan years beginning on or after October 1, 2002 (in
3 this section referred to as the “general effective
4 date”).

5 (2) TREATMENT OF COLLECTIVE BARGAINING
6 AGREEMENTS.—In the case of a group health plan
7 maintained pursuant to one or more collective bar-
8 gaining agreements between employee representa-
9 tives and one or more employers ratified before the
10 date of the enactment of this Act, the amendments
11 made by sections 201(a), 301, and 303 (and title I
12 insofar as it relates to such sections) shall not apply
13 to plan years beginning before the later of—

14 (A) the date on which the last collective
15 bargaining agreements relating to the plan ter-
16 minates (determined without regard to any ex-
17 tension thereof agreed to after the date of the
18 enactment of this Act); or

19 (B) the general effective date.

20 For purposes of subparagraph (A), any plan amend-
21 ment made pursuant to a collective bargaining
22 agreement relating to the plan which amends the
23 plan solely to conform to any requirement added by
24 this Act shall not be treated as a termination of
25 such collective bargaining agreement.

1 (b) INDIVIDUAL HEALTH INSURANCE COVERAGE.—
2 Subject to subsection (d), the amendments made by sec-
3 tion 202 shall apply with respect to individual health in-
4 surance coverage offered, sold, issued, renewed, in effect,
5 or operated in the individual market on or after the gen-
6 eral effective date.

7 (c) TREATMENT OF RELIGIOUS NONMEDICAL PRO-
8 VIDERS.—

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

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

15 (B) require such plans or issuers to—

16 (i) utilize medically based eligibility
17 standards or criteria in deciding provider
18 status of religious nonmedical providers;

19 (ii) use medical professionals or cri-
20 teria to decide patient access to religious
21 nonmedical providers;

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

1 (iv) compel a participant or bene-
2 ficiary to undergo a medical examination
3 or test as a condition of receiving health
4 insurance coverage for treatment by a reli-
5 gious nonmedical provider; or

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

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

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

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

1 in connection with the plan under such subsection;
2 or

3 (2) subsection (b) with respect to a individual
4 health insurance coverage that is in effect as of the
5 general effective date, not later than 30 days before
6 the first date as of which title I applies to the cov-
7 erage under such subsection.

8 **SEC. 402. COORDINATION IN IMPLEMENTATION.**

9 The Secretary of Labor and the Secretary of Health
10 and Human Services shall ensure, through the execution
11 of an interagency memorandum of understanding among
12 such Secretaries, that—

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

19 (2) coordination of policies relating to enforcing
20 the same requirements through such Secretaries in
21 order to have a coordinated enforcement strategy
22 that avoids duplication of enforcement efforts and
23 assigns priorities in enforcement.

1 **SEC. 403. 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 V—MISCELLANEOUS**
10 **PROVISIONS**

11 **SEC. 501. 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. 502. 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. 503. 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.

○