

Calendar No. 75

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

JUNE 18, 2001

Read the second time and placed on the calendar

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”.

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

Sec. 1. Short title; table of contents.

TITLE I—IMPROVING MANAGED CARE

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

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

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. 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.

Sec. 401. Effective dates.

Sec. 402. Coordination in implementation.

Sec. 403. Severability.

Sec. 501. No impact on Social Security Trust Fund.

Sec. 502. Customs user fees.

Sec. 503. Fiscal year 2002 medicare payments.

3 **Subtitle A—Utilization Review;**
4 **Claims; and Internal and Exter-**
5 **nal Appeals**

7 (a) COMPLIANCE WITH REQUIREMENTS.—

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

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

18 (b) WRITTEN POLICIES AND CRITERIA.—

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

23 (2) USE OF WRITTEN CRITERIA.—

24 (A) IN GENERAL.—Such a program shall
25 utilize written clinical review criteria developed

1 with input from a range of appropriate actively
2 practicing health care professionals, as deter-
3 mined by the plan, pursuant to the program.
4 Such criteria shall include written clinical re-
5 view criteria that are based on valid clinical evi-
6 dence where available and that are directed spe-
7 cifically at meeting the needs of at-risk popu-
8 lations and covered individuals with chronic
9 conditions or severe illnesses, including gender-
10 specific criteria and pediatric-specific criteria
11 where available and appropriate.

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

22 (C) REVIEW OF SAMPLE OF CLAIMS DENI-
23 ALS.—Such a program shall provide for a peri-
24 odic evaluation of the clinical appropriateness of

1 at least a sample of denials of claims for bene-
2 fits.

3 (c) CONDUCT OF PROGRAM ACTIVITIES.—

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

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

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

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

23 (C) PROHIBITION OF CONFLICTS.—Such a
24 program shall not permit a health care profes-
25 sional who is providing health care services to

1 an individual to perform utilization review ac-
2 tivities in connection with the health care serv-
3 ices being provided to the individual.

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

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

20 **SEC. 102. PROCEDURES FOR INITIAL CLAIMS FOR BENE-**
21 **FITS AND PRIOR AUTHORIZATION DETER-**
22 **MINATIONS.**

23 (a) PROCEDURES OF INITIAL CLAIMS FOR BENE-
24 FITS.—

1 (1) IN GENERAL.—A group health plan, or
2 health insurance issuer offering health insurance
3 coverage, shall—

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

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

24 (2) ACCESS TO INFORMATION.—

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

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

1 obligation of the plan or issuer to comply with
2 the requirements of this section.

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

19 (b) TIMELINE FOR MAKING DETERMINATIONS.—

20 (1) PRIOR AUTHORIZATION DETERMINATION.—

21 (A) IN GENERAL.—A group health plan, or
22 health insurance issuer offering health insur-
23 ance coverage, shall make a prior authorization
24 determination on a claim for benefits (whether
25 oral or written) in accordance with the medical

1 exigencies of the case and as soon as possible,
2 but in no case later than 14 days from the date
3 on which the plan or issuer receives information
4 that is reasonably necessary to enable the plan
5 or issuer to make a determination on the re-
6 quest for prior authorization and in no case
7 later than 28 days after the date of the claim
8 for benefits is received.

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

1 mination shall be made in accordance with the
2 medical exigencies of the case and as soon as
3 possible, but in no case later than 72 hours
4 after the time the request is received by the
5 plan or issuer under this subparagraph.

6 (C) ONGOING CARE.—

7 (i) CONCURRENT REVIEW.—

8 (I) IN GENERAL.—Subject to
9 clause (ii), in the case of a concurrent
10 review of ongoing care (including hos-
11 pitalization), which results in a termi-
12 nation or reduction of such care, the
13 plan or issuer must provide by tele-
14 phone and in printed form notice of
15 the concurrent review determination
16 to the individual or the individual's
17 designee and the individual's health
18 care provider in accordance with the
19 medical exigencies of the case and as
20 soon as possible, with sufficient time
21 prior to the termination or reduction
22 to allow for an appeal under section
23 103(b)(3) to be completed before the
24 termination or reduction takes effect.

1 (II) CONTENTS OF NOTICE.—

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

10 (ii) RULE OF CONSTRUCTION.—Clause

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

15 (2) RETROSPECTIVE DETERMINATION.—A

16 group health plan, or health insurance issuer offer-
17 ing health insurance coverage, shall make a retro-
18 spective determination on a claim for benefits in ac-
19 cordance with the medical exigencies of the case and
20 as soon as possible, but not later than 30 days after
21 the date on which the plan or issuer receives infor-
22 mation that is reasonably necessary to enable the
23 plan or issuer to make a determination on the claim,
24 or, if earlier, 60 days after the date of receipt of the
25 claim for benefits.

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

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

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

20 (2) the procedures for obtaining additional in-
 21 formation concerning the determination; and

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

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

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

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

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

21 (4) TREATING HEALTH CARE PROFESSIONAL.—
22 The term “treating health care professional” means,
23 with respect to services to be provided to a partici-
24 pant, beneficiary, or enrollee, a health care profes-
25 sional who is primarily responsible for delivering

1 those services to the participant, beneficiary, or en-
2 rollee.

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

4 (a) RIGHT TO INTERNAL APPEAL.—

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

9 (2) TIME FOR APPEAL.—

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

18 (B) DATE OF DENIAL.—For purposes of
19 subparagraph (A), the date of the denial shall
20 be deemed to be the date as of which the partic-
21 ipant, beneficiary, or enrollee knew of the denial
22 of the claim for benefits.

23 (3) FAILURE TO ACT.—The failure of a plan or
24 issuer to issue a determination on a claim for bene-
25 fits under section 102 within the applicable timeline

1 established for such a determination under such sec-
2 tion is a denial of a claim for benefits for purposes
3 this subtitle as of the date of the applicable deadline.

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

17 (b) TIMELINES FOR MAKING DETERMINATIONS.—

18 (1) ORAL REQUESTS.—In the case of an appeal
19 of a denial of a claim for benefits under this section
20 that involves an expedited or concurrent determina-
21 tion, a participant, beneficiary, or enrollee (or au-
22 thorized representative) may request such appeal
23 orally. A group health plan, or health insurance
24 issuer offering health insurance coverage, may re-
25 quire that the participant, beneficiary, or enrollee

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

10 (2) ACCESS TO INFORMATION.—

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

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

13 (3) PRIOR AUTHORIZATION DETERMINA-
14 TIONS.—

15 (A) IN GENERAL.—A group health plan, or
16 health insurance issuer offering health insur-
17 ance coverage, shall make a determination on
18 an appeal of a denial of a claim for benefits
19 under this subsection in accordance with the
20 medical exigencies of the case and as soon as
21 possible, but in no case later than 14 days from
22 the date on which the plan or issuer receives in-
23 formation that is reasonably necessary to enable
24 the plan or issuer to make a determination on
25 the appeal and in no case later than 28 days

1 after the date the request for the appeal is re-
2 ceived.

3 (B) EXPEDITED DETERMINATION.—Not-
4 withstanding subparagraph (A), a group health
5 plan, or health insurance issuer offering health
6 insurance coverage, shall expedite a prior au-
7 thorization determination on an appeal of a de-
8 nial of a claim for benefits described in sub-
9 paragraph (A), when a request for such an ex-
10 pedited determination is made by a participant,
11 beneficiary, or enrollee (or authorized represent-
12 ative) at any time during the process for mak-
13 ing a determination and a health care profes-
14 sional certifies, with the request, that a deter-
15 mination under the procedures described in sub-
16 paragraph (A) would seriously jeopardize the
17 life or health of the participant, beneficiary, or
18 enrollee or the ability of the participant, bene-
19 ficiary, or enrollee to maintain or regain max-
20 imum function. Such determination shall be
21 made in accordance with the medical exigencies
22 of the case and as soon as possible, but in no
23 case later than 72 hours after the time the re-
24 quest for such appeal is received by the plan or
25 issuer under this subparagraph.

1 (C) ONGOING CARE DETERMINATIONS.—

2 (i) IN GENERAL.—Subject to clause
3 (ii), in the case of a concurrent review de-
4 termination described in section
5 102(b)(1)(C)(i)(I), which results in a ter-
6 mination or reduction of such care, the
7 plan or issuer must provide notice of the
8 determination on the appeal under this
9 section by telephone and in printed form to
10 the individual or the individual's designee
11 and the individual's health care provider in
12 accordance with the medical exigencies of
13 the case and as soon as possible, with suf-
14 ficient time prior to the termination or re-
15 duction to allow for an external appeal
16 under section 104 to be completed before
17 the termination or reduction takes effect.

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

23 (4) RETROSPECTIVE DETERMINATION.—A
24 group health plan, or health insurance issuer offer-
25 ing health insurance coverage, shall make a retro-

1 spective determination on an appeal of a claim for
2 benefits in no case later than 30 days after the date
3 on which the plan or issuer receives necessary infor-
4 mation that is reasonably necessary to enable the
5 plan or issuer to make a determination on the ap-
6 peal and in no case later than 60 days after the
7 date the request for the appeal is received.

8 (c) CONDUCT OF REVIEW.—

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

13 (2) REVIEW OF MEDICAL DECISIONS BY PHYSI-
14 CIANS.—A review of an appeal of a denial of a claim
15 for benefits that is based on a lack of medical neces-
16 sity and appropriateness, or based on an experi-
17 mental or investigational treatment, or requires an
18 evaluation of medical facts, shall be made by a phy-
19 sician (allopathic or osteopathic) with appropriate
20 expertise (including, in the case of a child, appro-
21 priate pediatric expertise) who was not involved in
22 the initial determination.

23 (d) NOTICE OF DETERMINATION.—

24 (1) IN GENERAL.—Written notice of a deter-
25 mination made under an internal appeal of a denial

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

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

21 (3) REQUIREMENTS OF NOTICE.—With respect
22 to a determination made under this section, the no-
23 tice described in paragraph (1) shall be provided in
24 printed form and written in a manner calculated to

1 be understood by the participant, beneficiary, or en-
 2 rollee and shall include—

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

7 (B) the procedures for obtaining additional
 8 information concerning the determination; and

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

12 **SEC. 104. INDEPENDENT EXTERNAL APPEALS PROCE-**
 13 **DURES.**

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

20 (b) **INITIATION OF THE INDEPENDENT EXTERNAL**
 21 **REVIEW PROCESS.**—

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

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

11 (2) FILING OF REQUEST.—

12 (A) IN GENERAL.—Subject to the suc-
13 ceeding provisions of this subsection, a group
14 health plan, and a health insurance issuer offer-
15 ing health insurance coverage, may—

16 (i) except as provided in subparagraph

17 (B)(i), require that a request for review be
18 in writing;

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

22 (iii) except if waived by the plan or
23 issuer under section 103(a)(4), condition
24 access to an independent external review
25 under this section upon a final determina-

tion of a denial of a claim for benefits under the internal review procedure under section 103;

(iv) except as provided in subparagraph (B)(ii), require payment of a filing fee to the plan or issuer of a sum that does not exceed \$25; and

(v) require that a request for review include the consent of the participant, beneficiary, or enrollee (or authorized representative) for the release of necessary medical information or records of the participant, beneficiary, or enrollee to the qualified external review entity only for purposes of conducting external review activities.

(B) REQUIREMENTS AND EXCEPTION RELATING TO GENERAL RULE.—

(i) ORAL REQUESTS PERMITTED IN EXPEDITED OR CONCURRENT CASES.—In the case of an expedited or concurrent external review as provided for under subsection (e), the request may be made orally. A group health plan, or health insurance issuer offering health insurance cov-

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

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

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

1 indigent (as defined in such guide-
2 lines).

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

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

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

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

24 (1) IN GENERAL.—Upon the filing of a request
25 for independent external review with the group

1 health plan, or health insurance issuer offering
2 health insurance coverage, the plan or issuer shall
3 immediately refer such request, and forward the
4 plan or issuer's initial decision (including the infor-
5 mation described in section 103(d)(3)(A)), to a
6 qualified external review entity selected in accord-
7 ance with this section.

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

23 (3) SCREENING OF REQUESTS BY QUALIFIED
24 EXTERNAL REVIEW ENTITIES.—

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

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

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

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

20 (iv) the denial of the claim for bene-
21 fits is a decision as to the application of
22 cost-sharing requirements or the applica-
23 tion of a specific exclusion or express limi-
24 tation on the amount, duration, or scope of
25 coverage of items or services under the

1 terms and conditions of the plan or cov-
2 erage unless the decision is a denial de-
3 scribed in subsection (d)(2).

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

10 (B) PROCESS FOR MAKING DETERMINA-
11 TIONS.—

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

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

24 (C) NOTICES AND GENERAL TIMELINES
25 FOR DETERMINATION.—

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

(I) shall be written (and, in addition, may be provided orally) in a manner calculated to be understood by a participant or enrollee;

(II) shall include the reasons for the determination;

(III) include any relevant terms and conditions of the plan or coverage; and

(IV) include a description of any further recourse available to the individual.

(ii) GENERAL TIMELINE FOR DETERMINATIONS.—Upon receipt of information under paragraph (2), the qualified external

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

14 (d) INDEPENDENT MEDICAL REVIEW.—

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

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

1 ered benefit under the terms and conditions of the
2 plan or coverage but for one (or more) of the fol-
3 lowing determinations:

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

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

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

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

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

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

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

1 services for which benefits are specifically ex-
2 cluded or expressly limited under the plan or
3 coverage in the plain language of the plan docu-
4 ment (and which are disclosed under section
5 121(b)(1)(C)) except to the extent that the ap-
6 plication or interpretation of the exclusion or
7 limitation involves a determination described in
8 paragraph (2).

9 (D) EVIDENCE AND INFORMATION TO BE
10 USED IN MEDICAL REVIEWS.—In making a de-
11 termination under this subsection, the inde-
12 pendent medical reviewer shall also consider ap-
13 propriate and available evidence and informa-
14 tion, including the following:

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

20 (ii) The recommendation of the treat-
21 ing health care professional and the evi-
22 dence, guidelines, and rationale used by
23 the treating health care professional in
24 reaching such recommendation.

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

(iv) The plan or coverage document.

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

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

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

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

8 (i) the determination of the reviewer;

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

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

19 (G) NONBINDING NATURE OF ADDITIONAL
20 RECOMMENDATIONS.—In addition to the deter-
21 mination under subparagraph (F), the reviewer
22 may provide the plan or issuer and the treating
23 health care professional with additional rec-
24 ommendations in connection with such a deter-
25 mination, but any such recommendations shall

1 not affect (or be treated as part of) the deter-
2 mination and shall not be binding on the plan
3 or issuer.

4 (e) TIMELINES AND NOTIFICATIONS.—

5 (1) TIMELINES FOR INDEPENDENT MEDICAL
6 REVIEW.—

7 (A) PRIOR AUTHORIZATION DETERMINA-
8 TION.—

9 (i) IN GENERAL.—The independent
10 medical reviewer (or reviewers) shall make
11 a determination on a denial of a claim for
12 benefits that is referred to the reviewer
13 under subsection (c)(3) in accordance with
14 the medical exigencies of the case and as
15 soon as possible, but in no case later than
16 14 days after the date of receipt of infor-
17 mation under subsection (c)(2) if the re-
18 view involves a prior authorization of items
19 or services and in no case later than 21
20 days after the date the request for external
21 review is received.

22 (ii) EXPEDITED DETERMINATION.—
23 Notwithstanding clause (i) and subject to
24 clause (iii), the independent medical re-
25 viewer (or reviewers) shall make an expe-

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

21 (iii) ONGOING CARE DETERMINA-
22 TION.—Notwithstanding clause (i), in the
23 case of a review described in such sub-
24 clause that involves a termination or reduc-
25 tion of care, the notice of the determina-

tion shall be completed not later than 24 hours after the time the request for external review is received by the qualified external review entity and before the end of the approved period of care.

(B) RETROSPECTIVE DETERMINATION.—

The independent medical reviewer (or reviewers) shall complete a review in the case of a retrospective determination on an appeal of a denial of a claim for benefits that is referred to the reviewer under subsection (c)(3) in no case later than 30 days after the date of receipt of information under subsection (c)(2) and in no case later than 60 days after the date the request for external review is received by the qualified external review entity.

(2) NOTIFICATION OF DETERMINATION.—The

external review entity shall ensure that the plan or issuer, the participant, beneficiary, or enrollee (or authorized representative) and the treating health care professional (if any) receives a copy of the written determination of the independent medical reviewer prepared under subsection (d)(3)(F). Nothing in this paragraph shall be construed as preventing

1 an entity or reviewer from providing an initial oral
 2 notice of the reviewer's determination.

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

6 (f) COMPLIANCE.—

7 (1) APPLICATION OF DETERMINATIONS.—

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

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

21 (2) FAILURE TO COMPLY.—

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

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

8 (B) REIMBURSEMENT.—

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

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

1 such items or services) so long as the items
2 or services were provided in a manner con-
3 sistent with the determination of the inde-
4 pendent medical reviewer.

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

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

20 (3) PENALTIES AGAINST AUTHORIZED OFFI-
21 CIALS FOR REFUSING TO AUTHORIZE THE DETER-
22 MINATION OF AN EXTERNAL REVIEW ENTITY.—

23 (A) MONETARY PENALTIES.—

24 (i) IN GENERAL.—In any case in
25 which the determination of an external re-

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

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

24 (B) CEASE AND DESIST ORDER AND
25 ORDER OF ATTORNEY'S FEES.—In any action

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

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

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

22 (C) ADDITIONAL CIVIL PENALTIES.—

23 (i) IN GENERAL.—In addition to any
24 penalty imposed under subparagraph (A)
25 or (B), the appropriate Secretary may as-

1 sess a civil penalty against a person acting
2 in the capacity of authorizing a benefit de-
3 termined by an external review entity for
4 one or more group health plans, or health
5 insurance issuers offering health insurance
6 coverage, for—

7 (I) any pattern or practice of re-
8 peated refusal to authorize a benefit
9 determined by an external appeal enti-
10 ty to be covered; or

11 (II) any pattern or practice of re-
12 peated violations of the requirements
13 of this section with respect to such
14 plan or coverage.

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

21 (I) 25 percent of the aggregate
22 value of benefits shown by the appro-
23 priate Secretary to have not been pro-
24 vided, or unlawfully delayed, in viola-

tion of this section under such pattern
or practice; or

(II) \$500,000.

(D) REMOVAL AND DISQUALIFICATION.—

Any person acting in the capacity of authorizing benefits who has engaged in any such pattern or practice described in subparagraph (C)(i) with respect to a plan or coverage, upon the petition of the appropriate Secretary, may be removed by the court from such position, and from any other involvement, with respect to such a plan or coverage, and may be precluded from returning to any such position or involvement for a period determined by the court.

(4) PROTECTION OF LEGAL RIGHTS.—Nothing

in this subsection or subtitle shall be construed as altering or eliminating any cause of action or legal rights or remedies of participants, beneficiaries, enrollees, and others under State or Federal law (including sections 502 and 503 of the Employee Retirement Income Security Act of 1974), including the right to file judicial actions to enforce rights.

(g) QUALIFICATIONS OF INDEPENDENT MEDICAL

REVIEWERS.—

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

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

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

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

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

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

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

23 (3) INDEPENDENCE.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 (i) by a physician, a reviewer shall be
2 a practicing physician (allopathic or osteo-
3 pathic) of the same or similar specialty, as
4 a physician who typically treats the condi-
5 tion, makes the diagnosis, or provides the
6 type of treatment under review; or

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

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

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

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

9 (A) not exceed a reasonable level; and

10 (B) not be contingent on the decision ren-
 11 dered by the reviewer.

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

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

20 (B) The participant, beneficiary, or en-
 21 rollee (or authorized representative).

22 (C) The health care professional that pro-
 23 vides the items or services involved in the de-
 24 nial.

1 (D) The institution at which the items or
 2 services (or treatment) involved in the denial
 3 are provided.

4 (E) The manufacturer of any drug or
 5 other item that is included in the items or serv-
 6 ices involved in the denial.

7 (F) Any other party determined under any
 8 regulations to have a substantial interest in the
 9 denial involved.

10 (h) QUALIFIED EXTERNAL REVIEW ENTITIES.—

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

13 (A) LIMITATION ON PLAN OR ISSUER SE-
 14 LECTION.—The appropriate Secretary shall im-
 15 plement procedures—

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

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

24 No such selection process under the procedures
 25 implemented by the appropriate Secretary may

1 give either the patient or the plan or issuer any
2 ability to determine or influence the selection of
3 a qualified external review entity to review the
4 case of any participant, beneficiary, or enrollee.

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

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

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

1 (A) be consistent with the standards the
 2 appropriate Secretary shall establish to assure
 3 there is no real or apparent conflict of interest
 4 in the conduct of external review activities; and

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

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

15 (4) QUALIFICATIONS.—

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

22 (i) The entity has (directly or through
 23 contracts or other arrangements) sufficient
 24 medical, legal, and other expertise and suf-
 25 ficient staffing to carry out duties of a

1 qualified external review entity under this
2 section on a timely basis, including making
3 determinations under subsection (b)(2)(A)
4 and providing for independent medical re-
5 views under subsection (d).

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

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

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

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

1 (B) INDEPENDENCE REQUIREMENTS.—

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

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

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

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

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

22 (iii) LIMITATIONS ON ENTITY COM-
23 PENSATION.—Compensation provided by a
24 plan or issuer to a qualified external review

entity in connection with reviews under
this section shall—

(I) not exceed a reasonable level;

and

(II) not be contingent on any de-

cision rendered by the entity or by

any independent medical reviewer.

(C) CERTIFICATION AND RECERTIFICATION

PROCESS.—

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

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

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

In taking action under subclause (I), the
appropriate Secretary shall give deference
to entities that are under contract with the
Federal Government or with an applicable
State authority to perform functions of the

1 type performed by qualified external review
2 entities.

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

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

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

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

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

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

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

24 (I) Provision of information
25 under subparagraph (D).

1 (II) Adherence to applicable
2 deadlines (both by the entity and by
3 independent medical reviewers it re-
4 fers cases to).

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

9 (IV) Compliance with applicable
10 independence requirements.

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

16 (vi) REVOCATION.—A certification or
17 recertification under this paragraph may
18 be revoked by the appropriate Secretary or
19 by the organization providing such certifi-
20 cation upon a showing of cause.

21 (vii) SUFFICIENT NUMBER OF ENTI-
22 TIES.—The appropriate Secretary shall
23 certify and recertify a number of external
24 review entities which is sufficient to ensure

1 the timely and efficient provision of review
2 services.

3 (D) PROVISION OF INFORMATION.—

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

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

1 (I) The number and types of de-
2 nials for which a request for review
3 has been received by the entity.

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

12 (III) The length of time in mak-
13 ing determinations with respect to
14 such denials.

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

20 (iii) INFORMATION TO BE PROVIDED
21 TO CERTIFYING ORGANIZATION.—

22 (I) IN GENERAL.—In the case of
23 a qualified external review entity
24 which is certified (or recertified)
25 under this subsection by a qualified

1 private standard-setting organization,
2 at the request of the organization, the
3 entity shall provide the organization
4 with the information provided to the
5 appropriate Secretary under clause
6 (i).

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

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

23 (E) LIMITATION ON LIABILITY.—No quali-
24 fied external review entity having a contract
25 with a plan or issuer, and no person who is em-

1 employed by any such entity or who furnishes pro-
 2 fessional services to such entity (including as an
 3 independent medical reviewer), shall be held by
 4 reason of the performance of any duty, func-
 5 tion, or activity required or authorized pursuant
 6 to this section, to be civilly liable under any law
 7 of the United States or of any State (or polit-
 8 ical subdivision thereof) if there was no actual
 9 malice or gross misconduct in the performance
 10 of such duty, function, or activity.

11 **Subtitle B—Access to Care**

12 **SEC. 111. CONSUMER CHOICE OPTION.**

13 (a) IN GENERAL.—If—

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

23 (2) a group health plan offers to participants or
 24 beneficiaries health benefits which provide for cov-
 25 erage of services only if such services are furnished

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

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

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

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

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

15 (b) SPECIALISTS.—

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

24 (2) LIMITATION.—Paragraph (1) shall not
25 apply to specialty care if the plan or issuer clearly

1 informs participants, beneficiaries, and enrollees of
2 the limitations on choice of participating health care
3 professionals with respect to such care.

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

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

9 (a) COVERAGE OF EMERGENCY SERVICES.—

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

16 (A) without the need for any prior author-
17 ization determination;

18 (B) whether the health care provider fur-
19 nishing such services is a participating provider
20 with respect to such services;

21 (C) in a manner so that, if such services
22 are provided to a participant, beneficiary, or
23 enrollee—

1 (i) by a nonparticipating health care
 2 provider with or without prior authoriza-
 3 tion, or

4 (ii) by a participating health care pro-
 5 vider without prior authorization,
 6 the participant, beneficiary, or enrollee is not
 7 liable for amounts that exceed the amounts of
 8 liability that would be incurred if the services
 9 were provided by a participating health care
 10 provider with prior authorization; and

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

20 (2) DEFINITIONS.—In this section:

21 (A) EMERGENCY MEDICAL CONDITION.—
 22 The term “emergency medical condition” means
 23 a medical condition manifesting itself by acute
 24 symptoms of sufficient severity (including se-
 25 vere pain) such that a prudent layperson, who

1 possesses an average knowledge of health and
2 medicine, could reasonably expect the absence
3 of immediate medical attention to result in a
4 condition described in clause (i), (ii), or (iii) of
5 section 1867(e)(1)(A) of the Social Security
6 Act.

7 (B) EMERGENCY SERVICES.—The term
8 “emergency services” means, with respect to an
9 emergency medical condition—

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

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

23 (C) STABILIZE.—The term “to stabilize”,
24 with respect to an emergency medical condition
25 (as defined in subparagraph (A)), has the

1 meaning give in section 1867(e)(3) of the Social
2 Security Act (42 U.S.C. 1395dd(e)(3)).

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

11 (c) COVERAGE OF EMERGENCY AMBULANCE SERV-
12 ICES.—

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

23 (2) EMERGENCY AMBULANCE SERVICES.—For
24 purposes of this subsection, the term “emergency
25 ambulance services” means ambulance services (as

1 defined for purposes of section 1861(s)(7) of the So-
2 cial Security Act) furnished to transport an indi-
3 vidual who has an emergency medical condition (as
4 defined in subsection (a)(2)(A)) to a hospital for the
5 receipt of emergency services (as defined in sub-
6 section (a)(2)(B)) in a case in which the emergency
7 services are covered under the plan or coverage pur-
8 suant to subsection (a)(1) and a prudent layperson,
9 with an average knowledge of health and medicine,
10 could reasonably expect that the absence of such
11 transport would result in placing the health of the
12 individual in serious jeopardy, serious impairment of
13 bodily function, or serious dysfunction of any bodily
14 organ or part.

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

16 (a) TIMELY ACCESS.—

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

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

3 (A) to require the coverage under a group
4 health plan or health insurance coverage of ben-
5 efits or services;

6 (B) to prohibit a plan or issuer from in-
7 cluding providers in the network only to the ex-
8 tent necessary to meet the needs of the plan's
9 or issuer's participants, beneficiaries, or enroll-
10 ees; or

11 (C) to override any State licensure or
12 scope-of-practice law.

13 (3) ACCESS TO CERTAIN PROVIDERS.—

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

21 (B) TREATMENT OF NONPARTICIPATING
22 PROVIDERS.—If a participant, beneficiary, or
23 enrollee receives care from a nonparticipating
24 specialist pursuant to subparagraph (A), such
25 specialty care shall be provided at no additional

1 cost to the participant, beneficiary, or enrollee
 2 beyond what the participant, beneficiary, or en-
 3 rollee would otherwise pay for such specialty
 4 care if provided by a participating specialist.

5 (b) REFERRALS.—

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

11 (A) shall be for an appropriate duration of
 12 time or number of referrals, including an au-
 13 thorization for a standing referral where appro-
 14 priate; and

15 (B) may not be refused solely because the
 16 authorization involves services of a nonpartici-
 17 pating specialist (described in subsection
 18 (a)(3)).

19 (2) REFERRALS FOR ONGOING SPECIAL CONDI-
 20 TIONS.—

21 (A) IN GENERAL.—Subject to subsection
 22 (a)(1), a group health plan or health insurance
 23 issuer shall permit a participant, beneficiary, or
 24 enrollee who has an ongoing special condition
 25 (as defined in subparagraph (B)) to receive a

1 referral to a specialist for the treatment of such
 2 condition and such specialist may authorize
 3 such referrals, procedures, tests, and other
 4 medical services with respect to such condition,
 5 or coordinate the care for such condition, sub-
 6 ject to the terms of a treatment plan (if any)
 7 referred to in subsection (c) with respect to the
 8 condition.

9 (B) ONGOING SPECIAL CONDITION DE-
 10 FINED.—In this subsection, the term “ongoing
 11 special condition” means a condition or disease
 12 that—

13 (i) is life-threatening, degenerative,
 14 potentially disabling, or congenital; and

15 (ii) requires specialized medical care
 16 over a prolonged period of time.

17 (c) TREATMENT PLANS.—

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

21 (A) pursuant to a treatment plan, but only
 22 if the treatment plan—

23 (i) is developed by the specialist, in
 24 consultation with the case manager or pri-

1 mary care provider, and the participant,
2 beneficiary, or enrollee, and

3 (ii) is approved by the plan or issuer
4 in a timely manner, if the plan or issuer
5 requires such approval; and

6 (B) in accordance with applicable quality
7 assurance and utilization review standards of
8 the plan or issuer.

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

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

22 **SEC. 115. PATIENT ACCESS TO OBSTETRIC AND GYNECO-**
23 **LOGICAL CARE.**

24 (a) GENERAL RIGHTS.—

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

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

21 (b) APPLICATION OF SECTION.—A group health plan,
22 or health insurance issuer offering health insurance cov-
23 erage, described in this subsection is a group health plan
24 or coverage that—

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

3 (2) requires the designation by a participant,
4 beneficiary, or enrollee of a participating primary
5 care provider.

6 (c) CONSTRUCTION.—Nothing in subsection (a) shall
7 be construed to—

8 (1) waive any exclusions of coverage under the
9 terms and conditions of the plan or health insurance
10 coverage with respect to coverage of obstetrical or
11 gynecological care; or

12 (2) preclude the group health plan or health in-
13 surance issuer involved from requiring that the ob-
14 stetrical or gynecological provider notify the primary
15 care health care professional or the plan or issuer of
16 treatment decisions.

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

18 (a) PEDIATRIC CARE.—In the case of a person who
19 has a child who is a participant, beneficiary, or enrollee
20 under a group health plan, or health insurance coverage
21 offered by a health insurance issuer, if the plan or issuer
22 requires or provides for the designation of a participating
23 primary care provider for the child, the plan or issuer shall
24 permit such person to designate a physician (allopathic or
25 osteopathic) who specializes in pediatrics as the child's pri-

1 mary care provider if such provider participates in the net-
2 work of the plan or issuer.

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

7 **SEC. 117. CONTINUITY OF CARE.**

8 (a) TERMINATION OF PROVIDER.—

9 (1) IN GENERAL.—If—

10 (A) a contract between a group health
11 plan, or a health insurance issuer offering
12 health insurance coverage, and a treating health
13 care provider is terminated (as defined in para-
14 graph (e)(4)), or

15 (B) benefits or coverage provided by a
16 health care provider are terminated because of
17 a change in the terms of provider participation
18 in such plan or coverage,

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

22 (2) TREATMENT OF TERMINATION OF CON-
23 TRACT WITH HEALTH INSURANCE ISSUER.—If a
24 contract for the provision of health insurance cov-
25 erage between a group health plan and a health in-

1 surance issuer is terminated and, as a result of such
2 termination, coverage of services of a health care
3 provider is terminated with respect to an individual,
4 the provisions of paragraph (1) (and the succeeding
5 provisions of this section) shall apply under the plan
6 in the same manner as if there had been a contract
7 between the plan and the provider that had been ter-
8 minated, but only with respect to benefits that are
9 covered under the plan after the contract termi-
10 nation.

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

13 (A) notify the continuing care patient in-
14 volved, or arrange to have the patient notified
15 pursuant to subsection (d)(2), on a timely basis
16 of the termination described in paragraph (1)
17 (or paragraph (2), if applicable) and the right
18 to elect continued transitional care from the
19 provider under this section;

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

23 (C) subject to subsection (c), permit the
24 patient to elect to continue to be covered with
25 respect to the course of treatment by such pro-

1 vider with the provider’s consent during a tran-
2 sitional period (as provided for under subsection
3 (b)).

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

7 (A) is undergoing a course of treatment
8 for a serious and complex condition from the
9 provider at the time the plan or issuer receives
10 or provides notice of provider, benefit, or cov-
11 erage termination described in paragraph (1)
12 (or paragraph (2), if applicable);

13 (B) is undergoing a course of institutional
14 or inpatient care from the provider at the time
15 of such notice;

16 (C) is scheduled to undergo non-elective
17 surgery from the provider at the time of such
18 notice;

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

22 (E) is or was determined to be terminally
23 ill (as determined under section 1861(dd)(3)(A)
24 of the Social Security Act) at the time of such
25 notice, but only with respect to a provider that

1 was treating the terminal illness before the date
2 of such notice.

3 (b) TRANSITIONAL PERIODS.—

4 (1) SERIOUS AND COMPLEX CONDITIONS.—The
5 transitional period under this subsection with re-
6 spect to a continuing care patient described in sub-
7 section (a)(4)(A) shall extend for up to 90 days (as
8 determined by the treating health care professional)
9 from the date of the notice described in subsection
10 (a)(3)(A).

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

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

18 (B) the date of discharge of the patient
19 from such care or the termination of the period
20 of institutionalization, or, if later, the date of
21 completion of reasonable follow-up care.

22 (3) SCHEDULED NON-ELECTIVE SURGERY.—
23 The transitional period under this subsection for a
24 continuing care patient described in subsection
25 (a)(4)(C) shall extend until the completion of the

1 surgery involved and post-surgical follow-up care re-
2 lating to the surgery and occurring within 90 days
3 after the date of the surgery.

4 (4) PREGNANCY.—The transitional period
5 under this subsection for a continuing care patient
6 described in subsection (a)(4)(D) shall extend
7 through the provision of post-partum care directly
8 related to the delivery.

9 (5) TERMINAL ILLNESS.—The transitional pe-
10 riod under this subsection for a continuing care pa-
11 tient described in subsection (a)(4)(E) shall extend
12 for the remainder of the patient's life for care that
13 is directly related to the treatment of the terminal
14 illness or its medical manifestations.

15 (c) PERMISSIBLE TERMS AND CONDITIONS.—A
16 group health plan or health insurance issuer may condi-
17 tion coverage of continued treatment by a provider under
18 this section upon the provider agreeing to the following
19 terms and conditions:

20 (1) The treating health care provider agrees to
21 accept reimbursement from the plan or issuer and
22 continuing care patient involved (with respect to
23 cost-sharing) at the rates applicable prior to the
24 start of the transitional period as payment in full
25 (or, in the case described in subsection (a)(2), at the

1 rates applicable under the replacement plan or cov-
2 erage after the date of the termination of the con-
3 tract with the group health plan or health insurance
4 issuer) and not to impose cost-sharing with respect
5 to the patient in an amount that would exceed the
6 cost-sharing that could have been imposed if the
7 contract referred to in subsection (a)(1) had not
8 been terminated.

9 (2) The treating health care provider agrees to
10 adhere to the quality assurance standards of the
11 plan or issuer responsible for payment under para-
12 graph (1) and to provide to such plan or issuer nec-
13 essary medical information related to the care pro-
14 vided.

15 (3) The treating health care provider agrees
16 otherwise to adhere to such plan's or issuer's policies
17 and procedures, including procedures regarding re-
18 ferrals and obtaining prior authorization and pro-
19 viding services pursuant to a treatment plan (if any)
20 approved by the plan or issuer.

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

23 (1) to require the coverage of benefits which
24 would not have been covered if the provider involved
25 remained a participating provider; or

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

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

7 (B) provide the plan or issuer with the
 8 name of each participant, beneficiary, or en-
 9 rollee who the provider believes is a continuing
 10 care patient.

11 (e) DEFINITIONS.—In this section:

12 (1) CONTRACT.—The term “contract” includes,
 13 with respect to a plan or issuer and a treating
 14 health care provider, a contract between such plan
 15 or issuer and an organized network of providers that
 16 includes the treating health care provider, and (in
 17 the case of such a contract) the contract between the
 18 treating health care provider and the organized net-
 19 work.

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

22 (A) any individual who is engaged in the
 23 delivery of health care services in a State and
 24 who is required by State law or regulation to be

1 licensed or certified by the State to engage in
2 the delivery of such services in the State; and

3 (B) any entity that is engaged in the deliv-
4 ery of health care services in a State and that,
5 if it is required by State law or regulation to be
6 licensed or certified by the State to engage in
7 the delivery of such services in the State, is so
8 licensed.

9 (3) SERIOUS AND COMPLEX CONDITION.—The
10 term “serious and complex condition” means, with
11 respect to a participant, beneficiary, or enrollee
12 under the plan or coverage—

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

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

20 (4) TERMINATED.—The term “terminated” in-
21 cludes, with respect to a contract, the expiration or
22 nonrenewal of the contract, but does not include a
23 termination of the contract for failure to meet appli-
24 cable quality standards or for fraud.

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

2 (a) IN GENERAL.—To the extent that a group health
3 plan, or health insurance coverage offered by a health in-
4 surance issuer, provides coverage for benefits with respect
5 to prescription drugs, and limits such coverage to drugs
6 included in a formulary, the plan or issuer shall—

7 (1) ensure the participation of physicians and
8 pharmacists in developing and reviewing such for-
9 mulary;

10 (2) provide for disclosure of the formulary to
11 providers; and

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

20 (b) COVERAGE OF APPROVED DRUGS AND MEDICAL
21 DEVICES.—

22 (1) IN GENERAL.—A group health plan (or
23 health insurance coverage offered in connection with
24 such a plan) that provides any coverage of prescrip-
25 tion drugs or medical devices shall not deny coverage

1 of such a drug or device on the basis that the use
2 is investigational, if the use—

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

4 (i) is included in the labeling author-
5 ized by the application in effect for the
6 drug pursuant to subsection (b) or (j) of
7 section 505 of the Federal Food, Drug,
8 and Cosmetic Act, without regard to any
9 postmarketing requirements that may
10 apply under such Act; or

11 (ii) is included in the labeling author-
12 ized by the application in effect for the
13 drug under section 351 of the Public
14 Health Service Act, without regard to any
15 postmarketing requirements that may
16 apply pursuant to such section; or

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

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

6 **SEC. 119. COVERAGE FOR INDIVIDUALS PARTICIPATING IN**
 7 **APPROVED CLINICAL TRIALS.**

8 (a) COVERAGE.—

9 (1) IN GENERAL.—If a group health plan, or
 10 health insurance issuer that is providing health in-
 11 surance coverage, provides coverage to a qualified in-
 12 dividual (as defined in subsection (b)), the plan or
 13 issuer—

14 (A) may not deny the individual partici-
 15 pation in the clinical trial referred to in subsection
 16 (b)(2);

17 (B) subject to subsection (c), may not deny
 18 (or limit or impose additional conditions on) the
 19 coverage of routine patient costs for items and
 20 services furnished in connection with participa-
 21 tion in the trial; and

22 (C) may not discriminate against the indi-
 23 vidual on the basis of the enrollee's participa-
 24 tion in such trial.

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

6 (3) USE OF IN-NETWORK PROVIDERS.—If one
7 or more participating providers is participating in a
8 clinical trial, nothing in paragraph (1) shall be con-
9 strued as preventing a plan or issuer from requiring
10 that a qualified individual participate in the trial
11 through such a participating provider if the provider
12 will accept the individual as a participant in the
13 trial.

14 (b) QUALIFIED INDIVIDUAL DEFINED.—For pur-
15 poses of subsection (a), the term “qualified individual”
16 means an individual who is a participant or beneficiary
17 in a group health plan, or who is an enrollee under health
18 insurance coverage, and who meets the following condi-
19 tions:

20 (1)(A) The individual has a life-threatening or
21 serious illness for which no standard treatment is ef-
22 fective.

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

1 (C) The individual's participation in the trial
2 offers meaningful potential for significant clinical
3 benefit for the individual.

4 (2) Either—

5 (A) the referring physician is a partici-
6 pating health care professional and has con-
7 cluded that the individual's participation in
8 such trial would be appropriate based upon the
9 individual meeting the conditions described in
10 paragraph (1); or

11 (B) the participant, beneficiary, or enrollee
12 provides medical and scientific information es-
13 tablishing that the individual's participation in
14 such trial would be appropriate based upon the
15 individual meeting the conditions described in
16 paragraph (1).

17 (c) PAYMENT.—

18 (1) IN GENERAL.—Under this section a group
19 health plan or health insurance issuer shall provide
20 for payment for routine patient costs described in
21 subsection (a)(2) but is not required to pay for costs
22 of items and services that are reasonably expected
23 (as determined by the appropriate Secretary) to be
24 paid for by the sponsors of an approved clinical trial.

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

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

5 (B) a nonparticipating provider, the pay-
6 ment rate shall be at the rate the plan or issuer
7 would normally pay for comparable services
8 under subparagraph (A).

9 (d) APPROVED CLINICAL TRIAL DEFINED.—

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

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

16 (i) the National Institutes of Health;

17 (ii) a cooperative group or center of
18 the National Institutes of Health;

19 (iii) either of the following if the con-
20 ditions described in paragraph (2) are
21 met—

22 (I) the Department of Veterans
23 Affairs;

24 (II) the Department of Defense;

25 or

1 (B) approved by the Food and Drug Ad-
 2 ministration.

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

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

12 (B) assures unbiased review of the highest
 13 scientific standards by qualified individuals who
 14 have no interest in the outcome of the review.

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

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

23 (a) INPATIENT CARE.—

24 (1) IN GENERAL.—A group health plan, and a
 25 health insurance issuer providing health insurance

1 coverage, that provides medical and surgical benefits
2 shall ensure that inpatient coverage with respect to
3 the treatment of breast cancer is provided for a pe-
4 riod of time as is determined by the attending physi-
5 cian, in consultation with the patient, to be medi-
6 cally necessary and appropriate following—

7 (A) a mastectomy;

8 (B) a lumpectomy; or

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

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

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

23 (c) SECONDARY CONSULTATIONS.—

24 (1) IN GENERAL.—A group health plan, and a
25 health insurance issuer providing health insurance

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

24 (2) EXCEPTION.—Nothing in paragraph (1)
25 shall be construed as requiring the provision of sec-

1 ondary consultations where the patient determines
2 not to seek such a consultation.

3 (d) PROHIBITION ON PENALTIES OR INCENTIVES.—

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

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

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

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

1 **Subtitle C—Access to Information**

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

3 (a) REQUIREMENT.—

4 (1) DISCLOSURE.—

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

10 (i) of the information described in
11 subsection (b) at the time of the initial en-
12 rollment of the participant, beneficiary, or
13 enrollee under the plan or coverage;

14 (ii) of such information on an annual
15 basis—

16 (I) in conjunction with the elec-
17 tion period of the plan or coverage if
18 the plan or coverage has such an elec-
19 tion period; or

20 (II) in the case of a plan or cov-
21 erage that does not have an election
22 period, in conjunction with the begin-
23 ning of the plan or coverage year; and

24 (iii) of information relating to any
25 material reduction to the benefits or infor-

1 mation described in such subsection or
2 subsection (c), in the form of a notice pro-
3 vided not later than 30 days before the
4 date on which the reduction takes effect.

5 (B) PARTICIPANTS, BENEFICIARIES, AND
6 ENROLLEES.—The disclosure required under
7 subparagraph (A) shall be provided—

8 (i) jointly to each participant, bene-
9 ficiary, and enrollee who reside at the same
10 address; or

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

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

1 (b) REQUIRED INFORMATION.—The informational
2 materials to be distributed under this section shall include
3 for each option available under the group health plan or
4 health insurance coverage the following:

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

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

8 (B) specific preventive services covered
9 under the plan or coverage if such services are
10 covered;

11 (C) any specific exclusions or express limi-
12 tations of benefits described in section
13 104(b)(3)(C);

14 (D) any other benefit limitations, including
15 any annual or lifetime benefit limits and any
16 monetary limits or limits on the number of vis-
17 its, days, or services, and any specific coverage
18 exclusions; and

19 (E) any definition of medical necessity
20 used in making coverage determinations by the
21 plan, issuer, or claims administrator.

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

24 (A) any premiums, deductibles, coinsur-
25 ance, copayment amounts, and liability for bal-

1 ance billing, for which the participant, bene-
2 ficiary, or enrollee will be responsible under
3 each option available under the plan;

4 (B) any maximum out-of-pocket expense
5 for which the participant, beneficiary, or en-
6 rollee may be liable;

7 (C) any cost-sharing requirements for out-
8 of-network benefits or services received from
9 nonparticipating providers; and

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

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

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

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

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

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

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

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

5 (9) CLINICAL TRIALS.—A description of the cir-
6 cumstances and conditions under which participation
7 in clinical trials is covered under the terms and con-
8 ditions of the plan or coverage, and the right to ob-
9 tain coverage for approved clinical trials under sec-
10 tion 119 if such section applies.

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

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

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

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

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

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

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

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

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

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

1 paragraphs (1) through (16)) if such sections apply.

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

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

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

22 (1) STATUS OF PROVIDERS.—The State licen-
 23 sure status of the plan or issuer's participating
 24 health care professionals and participating health
 25 care facilities, and, if available, the education, train-

1 ing, specialty qualifications or certifications of such
2 professionals.

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

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

15 (4) UTILIZATION REVIEW ACTIVITIES.—A de-
16 scription of procedures used and requirements (in-
17 cluding circumstances, timeframes, and appeals
18 rights) under any utilization review program under
19 sections 101 and 102, including any drug formulary
20 program under section 118.

21 (5) EXTERNAL APPEALS INFORMATION.—Ag-
22 gregate information on the number and outcomes of
23 external medical reviews, relative to the sample size
24 (such as the number of covered lives) under the plan
25 or under the coverage of the issuer.

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

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

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

14 (2) complying with the provisions of this section
15 by providing information in brochures, through the
16 Internet or other electronic media, or through other
17 similar means, so long as—

18 (A) the disclosure of such information in
19 such form is in accordance with requirements
20 as the appropriate Secretary may impose, and

21 (B) in connection with any such disclosure
22 of information through the Internet or other
23 electronic media—

1 (i) the recipient has affirmatively con-
2 sented to the disclosure of such informa-
3 tion in such form,

4 (ii) the recipient is capable of access-
5 ing the information so disclosed on the re-
6 cipient's individual workstation or at the
7 recipient's home,

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

17 (iv) the plan administrator appro-
18 priately ensures that the intended recipient
19 is receiving the information so disclosed
20 and provides the information in printed
21 form if the information is not received.

1 **Subtitle D—Protecting the Doctor-**
2 **Patient Relationship**

3 **SEC. 131. PROHIBITION OF INTERFERENCE WITH CERTAIN**
4 **MEDICAL COMMUNICATIONS.**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 issuer, in a manner consistent with the provisions of sec-
 2 tion 1842(c)(2) of the Social Security Act (42 U.S.C.
 3 1395u(c)(2)).

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

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

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

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

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

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

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

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

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

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

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

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

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

21 (3) EXCEPTION AND SPECIAL RULE.—

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

1 of confidentiality of communications provided
2 by such law.

3 (B) NOTICE OF INTERNAL PROCEDURES.—

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

13 (C) INTERNAL PROCEDURE EXCEPTION.—

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

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

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

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

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

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

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

19 (6) CONSTRUCTIONS.—

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

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

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

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

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

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

6 **Subtitle E—Definitions**

7 **SEC. 151. DEFINITIONS.**

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

13 (b) SECRETARY.—Except as otherwise provided, the
14 term “Secretary” means the Secretary of Health and
15 Human Services, in consultation with the Secretary of
16 Labor and the term “appropriate Secretary” means the
17 Secretary of Health and Human Services in relation to
18 carrying out this title under sections 2706 and 2751 of
19 the Public Health Service Act and the Secretary of Labor
20 in relation to carrying out this title under section 713 of
21 the Employee Retirement Income Security Act of 1974.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 tially equivalent (within the meaning of subsection
 2 (c)) to a patient protection requirement (as defined
 3 in paragraph (3)) and does not prevent the applica-
 4 tion of other requirements under this Act (except in
 5 the case of other substantially equivalent require-
 6 ments), in applying the requirements of this title
 7 under section 2707 and 2753 (as applicable) of the
 8 Public Health Service Act (as added by title II),
 9 subject to subsection (a)(2)—

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

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

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

22 (3) PATIENT PROTECTION REQUIREMENT DE-
 23 FINED.—For purposes of this section, the term “pa-
 24 tient protection requirement” means a requirement
 25 under this title, and includes (as a single require-

1 ment) a group or related set of requirements under
2 a section or similar unit under this title.

3 (c) DETERMINATIONS OF SUBSTANTIAL EQUIVA-
4 LENCE.—

5 (1) CERTIFICATION BY STATES.—A State may
6 submit to the Secretary a certification that a State
7 law provides for patient protections that are at least
8 substantially equivalent to one or more patient pro-
9 tection requirements. Such certification shall be ac-
10 companied by such information as may be required
11 to permit the Secretary to make the determination
12 described in paragraph (2)(A).

13 (2) REVIEW.—

14 (A) IN GENERAL.—The Secretary shall
15 promptly review a certification submitted under
16 paragraph (1) with respect to a State law to de-
17 termine if the State law provides for at least
18 substantially equivalent and effective patient
19 protections to the patient protection require-
20 ment (or requirements) to which the law re-
21 lates.

22 (B) APPROVAL DEADLINES.—

23 (i) INITIAL REVIEW.—Such a certifi-
24 cation is considered approved unless the
25 Secretary notifies the State in writing,

1 within 90 days after the date of receipt of
2 the certification, that the certification is
3 disapproved (and the reasons for dis-
4 approval) or that specified additional infor-
5 mation is needed to make the determina-
6 tion described in subparagraph (A).

7 (ii) ADDITIONAL INFORMATION.—

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

17 (3) APPROVAL.—

18 (A) IN GENERAL.—The Secretary shall ap-
19 prove a certification under paragraph (1)
20 unless—

21 (i) the State fails to provide sufficient
22 information to enable the Secretary to
23 make a determination under paragraph
24 (2)(A); or

1 (ii) the Secretary determines that the
2 State law involved does not provide for pa-
3 tient protections that are at least substan-
4 tially equivalent to and as effective as the
5 patient protection requirement (or require-
6 ments) to which the law relates.

7 (B) STATE CHALLENGE.—A State that has
8 a certification disapproved by the Secretary
9 under subparagraph (A) may challenge such
10 disapproval in the appropriate United States
11 district court.

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

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

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

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

6 **SEC. 153. EXCLUSIONS.**

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

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

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

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

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

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

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

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

17 **SEC. 154. COVERAGE OF LIMITED SCOPE PLANS.**

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

1 **SEC. 155. REGULATIONS.**

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

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

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

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

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

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

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

13 “Each group health plan shall comply with patient
 14 protection requirements under title I of the Bipartisan Pa-
 15 tient Protection Act, and each health insurance issuer
 16 shall comply with patient protection requirements under
 17 such title with respect to group health insurance coverage
 18 it offers, and such requirements shall be deemed to be in-
 19 corporated into this subsection.”.

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

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

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

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

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

12 **TITLE III—AMENDMENTS TO**
 13 **THE EMPLOYEE RETIREMENT**
 14 **INCOME SECURITY ACT OF**
 15 **1974**

16 **SEC. 301. APPLICATION OF PATIENT PROTECTION STAND-**
 17 **ARDS TO GROUP HEALTH PLANS AND GROUP**
 18 **HEALTH INSURANCE COVERAGE UNDER THE**
 19 **EMPLOYEE RETIREMENT INCOME SECURITY**
 20 **ACT OF 1974.**

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

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

25 “(a) IN GENERAL.—Subject to subsection (b), a
 26 group health plan (and a health insurance issuer offering

1 group health insurance coverage in connection with such
 2 a plan) shall comply with the requirements of title I of
 3 the Bipartisan Patient Protection Act (as in effect as of
 4 the date of the enactment of such Act), and such require-
 5 ments shall be deemed to be incorporated into this sub-
 6 section.

7 “(b) PLAN SATISFACTION OF CERTAIN REQUIRE-
 8 MENTS.—

9 “(1) SATISFACTION OF CERTAIN REQUIRE-
 10 MENTS THROUGH INSURANCE.—For purposes of
 11 subsection (a), insofar as a group health plan pro-
 12 vides benefits in the form of health insurance cov-
 13 erage through a health insurance issuer, the plan
 14 shall be treated as meeting the following require-
 15 ments of title I of the Bipartisan Patient Protection
 16 Act with respect to such benefits and not be consid-
 17 ered as failing to meet such requirements because of
 18 a failure of the issuer to meet such requirements so
 19 long as the plan sponsor or its representatives did
 20 not cause such failure by the issuer:

21 “(A) Section 111 (relating to consumer
 22 choice option).

23 “(B) Section 112 (relating to choice of
 24 health care professional).

1 “(C) Section 113 (relating to access to
2 emergency care).

3 “(D) Section 114 (relating to timely access
4 to specialists).

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

7 “(F) Section 116 (relating to access to pe-
8 diatric care).

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

12 “(H) Section 118 (relating to access to
13 needed prescription drugs).

14 “(I) Section 119 (relating to coverage for
15 individuals participating in approved clinical
16 trials).

17 “(J) Section 120 (relating to required cov-
18 erage for minimum hospital stay for
19 mastectomies and lymph node dissections for
20 the treatment of breast cancer and coverage for
21 secondary consultations).

22 “(K) Section 134 (relating to payment of
23 claims).

24 “(2) INFORMATION.—With respect to informa-
25 tion required to be provided or made available under

1 section 121 of the Bipartisan Patient Protection
2 Act, in the case of a group health plan that provides
3 benefits in the form of health insurance coverage
4 through a health insurance issuer, the Secretary
5 shall determine the circumstances under which the
6 plan is not required to provide or make available the
7 information (and is not liable for the issuer's failure
8 to provide or make available the information), if the
9 issuer is obligated to provide and make available (or
10 provides and makes available) such information.

11 “(3) INTERNAL APPEALS.—With respect to the
12 internal appeals process required to be established
13 under section 103 of such Act, in the case of a
14 group health plan that provides benefits in the form
15 of health insurance coverage through a health insur-
16 ance issuer, the Secretary shall determine the cir-
17 cumstances under which the plan is not required to
18 provide for such process and system (and is not lia-
19 ble for the issuer's failure to provide for such proc-
20 ess and system), if the issuer is obligated to provide
21 for (and provides for) such process and system.

22 “(4) EXTERNAL APPEALS.—Pursuant to rules
23 of the Secretary, insofar as a group health plan en-
24 ters into a contract with a qualified external appeal
25 entity for the conduct of external appeal activities in

1 accordance with section 104 of such Act, the plan
2 shall be treated as meeting the requirement of such
3 section and is not liable for the entity's failure to
4 meet any requirements under such section.

5 “(5) APPLICATION TO PROHIBITIONS.—Pursu-
6 ant to rules of the Secretary, if a health insurance
7 issuer offers health insurance coverage in connection
8 with a group health plan and takes an action in vio-
9 lation of any of the following sections of the Bipar-
10 tisan Patient Protection Act, the group health plan
11 shall not be liable for such violation unless the plan
12 caused such violation:

13 “(A) Section 131 (relating to prohibition of
14 interference with certain medical communica-
15 tions).

16 “(B) Section 132 (relating to prohibition
17 of discrimination against providers based on li-
18 censure).

19 “(C) Section 133 (relating to prohibition
20 against improper incentive arrangements).

21 “(D) Section 135 (relating to protection
22 for patient advocacy).

23 “(6) CONSTRUCTION.—Nothing in this sub-
24 section shall be construed to affect or modify the re-

sponsibilities of the fiduciaries of a group health plan under part 4 of subtitle B.

“(7) TREATMENT OF SUBSTANTIALLY EQUIVALENT STATE LAWS.—For purposes of applying this subsection, any reference in this subsection to a requirement in a section or other provision in the Bipartisan Patient Protection Act with respect to a health insurance issuer is deemed to include a reference to a requirement under a State law that is substantially equivalent (as determined under section 152(c) of such Act) to the requirement in such section or other provisions.

“(8) APPLICATION TO CERTAIN PROHIBITIONS AGAINST RETALIATION.—With respect to compliance with the requirements of section 135(b)(1) of the Bipartisan Patient Protection Act, for purposes of this subtitle the term ‘group health plan’ is deemed to include a reference to an institutional health care provider.

“(c) ENFORCEMENT OF CERTAIN REQUIREMENTS.—

“(1) COMPLAINTS.—Any protected health care professional who believes that the professional has been retaliated or discriminated against in violation of section 135(b)(1) of the Bipartisan Patient Protection Act may file with the Secretary a complaint

1 within 180 days of the date of the alleged retaliation
2 or discrimination.

3 “(2) INVESTIGATION.—The Secretary shall in-
4 vestigate such complaints and shall determine if a
5 violation of such section has occurred and, if so,
6 shall issue an order to ensure that the protected
7 health care professional does not suffer any loss of
8 position, pay, or benefits in relation to the plan,
9 issuer, or provider involved, as a result of the viola-
10 tion found by the Secretary.

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

1 (b) SATISFACTION OF ERISA CLAIMS PROCEDURE

2 REQUIREMENT.—Section 503 of such Act (29 U.S.C.

3 1133) is amended by inserting “(a)” after “SEC. 503.”

4 and by adding at the end the following new subsection:

5 “(b) In the case of a group health plan (as defined

6 in section 733) compliance with the requirements of sub-

7 title A of title I of the Bipartisan Patient Protection Act,

8 and compliance with regulations promulgated by the Sec-

9 retary, in the case of a claims denial shall be deemed com-

10 pliance with subsection (a) with respect to such claims de-

11 nial.”.

12 (c) CONFORMING AMENDMENTS.—(1) Section 732(a)

13 of such Act (29 U.S.C. 1185(a)) is amended by striking

14 “section 711” and inserting “sections 711 and 714”.

15 (2) The table of contents in section 1 of such Act

16 is amended by inserting after the item relating to section

17 713 the following new item:

“Sec. 714. Patient protection standards.”.

18 (3) Section 502(b)(3) of such Act (29 U.S.C.

19 1132(b)(3)) is amended by inserting “(other than section

20 135(b))” after “part 7”.

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

22 (a) AVAILABILITY OF FEDERAL CIVIL REMEDIES IN

23 CASES NOT INVOLVING MEDICALLY REVIEWABLE DECI-

24 SIONS.—

1 (1) IN GENERAL.—Section 502 of the Employee
2 Retirement Income Security Act of 1974 (29 U.S.C.
3 1132) is amended by adding at the end the following
4 new subsection:

5 “(n) CAUSE OF ACTION RELATING TO PROVISION OF
6 HEALTH BENEFITS.—

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

8 “(A) a person who is a fiduciary of a
9 group health plan, a health insurance issuer of-
10 fering health insurance coverage in connection
11 with the plan, or an agent of the plan, issuer,
12 or plan sponsor—

13 “(i) upon consideration of a claim for
14 benefits of a participant or beneficiary
15 under section 102 of the Bipartisan Pa-
16 tient Protection Act of 2001 (relating to
17 procedures for initial claims for benefits
18 and prior authorization determinations) or
19 upon review of a denial of such a claim
20 under section 103 of such Act (relating to
21 internal appeal of a denial of a claim for
22 benefits), fails to exercise ordinary care in
23 making a decision—

24 “(I) regarding whether an item
25 or service is covered under the terms

1 and conditions of the plan or cov-
2 erage,

3 “(II) regarding whether an indi-
4 vidual is a participant or beneficiary
5 who is enrolled under the terms and
6 conditions of the plan or coverage (in-
7 cluding the applicability of any wait-
8 ing period under the plan or cov-
9 erage), or

10 “(III) as to the application of
11 cost-sharing requirements or the ap-
12 plication of a specific exclusion or ex-
13 press limitation on the amount, dura-
14 tion, or scope of coverage of items or
15 services under the terms and condi-
16 tions of the plan or coverage, or

17 “(ii) otherwise fails to exercise ordi-
18 nary care in the performance of a duty
19 under the terms and conditions of the plan
20 with respect to a participant or beneficiary,
21 and

22 “(B) such failure is a proximate cause of
23 personal injury to, or the death of, the partici-
24 pant or beneficiary,

1 such person shall be liable to the participant or ben-
 2 eficiary (or the estate of such participant or bene-
 3 ficiary) for economic and noneconomic damages (but
 4 not exemplary or punitive damages) in connection
 5 with such personal injury or death.

6 “(2) CAUSE OF ACTION MUST NOT INVOLVE
 7 MEDICALLY REVIEWABLE DECISION.—

8 “(A) IN GENERAL.—A cause of action is
 9 established under paragraph (1)(A) only if the
 10 decision referred to in clause (i) or the failure
 11 described in clause (ii) does not include a medi-
 12 cally reviewable decision.

13 “(B) MEDICALLY REVIEWABLE DECI-
 14 SION.—For purposes of this subsection, 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 “(3) LIMITATION REGARDING CERTAIN TYPES
 21 OF ACTIONS SAVED FROM PREEMPTION OF STATE
 22 LAW.—A cause of action is not established under
 23 paragraph (1)(A) in connection with a failure de-
 24 scribed in paragraph (1)(A) to the extent that a
 25 cause of action under State law (as defined in sec-

tion 514(c)) for such failure would not be preempted under section 514.

“(4) DEFINITIONS.—For purposes of this subsection.—

“(A) ORDINARY CARE.—The term ‘ordinary care’ means—

“(i) with respect to a determination on a claim for benefits, that degree of care, skill, and diligence that a reasonable and prudent individual would exercise in making a fair determination on a claim for benefits of like kind to the claim involved; and

“(ii) with respect to the performance of a duty, that degree of care, skill, and diligence that a reasonable and prudent individual would exercise in performing the duty or a duty of like character.

“(B) PERSONAL INJURY.—The term ‘personal injury’ means a physical injury and includes an injury arising out of the treatment (or failure to treat) a mental illness or disease.

“(C) CLAIM FOR BENEFITS; DENIAL.—The terms ‘claim for benefits’ and ‘denial of a claim for benefits’ have the meanings provided such

1 terms in section 102(e) of the Bipartisan Pa-
2 tient Protection Act of 2001.

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

9 “(E) GROUP HEALTH PLAN AND OTHER
10 RELATED TERMS.—The provisions of sections
11 732(d) and 733 apply for purposes of this sub-
12 section in the same manner as they apply for
13 purposes of part 7, except that the term ‘group
14 health plan’ includes a group health plan (as
15 defined in section 607(1)).

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

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

1 “(B) CERTAIN CAUSES OF ACTION PER-
2 MITTED.—Notwithstanding subparagraph (A),
3 a cause of action may arise against an employer
4 or other plan sponsor (or against an employee
5 of such an employer or sponsor acting within
6 the scope of employment)—

7 “(i) under clause (i) of paragraph
8 (1)(A), to the extent there was direct par-
9 ticipation by the employer or other plan
10 sponsor (or employee) in the decision of
11 the plan under section 102 of the Bipar-
12 tisan Patient Protection Act of 2001 upon
13 consideration of a claim for benefits or
14 under section 103 of such Act upon review
15 of a denial of a claim for benefits, or

16 “(ii) under clause (ii) of paragraph
17 (1)(A), to the extent there was direct par-
18 ticipation by the employer or other plan
19 sponsor (or employee) in the failure de-
20 scribed in such clause.

21 “(C) DIRECT PARTICIPATION.—

22 “(i) DIRECT PARTICIPATION IN DECI-
23 SIONS.—For purposes of subparagraph
24 (B), the term ‘direct participation’ means,
25 in connection with a decision described in

1 clause (i) of paragraph (1)(A) or a failure
2 described in clause (ii) of such paragraph,
3 the actual making of such decision or the
4 actual exercise of control in making such
5 decision or in the conduct constituting the
6 failure.

7 “(ii) RULES OF CONSTRUCTION.—For
8 purposes of clause (i), the employer or plan
9 sponsor (or employee) shall not be con-
10 strued to be engaged in direct participation
11 because of any form of decisionmaking or
12 other conduct that is merely collateral or
13 precedent to the decision described in
14 clause (i) of paragraph (1)(A) on a par-
15 ticular claim for benefits of a participant
16 or beneficiary or that is merely collateral
17 or precedent to the conduct constituting a
18 failure described in clause (ii) of paragraph
19 (1)(A) with respect to a particular partici-
20 pant or beneficiary, including (but not lim-
21 ited 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 “(6) EXCLUSION OF PHYSICIANS AND OTHER
25 HEALTH CARE PROFESSIONALS.—

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

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

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

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

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

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

17 “(9) REQUIREMENT OF EXHAUSTION.—

18 “(A) IN GENERAL.—Except as provided in
19 this paragraph, a cause of action may not be
20 brought under paragraph (1) in connection with
21 any denial of a claim for benefits of any indi-
22 vidual until all administrative processes under
23 sections 102 and 103 of the Bipartisan Patient
24 Protection Act of 2001 (if applicable) have been
25 exhausted.

1 “(B) LATE MANIFESTATION OF INJURY.—

2 The requirements under subparagraph (A) for a
3 cause of action in connection with any denial of
4 a claim for benefits shall be deemed satisfied,
5 notwithstanding any failure to timely commence
6 review under section 103 with respect to the de-
7 nial, if the personal injury is first known (or
8 first reasonably should have been known) to the
9 individual (or the death occurs) after the latest
10 date by which the applicable requirements of
11 subparagraph (A) can be met in connection
12 with such denial.

13 “(C) OCCURRENCE OF IMMEDIATE AND IR-

14 REPARABLE HARM OR DEATH PRIOR TO COM-
15 PLETION OF PROCESS.—

16 “(i) IN GENERAL.—The requirements
17 of subparagraph (A) shall not apply in any
18 case of immediate and irreparable harm or
19 death occurring, as a result of the denial
20 of a claim for benefits, prior to the comple-
21 tion of the administrative processes re-
22 ferred to in subparagraph (A) with respect
23 to such denial.

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

1 “(I) continuation of such proc-
2 esses to their conclusion if so moved
3 by any party, and

4 “(II) consideration in such action
5 of the final decisions issued in such
6 processes.

7 “(iii) DEFINITION.—In clause (i), the
8 term ‘irreparable harm’, with respect to an
9 individual, means an injury or condition
10 that, regardless of whether the individual
11 receives the treatment that is the subject
12 of the denial, cannot be repaired in a man-
13 ner that would restore the individual to the
14 individual’s pre-injured condition.

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

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

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

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

9 “(10) STATUTORY DAMAGES.—

10 “(A) IN GENERAL.—The remedies set
11 forth in this subsection (n) shall be the exclu-
12 sive remedies for causes of action brought
13 under this subsection.

14 “(B) ASSESSMENT OF CIVIL PENALTIES.—

15 In addition to the remedies provided for in
16 paragraph (1) (relating to the failure to provide
17 contract benefits in accordance with the plan),
18 a civil assessment, in an amount not to exceed
19 \$5,000,000, payable to the claimant may be
20 awarded in any action under such paragraph if
21 the claimant establishes by clear and convincing
22 evidence that the alleged conduct carried out by
23 the defendant demonstrated bad faith and fla-
24 grant disregard for the rights of the participant
25 or beneficiary under the plan and was a proxi-

1 mate cause of the personal injury or death that
2 is the subject of the claim.

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

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

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

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

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

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

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

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

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

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

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

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

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

16 (2) CONFORMING AMENDMENT.—Section
17 502(a)(1) of such Act (29 U.S.C. 1132(a)(1)) is
18 amended—

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

21 (B) in subparagraph (B), by striking
22 “plan;” and inserting “plan, or”; and

23 (C) by adding at the end the following new
24 subparagraph:

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

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

6 (1) by redesignating subsection (d) as sub-
7 section (f); and

8 (2) by inserting after subsection (c) the fol-
9 lowing new subsections:

10 “(d) PREEMPTION NOT TO APPLY TO CAUSES OF
11 ACTION UNDER STATE LAW INVOLVING MEDICALLY RE-
12 VIEWABLE DECISION.—

13 “(1) NON-PREEMPTION OF CERTAIN CAUSES OF
14 ACTION.—

15 “(A) IN GENERAL.—Except as provided in
16 this subsection, nothing in this title (including
17 section 502) shall be construed to supersede or
18 otherwise alter, amend, modify, invalidate, or
19 impair any cause of action under State law of
20 a participant or beneficiary under a group
21 health plan (or the estate of such a participant
22 or beneficiary) to recover damages resulting
23 from personal injury or for wrongful death
24 against any person if such cause of action

1 arises by reason of a medically reviewable deci-
2 sion.

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

10 “(C) LIMITATION ON PUNITIVE DAM-
11 AGES.—

12 “(i) IN GENERAL.—Except as pro-
13 vided in clauses (ii) and (iii), with respect
14 to a cause of action described in subpara-
15 graph (A) brought with respect to a partic-
16 ipant or beneficiary, State law is super-
17 seded insofar as it provides any punitive,
18 exemplary, or similar damages if, as of the
19 time of the personal injury or death, all
20 the requirements of the following sections
21 of the Bipartisan Patient Protection Act of
22 2001 were satisfied with respect to the
23 participant or beneficiary:

24 “(I) Section 102 (relating to pro-
25 cedures for initial claims for benefits

1 and prior authorization determina-
2 tions).

3 “(II) Section 103 of such Act
4 (relating to internal appeals of claims
5 denials).

6 “(III) Section 104 of such Act
7 (relating to independent external ap-
8 peals procedures).

9 “(ii) EXCEPTION FOR CERTAIN AC-
10 TIONS FOR WRONGFUL DEATH.—Clause (i)
11 shall not apply with respect to an action
12 for wrongful death if the applicable State
13 law provides (or has been construed to pro-
14 vide) for damages in such an action which
15 are only punitive or exemplary in nature.

16 “(iii) EXCEPTION FOR WILLFUL OR
17 WANTON DISREGARD FOR THE RIGHTS OR
18 SAFETY OF OTHERS.—Clause (i) shall not
19 apply with respect to any cause of action
20 described in subparagraph (A) if, in such
21 action, the plaintiff establishes by clear
22 and convincing evidence that conduct car-
23 ried out by the defendant with willful or
24 wanton disregard for the rights or safety
25 of others was a proximate cause of the per-

1 sonal injury or wrongful death that is the
2 subject of the action.

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

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

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

16 “(C) CLAIM FOR BENEFIT; DENIAL.—The
17 terms ‘claim for benefits’ and ‘denial of a claim
18 for benefits’ shall have the meaning provided
19 such terms under section 102(e) of the Bipar-
20 tisan Patient Protection Act of 2001.

21 “(3) EXCLUSION OF EMPLOYERS AND OTHER
22 PLAN SPONSORS.—

23 “(A) CAUSES OF ACTION AGAINST EM-
24 PLOYERS AND PLAN SPONSORS PRECLUDED.—

1 Subject to subparagraph (B), paragraph (1)
2 does not apply with respect to—

3 “(i) any cause of action against an
4 employer or other plan sponsor maintain-
5 ing the plan (or against an employee of
6 such an employer or sponsor acting within
7 the scope of employment), or

8 “(ii) a right of recovery, indemnity, or
9 contribution by a person against an em-
10 ployer or other plan sponsor (or such an
11 employee) for damages assessed against
12 the person pursuant to a cause of action to
13 which paragraph (1) applies.

14 “(B) CERTAIN CAUSES OF ACTION PER-
15 MITTED.—Notwithstanding subparagraph (A),
16 paragraph (1) applies with respect to any cause
17 of action described in paragraph (1) maintained
18 by a participant or beneficiary against an em-
19 ployer or other plan sponsor (or against an em-
20 ployee of such an employer or sponsor acting
21 within the scope of employment)—

22 “(i) in the case of any cause of action
23 based on a decision of the plan under sec-
24 tion 102 of the Bipartisan Patient Protec-
25 tion Act of 2001 upon consideration of a

1 claim for benefits or under section 103 of
 2 such Act upon review of a denial of a claim
 3 for benefits, to the extent there was direct
 4 participation by the employer or other plan
 5 sponsor (or employee) in the decision, or

6 “(ii) in the case of any cause of action
 7 based on a failure to otherwise perform a
 8 duty under the terms and conditions of the
 9 plan with respect to a claim for benefits of
 10 a participant or beneficiary, to the extent
 11 there was direct participation by the em-
 12 ployer or other plan sponsor (or employee)
 13 in the failure.

14 “(C) DIRECT PARTICIPATION.—

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

24 “(ii) RULES OF CONSTRUCTION.—For
 25 purposes of clause (i), the employer or plan

1 sponsor (or employee) shall not be con-
2 strued to be engaged in direct participation
3 because of any form of decisionmaking or
4 other conduct that is merely collateral or
5 precedent to the decision described in sub-
6 paragraph (B)(i) on a particular claim for
7 benefits of a particular participant or bene-
8 ficiary or that is merely collateral or prece-
9 dent to the conduct constituting a failure
10 described in subparagraph (B)(ii) with re-
11 spect to a particular participant or bene-
12 ficiary, including (but not limited to)—

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

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

1 “(III) any participation by the
2 employer or other plan sponsor (or
3 employee) in the process of creating,
4 continuing, modifying, or terminating
5 the plan or any benefit under the
6 plan, if such process was not substan-
7 tially focused solely on the particular
8 situation of the participant or bene-
9 ficiary referred to in paragraph
10 (1)(A); and

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

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

1 “(I) any efforts that may have
2 been made by the employer or plan
3 sponsor to advocate for authorization
4 of coverage for that or any other par-
5 ticipant or beneficiary (or any group
6 of participants or beneficiaries), or

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

15 “(4) REQUIREMENT OF EXHAUSTION.—

16 “(A) IN GENERAL.—Except as provided in
17 this paragraph, paragraph (1) shall not apply
18 with respect to a cause of action described in
19 such paragraph in connection with any denial of
20 a claim for benefits of any individual until all
21 administrative processes under sections 102,
22 103, and 104 of the Bipartisan Patient Protec-
23 tion Act of 2001 (if applicable) have been ex-
24 hausted.

1 “(B) LATE MANIFESTATION OF INJURY.—

2 The requirements under subparagraph (A) for a
3 cause of action in connection with any denial of
4 a claim for benefits shall be deemed satisfied,
5 notwithstanding any failure to timely commence
6 review under section 103 or 104 with respect to
7 the denial, if the personal injury is first known
8 (or first should have been known) to the indi-
9 vidual (or the death occurs) after the latest
10 date by which the applicable requirements of
11 subparagraph (A) can be met in connection
12 with such denial.

13 “(C) OCCURRENCE OF IMMEDIATE AN IR-
14 REPARABLE HARM OR DEATH PRIOR TO COM-
15 PLETION OF PROCESS.—

16 “(i) IN GENERAL.—The requirements
17 of subparagraph (A) shall not apply in any
18 case of immediate and irreparable harm or
19 death occurring, as a result of the denial
20 of a claim for benefits, prior to the comple-
21 tion of the administrative processes re-
22 ferred to in subparagraph (A) with respect
23 to such denial.

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

1 “(I) continuation of such proc-
2 esses to their conclusion if so moved
3 by any party, and

4 “(II) consideration in such action
5 of the final decisions issued in such
6 processes.

7 “(iii) DEFINITION.—In clause (i), the
8 term ‘irreparable harm’, with respect to an
9 individual, means an injury or condition
10 that, regardless of whether the individual
11 receives the treatment that is the subject
12 of the denial, cannot be repaired in a man-
13 ner that would restore the individual to the
14 individual’s pre-injured condition.

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

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

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

4 “(5) TOLLING PROVISION.—The statute of limi-
5 tations for any cause of action arising under section
6 502(n) relating to a denial of a claim for benefits
7 that is the subject of an action brought in State
8 court shall be tolled until such time as the State
9 court makes a final disposition, including all ap-
10 peals, of whether such claim should properly be
11 within the jurisdiction of the State court. The tolling
12 period shall be determined by the applicable Federal
13 or State law, whichever period is greater.

14 “(6) EXCLUSION OF DIRECTED RECORD-
15 KEEPERS.—

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

20 “(B) DIRECTED RECORDKEEPER.—For
21 purposes of this paragraph, the term ‘directed
22 recordkeeper’ means, in connection with a
23 group health plan, a person engaged in directed
24 recordkeeping activities pursuant to the specific
25 instructions of the plan or the employer or

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

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

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

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

20 “(i) the application or interpretation
21 of the exclusion involves a determination
22 described in section 104(d)(2) of the Bi-
23 partisan Patient Protection Act of 2001,
24 or

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

5 “(B) preempting a State law which re-
6 quires an affidavit or certificate of merit in a
7 civil action;

8 “(C) affecting a cause of action or remedy
9 under State law in connection with the provi-
10 sion or arrangement of excepted benefits (as de-
11 fined in section 733(c)), other than those de-
12 scribed in section 733(c)(2)(A); or

13 “(D) affecting a cause of action under
14 State law other than a cause of action described
15 in paragraph (1)(A).

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

22 “(e) RULES OF CONSTRUCTION RELATING TO
23 HEALTH CARE.—Nothing in this title shall be construed
24 as—

1 “(1) affecting any State law relating to the
 2 practice of medicine or the provision of, or the fail-
 3 ure to provide, medical care, or affecting any action
 4 (whether the liability is direct or vicarious) based
 5 upon such a State law,

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

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

11 (c) EFFECTIVE DATE.—The amendments made by
 12 this section shall apply to acts and omissions (from which
 13 a cause of action arises) occurring on or after October 1,
 14 2002.

15 **SEC. 303. LIMITATIONS ON ACTIONS.**

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

20 “(o) LIMITATIONS ON ACTIONS RELATING TO GROUP
 21 HEALTH PLANS.—

22 “(1) IN GENERAL.—Except as provided in para-
 23 graph (2), no action may be brought under sub-
 24 section (a)(1)(B), (a)(2), or (a)(3) by a participant
 25 or beneficiary seeking relief based on the application

1 of any provision in section 101, subtitle B, or sub-
2 title D of title I of the Bipartisan Patient Protection
3 Act (as incorporated under section 714).

4 “(2) CERTAIN ACTIONS ALLOWABLE.—An ac-
5 tion may be brought under subsection (a)(1)(B),
6 (a)(2), or (a)(3) by a participant or beneficiary seek-
7 ing relief based on the application of section 101,
8 113, 114, 115, 116, 117, 118(a)(3), 119, or 120 of
9 the Bipartisan Patient Protection Act (as incor-
10 porated under section 714) to the individual cir-
11 cumstances of that participant or beneficiary, except
12 that—

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

15 “(B) in such an action, relief may only
16 provide for the provision of (or payment of)
17 benefits, items, or services denied to the indi-
18 vidual participant or beneficiary involved (and
19 for attorney’s fees and the costs of the action,
20 at the discretion of the court) and shall not pro-
21 vide for any other relief to the participant or
22 beneficiary or for any relief to any other person.

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

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

5 **TITLE IV—EFFECTIVE DATES;**
 6 **COORDINATION IN IMPLE-**
 7 **MENTATION**

8 **SEC. 401. EFFECTIVE DATES.**

9 (a) GROUP HEALTH COVERAGE.—

10 (1) IN GENERAL.—Subject to paragraph (2)
 11 and subsection (d), the amendments made by sec-
 12 tions 201(a), 301, and 303 (and title I insofar as it
 13 relates to such sections) shall apply with respect to
 14 group health plans, and health insurance coverage
 15 offered in connection with group health plans, for
 16 plan years beginning on or after October 1, 2002 (in
 17 this section referred to as the “general effective
 18 date”).

19 (2) TREATMENT OF COLLECTIVE BARGAINING
 20 AGREEMENTS.—In the case of a group health plan
 21 maintained pursuant to one or more collective bar-
 22 gaining agreements between employee representa-
 23 tives and one or more employers ratified before the
 24 date of the enactment of this Act, the amendments
 25 made by sections 201(a), 301, and 303 (and title I

1 insofar as it relates to such sections) shall not apply
 2 to plan years beginning before the later of—

3 (A) the date on which the last collective
 4 bargaining agreements relating to the plan ter-
 5 minates (determined without regard to any ex-
 6 tension thereof agreed to after the date of the
 7 enactment of this Act); or

8 (B) the general effective date.

9 For purposes of subparagraph (A), any plan amend-
 10 ment made pursuant to a collective bargaining
 11 agreement relating to the plan which amends the
 12 plan solely to conform to any requirement added by
 13 this Act shall not be treated as a termination of
 14 such collective bargaining agreement.

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

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

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

1 (A) restrict or limit the right of group
2 health plans, and of health insurance issuers of-
3 fering health insurance coverage, to include as
4 providers religious nonmedical providers;

5 (B) require such plans or issuers to—

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

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

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

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

21 (C) require such plans or issuers to ex-
22 clude religious nonmedical providers because
23 they do not provide medical or other required
24 data, if such data is inconsistent with the reli-

1 religious nonmedical treatment or nursing care
2 provided by the provider.

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

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

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

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

23 **SEC. 402. COORDINATION IN IMPLEMENTATION.**

24 The Secretary of Labor and the Secretary of Health
25 and Human Services shall ensure, through the execution

1 of an interagency memorandum of understanding among
2 such Secretaries, that—

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

9 (2) coordination of policies relating to enforcing
10 the same requirements through such Secretaries in
11 order to have a coordinated enforcement strategy
12 that avoids duplication of enforcement efforts and
13 assigns priorities in enforcement.

14 **SEC. 403. SEVERABILITY.**

15 If any provision of this Act, an amendment made by
16 this Act, or the application of such provision or amend-
17 ment to any person or circumstance is held to be unconsti-
18 tutional, the remainder of this Act, the amendments made
19 by this Act, and the application of the provisions of such
20 to any person or circumstance shall not be affected there-
21 by.

1 **TITLE V—MISCELLANEOUS**
2 **PROVISIONS**

3 **SEC. 501. NO IMPACT ON SOCIAL SECURITY TRUST FUND.**

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

8 (b) TRANSFERS.—

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

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

1 **SEC. 502. CUSTOMS USER FEES.**

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

7 **SEC. 503. FISCAL YEAR 2002 MEDICARE PAYMENTS.**

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

Calendar No. 75

107TH CONGRESS
1ST SESSION

S. 1052

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.

JUNE 18, 2001

Read the second time and placed on the calendar