

108TH CONGRESS  
1ST SESSION

# H. R. 597

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

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## IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 5, 2003

Mr. NORWOOD introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Education and the Workforce, and Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## A BILL

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

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

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

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

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

Sec. 1. Short title; table of contents.

TITLE I—IMPROVING MANAGED CARE

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

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

Subtitle B—Access to Care

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

Subtitle C—Access to Information

- Sec. 121. Patient access to information.

Subtitle D—Protecting the Doctor-Patient Relationship

- Sec. 131. Prohibition of interference with certain medical communications.
- Sec. 132. Prohibition of discrimination against providers based on licensure.
- Sec. 133. Prohibition against improper incentive arrangements.
- Sec. 134. Payment of claims.
- Sec. 135. Protection for patient advocacy.

Subtitle E—Definitions

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

Sec. 157. Preservation of protections.

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

Sec. 201. Application to group health plans and group health insurance coverage.

Sec. 202. Application to individual health insurance coverage.

Sec. 203. Cooperation between Federal and State authorities.

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

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

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

Sec. 401. Application of patient protection standards to group health plans and group health insurance coverage under the Employee Retirement Income Security Act of 1974.

Sec. 402. Cooperation between Federal and State authorities.

Sec. 403. Sense of the Congress concerning the importance of certain unpaid services.

TITLE V—AMENDMENTS TO THE INTERNAL REVENUE CODE OF  
1986

Sec. 501. Application of requirements to group health plans under the Internal Revenue Code of 1986.

Sec. 502. Conforming enforcement for women's health and cancer rights.

TITLE VI—EFFECTIVE DATES; COORDINATION IN  
IMPLEMENTATION

Sec. 601. Effective dates.

Sec. 602. Coordination in implementation.

Sec. 603. Severability.

TITLE VII—MISCELLANEOUS PROVISIONS

Sec. 701. No impact on Social Security Trust Fund.

Sec. 702. Sense of Congress with respect to participation in clinical trials and access to specialty care.

Sec. 703. Sense of the Congress regarding fair review process.

Sec. 704. Annual review.

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

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

7 (a) COMPLIANCE WITH REQUIREMENTS.—

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

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

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

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

7 (b) WRITTEN POLICIES AND CRITERIA.—

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

12 (2) USE OF WRITTEN CRITERIA.—

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

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

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

16          (c) CONDUCT OF PROGRAM ACTIVITIES.—

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

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

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

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

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

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

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

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

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

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

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

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

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

12 (2) ACCESS TO INFORMATION.—

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

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

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

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

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

6 (b) TIMELINE FOR MAKING DETERMINATIONS.—

7 (1) PRIOR AUTHORIZATION DETERMINATION.—

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

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

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

18                   (C) ONGOING CARE.—

19                           (i) CONCURRENT REVIEW.—

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

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

12 (II) CONTENTS OF NOTICE.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

16 (a) RIGHT TO INTERNAL APPEAL.—

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

21           (2) TIME FOR APPEAL.—

22           (A) IN GENERAL.—A group health plan,  
23 and a health insurance issuer offering health in-  
24 surance coverage, shall ensure that a partici-  
25 pant, beneficiary, or enrollee (or authorized rep-

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

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

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

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

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

4 (b) TIMELINES FOR MAKING DETERMINATIONS.—

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

22 (2) ACCESS TO INFORMATION.—

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

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

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

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

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

17          (B)   EXPEDITED DETERMINATION.—Not-  
18          withstanding subparagraph (A), a group health  
19          plan, and a health insurance issuer offering  
20          health insurance coverage, shall expedite a prior  
21          authorization determination on an appeal of a  
22          denial of a claim for benefits described in sub-  
23          paragraph (A), when a request for such an ex-  
24          pedited determination is made by a participant,  
25          beneficiary, or enrollee (or authorized represent-

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

15                   (C) ONGOING CARE DETERMINATIONS.—

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

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

7           (ii) RULE OF CONSTRUCTION.—Clause

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

12          (4) RETROSPECTIVE DETERMINATION.—A

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

22          (c) CONDUCT OF REVIEW.—

23          (1) IN GENERAL.—A review of a denial of a

24          claim for benefits under this section shall be con-

1 ducted by an individual with appropriate expertise  
2 who was not involved in the initial determination.

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

9 (A) shall be made by a physician  
10 (allopathic or osteopathic); or

11 (B) in a claim for benefits provided by a  
12 non-physician health professional, shall be made  
13 by a review panel including at least one prac-  
14 ticing non-physician health professional of the  
15 same or similar specialty;

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

21 (d) NOTICE OF DETERMINATION.—

22 (1) IN GENERAL.—Written notice of a deter-  
23 mination made under an internal appeal of a denial  
24 of a claim for benefits shall be issued to the partici-  
25 pant, beneficiary, or enrollee (or authorized rep-

1       representative) and the treating health care professional  
2       in accordance with the medical exigencies of the case  
3       and as soon as possible, but in no case later than  
4       2 days after the date of completion of the review (or,  
5       in the case described in subparagraph (B) or (C) of  
6       subsection (b)(3), within the 72-hour or applicable  
7       period referred to in such subparagraph).

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

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

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

5 (B) the procedures for obtaining additional  
6 information concerning the determination; and

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

10 **SEC. 104. INDEPENDENT EXTERNAL APPEALS PROCE-**  
11 **DURES.**

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

18 (b) **INITIATION OF THE INDEPENDENT EXTERNAL**  
19 **REVIEW PROCESS.**—

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

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

9 (2) FILING OF REQUEST.—

10 (A) IN GENERAL.—Subject to the suc-  
11 ceeding provisions of this subsection, a group  
12 health plan, or health insurance issuer offering  
13 health insurance coverage, may—

14 (i) except as provided in subparagraph

15 (B)(i), require that a request for review be  
16 in writing;

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

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

1 under the internal review procedure under  
2 section 103;

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

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

16 (B) REQUIREMENTS AND EXCEPTION RE-  
17 LATING TO GENERAL RULE.—

18 (i) ORAL REQUESTS PERMITTED IN  
19 EXPEDITED OR CONCURRENT CASES.—In  
20 the case of an expedited or concurrent ex-  
21 ternal review as provided for under sub-  
22 section (e), the request for such review  
23 may be made orally. A group health plan,  
24 or health insurance issuer offering health  
25 insurance coverage, may require that the

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

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

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

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

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

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

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

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

1 plan or issuer's initial decision (including the infor-  
2 mation described in section 103(d)(3)(A)), to a  
3 qualified external review entity selected in accord-  
4 ance with this section.

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

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

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

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

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

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

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

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

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

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

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

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

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

24           (i) NOTICE IN CASE OF DENIAL OF  
25           REFERRAL.—If the entity under this para-

1 graph does not make a referral to an inde-  
2 pendent medical review panel, the entity  
3 shall provide notice to the plan or issuer,  
4 the participant, beneficiary, or enrollee (or  
5 authorized representative) filing the re-  
6 quest, and the treating health care profes-  
7 sional (if any) that the denial is not sub-  
8 ject to independent medical review. Such  
9 notice—

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

14 (II) shall include the reasons for  
15 the determination;

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

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

22 (ii) GENERAL TIMELINE FOR DETER-  
23 MINATIONS.—Upon receipt of information  
24 under paragraph (2), the qualified external  
25 review entity, and if required the inde-

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

13          (d) INDEPENDENT MEDICAL REVIEW.—

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

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

1 plan or coverage but for one (or more) of the fol-  
2 lowing determinations:

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

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

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

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

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

7           (B) STANDARD FOR DETERMINATION.—  
8           The independent medical review panel’s deter-  
9           mination relating to the medical necessity and  
10          appropriateness, or the experimental or inves-  
11          tigational nature, or the evaluation of the med-  
12          ical facts, of the item, service, or condition in-  
13          volved shall be based on the medical condition  
14          of the participant, beneficiary, or enrollee (in-  
15          cluding the medical records of the participant,  
16          beneficiary, or enrollee) and valid, relevant sci-  
17          entific evidence and clinical evidence, including  
18          peer-reviewed medical literature or findings and  
19          including 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 review  
23          panel 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)). Notwithstanding any other pro-  
6 vision of this Act, any exclusion of an exact  
7 medical procedure, any exact time limit on the  
8 duration or frequency of coverage, and any  
9 exact dollar limit on the amount of coverage  
10 that is specifically enumerated and defined (in  
11 the plain language of the plan or coverage docu-  
12 ments) under the plan or coverage offered by a  
13 group health plan or health insurance issuer of-  
14 fering health insurance coverage and that is  
15 disclosed under section 121(b)(1) shall be con-  
16 sidered to govern the scope of the benefits that  
17 may be required: *Provided*, That the terms and  
18 conditions of the plan or coverage relating to  
19 such an exclusion or limit are in compliance  
20 with the requirements of law.

21 (D) EVIDENCE AND INFORMATION TO BE  
22 USED IN MEDICAL REVIEWS.—In making a de-  
23 termination under this subsection, the inde-  
24 pendent medical review panel shall also consider

1 appropriate and available evidence and informa-  
2 tion, including the following:

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

8 (ii) The recommendation of the treat-  
9 ing health care professional and the evi-  
10 dence, guidelines, and rationale used by  
11 the treating health care professional in  
12 reaching such recommendation.

13 (iii) Additional relevant evidence or  
14 information obtained by the review panel  
15 or submitted by the plan, issuer, partici-  
16 pant, beneficiary, or enrollee (or an au-  
17 thorized representative), or treating health  
18 care professional.

19 (iv) The plan or coverage document.

20 (E) INDEPENDENT DETERMINATION.—In  
21 making determinations under this section, a  
22 qualified external review entity and an inde-  
23 pendent medical review panel shall—

24 (i) consider the claim under review  
25 without deference to the determinations

1 made by the plan or issuer or the rec-  
2 ommendation of the treating health care  
3 professional (if any); and

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

13 (F) DETERMINATION OF INDEPENDENT  
14 MEDICAL REVIEW PANEL.—An independent  
15 medical review panel shall, in accordance with  
16 the deadlines described in subsection (e), pre-  
17 pare a written determination to uphold or re-  
18 verse the denial under review. Such written de-  
19 termination shall include—

20 (i) the determination of the review  
21 panel;

22 (ii) the specific reasons of the review  
23 panel for such determination, including a  
24 summary of the clinical or scientific evi-

1                   dence used in making the determination;  
2                   and

3                   (iii) with respect to a determination to  
4                   reverse the denial under review, a time-  
5                   frame within which the plan or issuer must  
6                   comply with such determination.

7                   (G) NONBINDING NATURE OF ADDITIONAL  
8                   RECOMMENDATIONS.—In addition to the deter-  
9                   mination under subparagraph (F), the review  
10                  panel may provide the plan or issuer and the  
11                  treating health care professional with additional  
12                  recommendations in connection with such a de-  
13                  termination, but any such recommendations  
14                  shall not affect (or be treated as part of) the  
15                  determination and shall not be binding on the  
16                  plan or issuer.

17                  (e) TIMELINES AND NOTIFICATIONS.—

18                  (1) TIMELINES FOR INDEPENDENT MEDICAL  
19                  REVIEW.—

20                  (A) PRIOR AUTHORIZATION DETERMINA-  
21                  TION.—

22                  (i) IN GENERAL.—The independent  
23                  medical review panel shall make a deter-  
24                  mination on a denial of a claim for benefits  
25                  that is referred to the review panel under

1 subsection (c)(3) in accordance with the  
2 medical exigencies of the case and as soon  
3 as possible, but in no case later than 14  
4 days after the date of receipt of informa-  
5 tion under subsection (c)(2) if the review  
6 involves a prior authorization of items or  
7 services and in no case later than 21 days  
8 after the date the request for external re-  
9 view is received.

10 (ii) EXPEDITED DETERMINATION.—  
11 Notwithstanding clause (i) and subject to  
12 clause (iii), the independent medical review  
13 panel shall make an expedited determina-  
14 tion on a denial of a claim for benefits de-  
15 scribed in clause (i), when a request for  
16 such an expedited determination is made  
17 by a participant, beneficiary, or enrollee  
18 (or authorized representative) at any time  
19 during the process for making a deter-  
20 mination, and a health care professional  
21 certifies, with the request, that a deter-  
22 mination under the timeline described in  
23 clause (i) would seriously jeopardize the  
24 life or health of the participant, bene-  
25 ficiary, or enrollee or the ability of the par-

1            participant, beneficiary, or enrollee to main-  
2            tain or regain maximum function. Such de-  
3            termination shall be made in accordance  
4            with the medical exigencies of the case and  
5            as soon as possible, but in no case later  
6            than 72 hours after the time the request  
7            for external review is received by the quali-  
8            fied external review entity.

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

19           (B) RETROSPECTIVE DETERMINATION.—  
20           The independent medical review panel shall  
21           complete a review in the case of a retrospective  
22           determination on an appeal of a denial of a  
23           claim for benefits that is referred to the review  
24           panel under subsection (c)(3) in no case later  
25           than 30 days after the date of receipt of infor-

1           mation under subsection (c)(2) and in no case  
2           later than 60 days after the date the request  
3           for external review is received by the qualified  
4           external review entity.

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

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

18          (f) COMPLIANCE.—

19                  (1) APPLICATION OF DETERMINATIONS.—

20                          (A) EXTERNAL REVIEW DETERMINATIONS  
21                          BINDING ON PLAN.—The determinations of an  
22                          external review entity and an independent med-  
23                          ical review panel under this section shall be  
24                          binding upon the plan or issuer involved.

1 (B) COMPLIANCE WITH DETERMINA-  
2 TION.—If the determination of an independent  
3 medical review panel is to reverse the denial,  
4 the plan or issuer, upon the receipt of such de-  
5 termination, shall authorize coverage to comply  
6 with the medical reviewer’s determination in ac-  
7 cordance with the timeframe established by the  
8 medical review panel.

9 (2) FAILURE TO COMPLY.—

10 (A) IN GENERAL.—If a plan or issuer fails  
11 to comply with the timeframe established under  
12 paragraph (1)(B) with respect to a participant,  
13 beneficiary, or enrollee, where such failure to  
14 comply is caused by the plan or issuer, the par-  
15 ticipant, beneficiary, or enrollee may obtain the  
16 items or services involved (in a manner con-  
17 sistent with the determination of the inde-  
18 pendent external review panel) from any pro-  
19 vider regardless of whether such provider is a  
20 participating provider under the plan or cov-  
21 erage.

22 (B) REIMBURSEMENT.—

23 (i) IN GENERAL.—Where a partici-  
24 pant, beneficiary, or enrollee obtains items  
25 or services in accordance with subpara-

1 graph (A), the plan or issuer involved shall  
2 provide for reimbursement of the costs of  
3 such items or services. Such reimburse-  
4 ment shall be made to the treating health  
5 care professional or to the participant, ben-  
6 eficiary, or enrollee (in the case of a partic-  
7 ipant, beneficiary, or enrollee who pays for  
8 the costs of such items or services).

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

19 (C) FAILURE TO REIMBURSE.—Where a  
20 plan or issuer fails to provide reimbursement to  
21 a professional, participant, beneficiary, or en-  
22 rollee in accordance with this paragraph, the  
23 professional, participant, beneficiary, or enrollee  
24 may commence a civil action (or utilize other  
25 remedies available under law) to recover only

1 the amount of any such reimbursement that is  
2 owed by the plan or issuer and any necessary  
3 legal costs or expenses (including attorney's  
4 fees) incurred in recovering such reimburse-  
5 ment.

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

9 (3) PENALTIES AGAINST AUTHORIZED OFFI-  
10 CIALS FOR REFUSING TO AUTHORIZE THE DETER-  
11 MINATION OF AN EXTERNAL REVIEW ENTITY.—

12 (A) MONETARY PENALTIES.—

13 (i) IN GENERAL.—In any case in  
14 which the determination of an external re-  
15 view entity is not followed by a group  
16 health plan, or by a health insurance issuer  
17 offering health insurance coverage, any  
18 person who, acting in the capacity of au-  
19 thORIZING the benefit, causes such refusal  
20 may, in the discretion of a court of com-  
21 petent jurisdiction, be liable to an ag-  
22 grieved participant, beneficiary, or enrollee  
23 for a civil penalty in an amount of up to  
24 \$1,000 a day from the date on which the  
25 determination was transmitted to the plan

1 or issuer by the external review entity until  
2 the date the refusal to provide the benefit  
3 is corrected.

4 (ii) ADDITIONAL PENALTY FOR FAIL-  
5 ING TO FOLLOW TIMELINE.—In any case  
6 in which treatment was not commenced by  
7 the plan in accordance with the determina-  
8 tion of an independent external review  
9 panel, the Secretary shall assess a civil  
10 penalty of \$10,000 against the plan and  
11 the plan shall pay such penalty to the par-  
12 ticipant, beneficiary, or enrollee involved.

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

1 under the plan or coverage for authorizing a  
2 benefit, the court shall cause to be served on  
3 the defendant an order requiring the defend-  
4 ant—

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

7 (ii) to pay to the plaintiff a reasonable  
8 attorney's fee and other reasonable costs  
9 relating to the prosecution of the action on  
10 the charges on which the plaintiff prevails.

11 (C) ADDITIONAL CIVIL PENALTIES.—

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

21 (I) any pattern or practice of re-  
22 peated refusal to authorize a benefit  
23 determined by an external appeal enti-  
24 ty to be covered; or

1 (II) any pattern or practice of re-  
2 peated violations of the requirements  
3 of this section with respect to such  
4 plan or coverage.

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

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

17 (II) \$500,000.

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

1           such a plan or coverage, and may be precluded  
2           from returning to any such position or involve-  
3           ment for a period determined by the court.

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

12          (g) QUALIFICATIONS OF INDEPENDENT MEDICAL  
13 REVIEWERS.—

14           (1) IN GENERAL.—In referring a denial to an  
15          independent medical review panel to conduct inde-  
16          pendent medical review under subsection (c), the  
17          qualified external review entity shall ensure that—

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

21                   (B) with respect to each review, the review  
22                   panel meets the requirements of paragraph (4)  
23                   and at least 1 reviewer on the panel meets the  
24                   requirements described in paragraph (5); and

1 (C) compensation provided by the entity to  
2 each reviewer is consistent with paragraph (6).

3 (2) LICENSURE AND EXPERTISE.—Each inde-  
4 pendent medical reviewer shall be a physician  
5 (allopathic or osteopathic) or health care profes-  
6 sional who—

7 (A) is appropriately credentialed or li-  
8 censed in 1 or more States to deliver health  
9 care services; and

10 (B) typically treats the condition, makes  
11 the diagnosis, or provides the type of treatment  
12 under review.

13 (3) INDEPENDENCE.—

14 (A) IN GENERAL.—Subject to subpara-  
15 graph (B), each independent medical reviewer  
16 in a case shall—

17 (i) not be a related party (as defined  
18 in paragraph (7));

19 (ii) not have a material familial, fi-  
20 nancial, or professional relationship with  
21 such a party; and

22 (iii) not otherwise have a conflict of  
23 interest with such a party (as determined  
24 under regulations).

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

3 (i) prohibit an individual, solely on the  
4 basis of affiliation with the plan or issuer,  
5 from serving as an independent medical re-  
6 viewer if—

7 (I) a non-affiliated individual is  
8 not reasonably available;

9 (II) the affiliated individual is  
10 not involved in the provision of items  
11 or services in the case under review;

12 (III) the fact of such an affili-  
13 ation is disclosed to the plan or issuer  
14 and the participant, beneficiary, or  
15 enrollee (or authorized representative)  
16 and neither party objects; and

17 (IV) the affiliated individual is  
18 not an employee of the plan or issuer  
19 and does not provide services exclu-  
20 sively or primarily to or on behalf of  
21 the plan or issuer;

22 (ii) prohibit an individual who has  
23 staff privileges at the institution where the  
24 treatment involved takes place from serv-  
25 ing as an independent medical reviewer

1 merely on the basis of such affiliation if  
2 the affiliation is disclosed to the plan or  
3 issuer and the participant, beneficiary, or  
4 enrollee (or authorized representative), and  
5 neither party objects; or

6 (iii) prohibit receipt of compensation  
7 by an independent medical reviewer from  
8 an entity if the compensation is provided  
9 consistent with paragraph (6).

10 (4) PRACTICING HEALTH CARE PROFESSIONAL  
11 IN SAME FIELD.—

12 (A) IN GENERAL.—In a case involving  
13 treatment, or the provision of items or serv-  
14 ices—

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

24 (ii) by a non-physician health care  
25 professional, the independent medical re-

1 view panel shall include at least one prac-  
2 ticing non-physician health care profes-  
3 sional of the same or similar specialty as  
4 the non-physician health care professional  
5 who, acting within the appropriate scope of  
6 practice within the State in which the serv-  
7 ice is provided or rendered, typically treats  
8 the condition, makes the diagnosis, or pro-  
9 vides the type of treatment under review.

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

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

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

24 (A) not exceed a reasonable level; and

1 (B) not be contingent on the decision ren-  
2 dered by the reviewer.

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

8 (A) The plan, plan sponsor, or issuer in-  
9 volved, or any fiduciary, officer, director, or em-  
10 ployee of such plan, plan sponsor, or issuer.

11 (B) The participant, beneficiary, or en-  
12 rollee (or authorized representative).

13 (C) The health care professional that pro-  
14 vides the items or services involved in the de-  
15 nial.

16 (D) The institution at which the items or  
17 services (or treatment) involved in the denial  
18 are provided.

19 (E) The manufacturer of any drug or  
20 other item that is included in the items or serv-  
21 ices involved in the denial.

22 (F) Any other party determined under any  
23 regulations to have a substantial interest in the  
24 denial involved.

25 (h) QUALIFIED EXTERNAL REVIEW ENTITIES.—

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

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

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

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

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

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

1 a qualified external appeal entity that is des-  
2 igned by the State or that is selected by the  
3 State in a manner determined by the State to  
4 assure an unbiased determination.

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

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

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

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

22 Subparagraph (B) shall not be construed as apply-  
23 ing to the imposition of a filing fee under subsection  
24 (b)(2)(A)(iv) or costs incurred by the participant,  
25 beneficiary, or enrollee (or authorized representative)

1 or treating health care professional (if any) in sup-  
2 port of the review, including the provision of addi-  
3 tional evidence or information.

4 (4) QUALIFICATIONS.—

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

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

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

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

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

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

16           (B) INDEPENDENCE REQUIREMENTS.—

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

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

23                   (II) does not have a material fa-  
24                   miliar, financial, or professional rela-  
25                   tionship with such a party; and

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

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

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

17 (I) not exceed a reasonable level;

18 and

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

22 (C) CERTIFICATION AND RECERTIFICATION  
23 PROCESS.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

14                   (II) Adherence to applicable  
15                   deadlines (both by the entity and by  
16                   independent medical review panels it  
17                   refers cases to).

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

22                   (IV) Compliance with applicable  
23                   independence requirements.

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

1 medically reviewable decisions shall be  
2 the subject of independent medical re-  
3 view and with the requirement of sub-  
4 section (d)(3) that independent med-  
5 ical review panels may not require  
6 coverage for specifically excluded ben-  
7 efits.

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

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

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

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

16 (D) PROVISION OF INFORMATION.—

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

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

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

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

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

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

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

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

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

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

1 certification or recertification of an  
2 entity.

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

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

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

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

8                   (B) the number of denials that have been  
9 upheld by independent medical review panels  
10 and the number of denials that have been re-  
11 versed by such panels; and

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

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

17           (a) GRANTS.—

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

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

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

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

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

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

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

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

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

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

20 (3) AMOUNT OF GRANT.—

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

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

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

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

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

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

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

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

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

20 (b) USE OF FUNDS.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

9               (4) DESIGNATION OF RESPONSIBILITIES.—

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

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

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

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

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

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

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

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

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

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

## 8 **Subtitle B—Access to Care**

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

10 (a) IN GENERAL.—If—

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

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

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

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

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

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

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

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

12 (b) SPECIALISTS.—

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

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

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

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

5           (a) COVERAGE OF EMERGENCY SERVICES.—

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

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

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

17                   (C) in a manner so that, if such services  
18                   are provided to a participant, beneficiary, or en-  
19                   rollee—

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

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

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

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

15 (2) DEFINITIONS.—In this section:

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

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

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

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

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

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

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

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

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

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

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

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

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

12 (a) **TIMELY ACCESS.**—

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

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

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

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

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

8 (3) ACCESS TO CERTAIN PROVIDERS.—

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

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

25 (b) REFERRALS.—

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

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

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

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

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

1           tion, subject to the terms of a treatment plan  
2           (if any) referred to in subsection (c) with re-  
3           spect to the condition.

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

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

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

12       (c) TREATMENT PLANS.—

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

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

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

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

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

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

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

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

19 (a) GENERAL RIGHTS.—

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

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

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

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

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

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

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

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

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

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

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

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

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

2 (a) **TERMINATION OF PROVIDER.—**

3 (1) **IN GENERAL.—If—**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 (b) TRANSITIONAL PERIODS.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

5 (e) DEFINITIONS.—In this section:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3 (a) **COVERAGE.**—

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

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

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

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

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

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

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

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

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

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

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

22 (2) Either—

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

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

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

10 (c) PAYMENT.—

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

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

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

23 (B) a nonparticipating provider, the pay-  
24 ment rate shall be at the rate the plan or issuer

1           would normally pay for comparable services  
2           under subparagraph (A).

3           (d) APPROVED CLINICAL TRIAL DEFINED.—

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

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

10                   (i) the National Institutes of Health;

11                   (ii) a cooperative group or center of  
12                   the National Institutes of Health, includ-  
13                   ing a qualified nongovernmental research  
14                   entity to which the National Cancer Insti-  
15                   tute has awarded a center support grant;

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

19                           (I) the Department of Veterans  
20                           Affairs;

21                           (II) the Department of Defense;

22                           or

23                   (B) approved by the Food and Drug Ad-  
24                   ministration.

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

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

10           (B) assures unbiased review of the highest  
11 ethical standards by qualified individuals who  
12 have no interest in the outcome of the review.

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

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

21       (a) INPATIENT CARE.—

22           (1) IN GENERAL.—A group health plan, and a  
23 health insurance issuer providing health insurance  
24 coverage, that provides medical and surgical benefits  
25 shall ensure that inpatient coverage with respect to

1 the treatment of breast cancer is provided for a pe-  
2 riod of time as is determined by the attending physi-  
3 cian, in consultation with the patient, to be medi-  
4 cally necessary and appropriate following—

5 (A) a mastectomy;

6 (B) a lumpectomy; or

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

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

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

21 (c) SECONDARY CONSULTATIONS.—

22 (1) IN GENERAL.—A group health plan, and a  
23 health insurance issuer providing health insurance  
24 coverage, that provides coverage with respect to  
25 medical and surgical services provided in relation to

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

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

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

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

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

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

## 22 **Subtitle C—Access to Information**

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

24 (a) REQUIREMENT.—

25 (1) DISCLOSURE.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

20 (12) EMERGENCY SERVICES.—A summary of  
21 the rules and procedures for accessing emergency  
22 services, including the right of a participant, bene-  
23 ficiary, or enrollee to obtain emergency services  
24 under the prudent layperson standard under section  
25 113, if such section applies, and any educational in-

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

10 (b) CONSTRUCTION.—Subsection (a) shall not be con-  
11 strued—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

21 (3) EXCEPTION AND SPECIAL RULE.—

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

1 of confidentiality of communications provided  
2 by such law.

3 (B) NOTICE OF INTERNAL PROCEDURES.—

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

13 (C) INTERNAL PROCEDURE EXCEPTION.—

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

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

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

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

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

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

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

19          (6) CONSTRUCTIONS.—

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

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

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

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

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

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

## 6 **Subtitle E—Definitions**

### 7 **SEC. 151. DEFINITIONS.**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 (3) DEFINITIONS.—In this section:

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

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

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

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

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

21 (2) REVIEW.—

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

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

3 (B) APPROVAL DEADLINES.—

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

13 (ii) ADDITIONAL INFORMATION.—

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

23 (3) APPROVAL.—

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

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

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

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

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

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

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

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

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

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

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

19 (5) PETITIONS.—

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

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

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

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

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

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

1 **SEC. 153. EXCLUSIONS.**

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

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

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

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

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

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

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

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

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

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

12 (a) IN GENERAL.—The requirements of this title  
13 shall not apply to excepted benefits (as defined in section  
14 733(c) of such Act), other than benefits described in sec-  
15 tion 733(c)(2)(A) of such Act, in the same manner as the  
16 provisions of part 7 of subtitle B of title I of such Act  
17 do not apply to such benefits under subsections (b) and  
18 (c) of section 732 of such Act.

19 (b) COVERAGE OF CERTAIN LIMITED SCOPE  
20 PLANS.—Only for purposes of applying the requirements  
21 of this title under sections 2707 and 2753 of the Public  
22 Health Service Act, section 714 of the Employee Retire-  
23 ment Income Security Act of 1974, and section 9813 of  
24 the Internal Revenue Code of 1986, the following sections  
25 shall be deemed not to apply:

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

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

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

7   **SEC. 155. REGULATIONS.**

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

16   **SEC. 156. INCORPORATION INTO PLAN OR COVERAGE DOC-**  
17                                   **UMENTS.**

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

1 **SEC. 157. PRESERVATION OF PROTECTIONS.**

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

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

16 **TITLE II—APPLICATION OF**  
17 **QUALITY CARE STANDARDS**  
18 **TO GROUP HEALTH PLANS**  
19 **AND HEALTH INSURANCE**  
20 **COVERAGE UNDER THE PUB-**  
21 **LIC HEALTH SERVICE ACT**

22 **SEC. 201. APPLICATION TO GROUP HEALTH PLANS AND**  
23 **GROUP HEALTH INSURANCE COVERAGE.**

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

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

2 “Each group health plan shall comply with patient  
3 protection requirements under title I of the Patient Pro-  
4 tection Act, and each health insurance issuer shall comply  
5 with patient protection requirements under such title with  
6 respect to group health insurance coverage it offers, and  
7 such requirements shall be deemed to be incorporated into  
8 this subsection.”.

9 (b) CONFORMING AMENDMENT.—Section  
10 2721(b)(2)(A) of such Act (42 U.S.C. 300gg–21(b)(2)(A))  
11 is amended by inserting “(other than section 2707)” after  
12 “requirements of such subparts”.

13 **SEC. 202. APPLICATION TO INDIVIDUAL HEALTH INSUR-**  
14 **ANCE COVERAGE.**

15 Part B of title XXVII of the Public Health Service  
16 Act is amended by inserting after section 2752 the fol-  
17 lowing new section:

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

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

1 **SEC. 203. COOPERATION BETWEEN FEDERAL AND STATE**  
2 **AUTHORITIES.**

3 Part C of title XXVII of the Public Health Service  
4 Act (42 U.S.C. 300gg–91 et seq.) is amended by adding  
5 at the end the following:

6 **“SEC. 2793. COOPERATION BETWEEN FEDERAL AND STATE**  
7 **AUTHORITIES.**

8 “(a) AGREEMENT WITH STATES.—A State may enter  
9 into an agreement with the Secretary for the delegation  
10 to the State of some or all of the Secretary’s authority  
11 under this title to enforce the requirements applicable  
12 under title I of the Patient Protection Act with respect  
13 to health insurance coverage offered by a health insurance  
14 issuer and with respect to a group health plan that is a  
15 non-Federal governmental plan.

16 “(b) DELEGATIONS.—Any department, agency, or in-  
17 strumentality of a State to which authority is delegated  
18 pursuant to an agreement entered into under this section  
19 may, if authorized under State law and to the extent con-  
20 sistent with such agreement, exercise the powers of the  
21 Secretary under this title which relate to such authority.”.

1 **TITLE III—APPLICATION OF PA-**  
2 **TIENT PROTECTION STAND-**  
3 **ARDS TO FEDERAL HEALTH**  
4 **INSURANCE PROGRAMS**

5 **SEC. 301. APPLICATION OF PATIENT PROTECTION STAND-**  
6 **ARDS TO FEDERAL HEALTH INSURANCE PRO-**  
7 **GRAMS.**

8 (a) SENSE OF CONGRESS.—It is the sense of Con-  
9 gress that enrollees in Federal health insurance programs  
10 should have the same rights and privileges as those af-  
11 forded under title I and under the amendments made by  
12 title IV to participants and beneficiaries under group  
13 health plans.

14 (b) CONFORMING FEDERAL HEALTH INSURANCE  
15 PROGRAMS.—It is the sense of Congress that the Presi-  
16 dent should require, by executive order, the Federal offi-  
17 cial with authority over each Federal health insurance pro-  
18 gram, to the extent feasible, to take such steps as are nec-  
19 essary to implement the rights and privileges described in  
20 subsection (a) with respect to such program.

21 (c) GAO REPORT ON ADDITIONAL STEPS RE-  
22 QUIRED.—Not later than 1 year after the date of the en-  
23 actment of this Act, the Comptroller General of the United  
24 States shall submit to Congress a report on statutory  
25 changes that are required to implement such rights and

1 privileges in a manner that is consistent with the missions  
2 of the Federal health insurance programs and that avoids  
3 unnecessary duplication or disruption of such programs.

4 (d) FEDERAL HEALTH INSURANCE PROGRAM.—In  
5 this section, the term “Federal health insurance program”  
6 means a Federal program that provides creditable cov-  
7 erage (as defined in section 2701(c)(1) of the Public  
8 Health Service Act) and includes a health program of the  
9 Department of Veterans Affairs.

10 **TITLE IV—AMENDMENTS TO THE**  
11 **EMPLOYEE RETIREMENT IN-**  
12 **COME SECURITY ACT OF 1974**

13 **SEC. 401. APPLICATION OF PATIENT PROTECTION STAND-**  
14 **ARDS TO GROUP HEALTH PLANS AND GROUP**  
15 **HEALTH INSURANCE COVERAGE UNDER THE**  
16 **EMPLOYEE RETIREMENT INCOME SECURITY**  
17 **ACT OF 1974.**

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

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

22 “(a) IN GENERAL.—Subject to subsection (b), a  
23 group health plan (and a health insurance issuer offering  
24 group health insurance coverage in connection with such  
25 a plan) shall comply with the requirements of title I of

1 the Patient Protection Act (as in effect as of the date of  
2 the enactment of such Act), and such requirements shall  
3 be deemed to be incorporated into this subsection.

4 “(b) PLAN SATISFACTION OF CERTAIN REQUIRE-  
5 MENTS.—

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

18 “(A) Section 111 (relating to consumer  
19 choice option).

20 “(B) Section 112 (relating to choice of  
21 health care professional).

22 “(C) Section 113 (relating to access to  
23 emergency care).

24 “(D) Section 114 (relating to timely access  
25 to specialists).

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

3           “(F) Section 116 (relating to access to pe-  
4           diatric care).

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

8           “(H) Section 118 (relating to access to  
9           needed prescription drugs).

10          “(I) Section 119 (relating to coverage for  
11          individuals participating in approved clinical  
12          trials).

13          “(J) Section 120 (relating to required cov-  
14          erage for minimum hospital stay for  
15          mastectomies and lymph node dissections for  
16          the treatment of breast cancer and coverage for  
17          secondary consultations).

18          “(K) Section 134 (relating to payment of  
19          claims).

20          “(2) INFORMATION.—With respect to informa-  
21          tion required to be provided or made available under  
22          section 121 of the Patient Protection Act, in the  
23          case of a group health plan that provides benefits in  
24          the form of health insurance coverage through a  
25          health insurance issuer, the Secretary shall deter-

1 mine the circumstances under which the plan is not  
2 required to provide or make available the informa-  
3 tion (and is not liable for the issuer’s failure to pro-  
4 vide or make available the information), if the issuer  
5 is obligated to provide and make available (or pro-  
6 vides and makes available) such information.

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

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

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

9                   “(A) Section 131 (relating to prohibition of  
10                  interference with certain medical communica-  
11                  tions).

12                  “(B) Section 132 (relating to prohibition  
13                  of discrimination against providers based on li-  
14                  censure).

15                  “(C) Section 133 (relating to prohibition  
16                  against improper incentive arrangements).

17                  “(D) Section 135 (relating to protection  
18                  for patient advocacy).

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

23           “(7) TREATMENT OF SUBSTANTIALLY COMPLI-  
24           ANT STATE LAWS.—For purposes of applying this  
25           subsection in connection with health insurance cov-

1 erage, any reference in this subsection to a require-  
2 ment in a section or other provision in the Patient  
3 Protection Act with respect to a health insurance  
4 issuer is deemed to include a reference to a require-  
5 ment under a State law that substantially complies  
6 (as determined under section 152(c) of such Act)  
7 with the requirement in such section or other provi-  
8 sions.

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

15 “(c) ENFORCEMENT OF CERTAIN REQUIREMENTS.—

16 “(1) COMPLAINTS.—Any protected health care  
17 professional who believes that the professional has  
18 been retaliated or discriminated against in violation  
19 of section 135(b)(1) of the Patient Protection Act  
20 may file with the Secretary a complaint within 180  
21 days of the date of the alleged retaliation or dis-  
22 crimination.

23 “(2) INVESTIGATION.—The Secretary shall in-  
24 vestigate such complaints and shall determine if a  
25 violation of such section has occurred and, if so,

1 shall issue an order to ensure that the protected  
2 health care professional does not suffer any loss of  
3 position, pay, or benefits in relation to the plan,  
4 issuer, or provider involved, as a result of the viola-  
5 tion found by the Secretary.

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

19 (b) SATISFACTION OF ERISA CLAIMS PROCEDURE  
20 REQUIREMENT.—Section 503 of such Act (29 U.S.C.  
21 1133) is amended by inserting “(a)” after “SEC. 503.”  
22 and by adding at the end the following new subsection:

23 “(b) In the case of a group health plan (as defined  
24 in section 733), compliance with the requirements of sub-  
25 title A of title I of the Patient Protection Act, and compli-

1 ance with regulations promulgated by the Secretary, in the  
2 case of a claims denial, shall be deemed compliance with  
3 subsection (a) with respect to such claims denial.”.

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

7 (2) The table of contents in section 1 of such Act  
8 is amended by inserting after the item relating to section  
9 713 the following new item:

“Sec. 714. Patient protection standards.”.

10 (3) Section 502(b)(3) of such Act (29 U.S.C.  
11 1132(b)(3)) is amended by inserting “(other than section  
12 135(b))” after “part 7”.

13 **SEC. 402. COOPERATION BETWEEN FEDERAL AND STATE**  
14 **AUTHORITIES.**

15 Subpart C of part 7 of subtitle B of title I of the  
16 Employee Retirement Income Security Act of 1974 (29  
17 U.S.C. 1191 et seq.) is amended by adding at the end  
18 the following new section:

19 **“SEC. 735. COOPERATION BETWEEN FEDERAL AND STATE**  
20 **AUTHORITIES.**

21 “(a) AGREEMENT WITH STATES.—A State may enter  
22 into an agreement with the Secretary for the delegation  
23 to the State of some or all of the Secretary’s authority  
24 under this title to enforce the requirements applicable  
25 under title I of the Patient Protection Act with respect

1 to health insurance coverage offered by a health insurance  
2 issuer.

3 “(b) DELEGATIONS.—Any department, agency, or in-  
4 strumentality of a State to which authority is delegated  
5 pursuant to an agreement entered into under this section  
6 may, if authorized under State law and to the extent con-  
7 sistent with such agreement, exercise the powers of the  
8 Secretary under this title which relate to such authority.”.

9 **SEC. 403. SENSE OF THE CONGRESS CONCERNING THE IM-  
10 PORTANCE OF CERTAIN UNPAID SERVICES.**

11 It is the sense of the Congress that the court should  
12 consider the loss of a nonwage earning spouse or parent  
13 as an economic loss for the purposes of this section. Fur-  
14 thermore, the court should define the compensation for the  
15 loss not as minimum services, but, rather, in terms that  
16 fully compensate for the true and whole replacement cost  
17 to the family.

18 **TITLE V—AMENDMENTS TO THE  
19 INTERNAL REVENUE CODE  
20 OF 1986**

21 **SEC. 501. APPLICATION TO GROUP HEALTH PLANS UNDER  
22 THE INTERNAL REVENUE CODE OF 1986.**

23 Subchapter B of chapter 100 of the Internal Revenue  
24 Code of 1986 is amended—

1 (1) in the table of sections, by inserting after  
 2 the item relating to section 9812 the following new  
 3 item:

“Sec. 9813. Standard relating to patients’ bill of rights.”;

4 and

5 (2) by inserting after section 9812 the fol-  
 6 lowing:

7 **“SEC. 9813. STANDARD RELATING TO PATIENTS’ BILL OF**  
 8 **RIGHTS.**

9 “A group health plan shall comply with the require-  
 10 ments of title I of the Patient Protection Act (as in effect  
 11 as of the date of the enactment of such Act), and such  
 12 requirements shall be deemed to be incorporated into this  
 13 section.”.

14 **SEC. 502. CONFORMING ENFORCEMENT FOR WOMEN’S**  
 15 **HEALTH AND CANCER RIGHTS.**

16 Subchapter B of chapter 100 of the Internal Revenue  
 17 Code of 1986, as amended by section 501, is further  
 18 amended—

19 (1) in the table of sections, by inserting after  
 20 the item relating to section 9813 the following new  
 21 item:

“Sec. 9814. Standard relating to women’s health and cancer  
 rights.”;

22 and

1           (2) by inserting after section 9813 the fol-  
2           lowing:

3   **“SEC. 9814. STANDARD RELATING TO WOMEN’S HEALTH**  
4                                   **AND CANCER RIGHTS.**

5           “The provisions of section 713 of the Employee Re-  
6   tirement Income Security Act of 1974 (as in effect as of  
7   the date of the enactment of this section) shall apply to  
8   group health plans as if included in this subchapter.”.

9   **TITLE VI—EFFECTIVE DATES;**  
10           **COORDINATION IN IMPLE-**  
11           **MENTATION**

12   **SEC. 601. EFFECTIVE DATES.**

13           (a) GROUP HEALTH COVERAGE.—

14           (1) IN GENERAL.—Subject to paragraph (2)  
15           and subsection (d), the amendments made by sec-  
16           tions 201(a), 401, 501, and 502 (and title I insofar  
17           as it relates to such sections) shall apply with re-  
18           spect to group health plans, and health insurance  
19           coverage offered in connection with group health  
20           plans, for plan years beginning on or after October  
21           1, 2003 (in this section referred to as the “general  
22           effective date”).

23           (2) TREATMENT OF COLLECTIVE BARGAINING  
24           AGREEMENTS.—In the case of a group health plan  
25           maintained pursuant to one or more collective bar-

1       gaining agreements between employee representa-  
2       tives and one or more employers ratified before the  
3       date of the enactment of this Act, the amendments  
4       made by sections 201(a), 401, 501, and 502 (and  
5       title I insofar as it relates to such sections) shall not  
6       apply to plan years beginning before the later of—

7               (A) the date on which the last collective  
8               bargaining agreements relating to the plan ter-  
9               minates (excluding any extension thereof agreed  
10              to after the date of the enactment of this Act);

11             or

12             (B) the general effective date;

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

20       (b) INDIVIDUAL HEALTH INSURANCE COVERAGE.—

21       Subject to subsection (d), the amendments made by sec-  
22       tion 202 shall apply with respect to individual health in-  
23       surance coverage offered, sold, issued, renewed, in effect,  
24       or operated in the individual market on or after the gen-  
25       eral effective date.

1 (c) TREATMENT OF RELIGIOUS NONMEDICAL PRO-  
2 VIDERS.—

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

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

9 (B) require such plans or issuers to—

10 (i) utilize medically based eligibility  
11 standards or criteria in deciding provider  
12 status of religious nonmedical providers;

13 (ii) use medical professionals or cri-  
14 teria to decide patient access to religious  
15 nonmedical providers;

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

20 (iv) compel a participant or bene-  
21 ficiary to undergo a medical examination  
22 or test as a condition of receiving health  
23 insurance coverage for treatment by a reli-  
24 gious nonmedical provider; or

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

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

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

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

22               (2) subsection (b) with respect to an individual  
23               health insurance coverage that is in effect as of the  
24               general effective date, not later than 30 days before

1 the first date as of which title I applies to the cov-  
2 erage under such subsection.

3 **SEC. 602. COORDINATION IN IMPLEMENTATION.**

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

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

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

19 **SEC. 603. SEVERABILITY.**

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

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

## 3 **TITLE VII—MISCELLANEOUS** 4 **PROVISIONS**

### 5 **SEC. 701. NO IMPACT ON SOCIAL SECURITY TRUST FUND.**

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

10 (b) TRANSFERS.—

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

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

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

3 **SEC. 702. SENSE OF CONGRESS WITH RESPECT TO PARTICI-**  
4 **PATION IN CLINICAL TRIALS AND ACCESS TO**  
5 **SPECIALTY CARE.**

6 (a) FINDINGS.—The Congress finds the following:

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

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

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

15 (4) Breast cancer is the second leading cause of  
16 cancer death among all women and the leading  
17 cause of cancer death among women between ages  
18 40 and 55.

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

21 (6) 1,500 children are expected to die from can-  
22 cer this year.

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

1           (8) Parkinson’s disease is a progressive disorder  
2 of the central nervous system affecting 1,000,000 in  
3 the United States.

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

6           (10) 31,500 men will die from prostate cancer  
7 this year. It is the second leading cause of cancer in  
8 men.

9           (11) While information obtained from clinical  
10 trials is essential to finding cures for diseases, it is  
11 still research which carries the risk of fatal results.  
12 Future efforts should be taken to protect the health  
13 and safety of adults and children who enroll in clin-  
14 ical trials.

15           (12) While employers and health plans should  
16 be responsible for covering the routine costs associ-  
17 ated with federally approved or funded clinical trials,  
18 such employers and health plans should not be held  
19 legally responsible for the design, implementation, or  
20 outcome of such clinical trials, consistent with any  
21 applicable State or Federal liability statutes.

22           (b) SENSE OF THE CONGRESS.—It is the sense of  
23 the Congress that—

24           (1) men and women battling life-threatening,  
25 deadly diseases, including advanced breast or ovar-

1       ian cancer, should have the opportunity to partici-  
2       pate in a federally approved or funded clinical trial  
3       recommended by their physician;

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

7               (A) that individual—

8                       (i) has a life-threatening or serious ill-  
9                       ness for which no standard treatment is ef-  
10                      fective;

11                     (ii) is eligible to participate in a feder-  
12                     ally approved or funded clinical trial ac-  
13                     cording to the trial protocol with respect to  
14                     treatment of the illness;

15               (B) that individual's participation in the  
16       trial offers meaningful potential for significant  
17       clinical benefit for the individual; and

18               (C) either—

19                     (i) the referring physician is a partici-  
20                     pating health care professional and has  
21                     concluded that the individual's participa-  
22                     tion in the trial would be appropriate,  
23                     based upon the individual meeting the con-  
24                     ditions described in subparagraph (A); or

1 (ii) the participant, beneficiary, or en-  
2 rollee provides medical and scientific infor-  
3 mation establishing that the individual's  
4 participation in the trial would be appro-  
5 priate, based upon the individual meeting  
6 the conditions described in subparagraph  
7 (A);

8 (3) a child with a life-threatening illness, in-  
9 cluding cancer, should be allowed to participate in a  
10 federally approved or funded clinical trial if that  
11 participation meets the requirements of paragraph  
12 (2);

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

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

23 **SEC. 703. SENSE OF THE CONGRESS REGARDING FAIR RE-**  
24 **VIEW PROCESS.**

25 (a) FINDINGS.—The Congress finds the following:

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

4           (2) The independence and objectivity of the re-  
5           view organization and review process must be en-  
6           sured.

7           (3) It is incompatible with a fair and inde-  
8           pendent appeals process to allow a health mainte-  
9           nance organization to select the review organization  
10          that is entrusted with providing a neutral and unbi-  
11          ased medical review.

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

18          (b) SENSE OF THE CONGRESS.—It is the sense of  
19          the Congress that—

20                 (1) every patient who is denied care by a health  
21                 maintenance organization or other health insurance  
22                 company should be entitled to a fair, speedy, impar-  
23                 tial appeal to a review organization that has not  
24                 been selected by the health plan;

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

4           (3) a child battling a rare cancer whose health  
5           maintenance organization has denied a covered  
6           treatment recommended by its physician should be  
7           entitled to a fair and impartial external appeal to a  
8           review organization that has not been chosen by the  
9           organization or plan that has denied the care; and

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

14 **SEC. 704. ANNUAL REVIEW.**

15          (a) IN GENERAL.—Not later than 24 months after  
16          the general effective date referred to in section 601(a)(1),  
17          and annually thereafter for each of the succeeding 4 cal-  
18          endar years (or until a repeal is effective under subsection  
19          (b)), the Secretary of Health and Human Services shall  
20          request that the Institute of Medicine of the National  
21          Academy of Sciences prepare and submit to the appro-  
22          priate committees of Congress a report concerning the im-  
23          pact of this Act, and the amendments made by this Act,  
24          on the number of individuals in the United States with  
25          health insurance coverage.

1           (b) FUNDING.—From funds appropriated to the De-  
2   partment of Health and Human Services for fiscal years  
3   2004 and 2005, the Secretary of Health and Human Serv-  
4   ices shall provide for such funding as the Secretary deter-  
5   mines necessary for the conduct of the study of the Na-  
6   tional Academy of Sciences under this section.

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