

105TH CONGRESS  
2D SESSION

# S. 1891

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

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## IN THE SENATE OF THE UNITED STATES

MARCH 31, 1998

Mr. DASCHLE (for himself, Mr. KENNEDY, Mrs. BOXER, Mr. DODD, Ms. MIKULSKI, Mrs. FEINSTEIN, Mr. DURBIN, Mr. REED, Mr. INOUE, Mr. TORRICELLI, Mr. KERRY, Ms. MOSELEY-BRAUN, Mr. WYDEN, Mr. LAUTENBERG, Mr. ROCKEFELLER, Mr. CLELAND, Mr. LEAHY, Mrs. MURRAY, Mr. WELLSTONE, Mr. SARBANES, Mr. AKAKA, and Mr. BINGAMAN) introduced the following bill; which was read twice and referred to the Committee on Finance

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## A BILL

To amend 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 “Patients’ Bill of Rights Act of 1998”.

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

Sec. 1. Short title; table of contents.

## TITLE I—HEALTH INSURANCE BILL OF RIGHTS

## Subtitle A—Access to Care

- Sec. 101. Access to emergency care.
- Sec. 102. Offering of choice of coverage options under group health plans.
- Sec. 103. Choice of providers.
- Sec. 104. Access to specialty care.
- Sec. 105. Continuity of care.
- Sec. 106. Coverage for individuals participating in approved clinical trials.
- Sec. 107. Access to needed prescription drugs.
- Sec. 108. Adequacy of provider network.
- Sec. 109. Nondiscrimination in delivery of services.

## Subtitle B—Quality Assurance

- Sec. 111. Internal quality assurance program.
- Sec. 112. Collection of standardized data.
- Sec. 113. Process for selection of providers.
- Sec. 114. Drug utilization program.
- Sec. 115. Standards for utilization review activities.
- Sec. 116. Health Care Quality Advisory Board.

## Subtitle C—Patient Information

- Sec. 121. Patient information.
- Sec. 122. Protection of patient confidentiality.
- Sec. 123. Health insurance ombudsmen.

## Subtitle D—Grievance and Appeals Procedures

- Sec. 131. Establishment of grievance process.
- Sec. 132. Internal appeals of adverse determinations.
- Sec. 133. External appeals of adverse determinations.

## Subtitle E—Protecting the Doctor-Patient Relationship

- Sec. 141. Prohibition of interference with certain medical communications.
- Sec. 142. Prohibition against transfer of indemnification or improper incentive arrangements.
- Sec. 143. Additional rules regarding participation of health care professionals.
- Sec. 144. Protection for patient advocacy.

## Subtitle F—Promoting Good Medical Practice

- Sec. 151. Promoting good medical practice.
- Sec. 152. Standards relating to benefits for certain breast cancer treatment.
- Sec. 153. Standards relating to benefits for reconstructive breast surgery.

## Subtitle G—Definitions

- Sec. 191. Definitions.
- Sec. 192. Preemption; State flexibility; construction.
- Sec. 193. Regulations.

TITLE II—APPLICATION TO GROUP HEALTH PLANS UNDER THE  
INTERNAL REVENUE CODE OF 1986

- Sec. 201. Amendments to the Internal Revenue Code of 1986.

## TITLE III—EFFECTIVE DATES

Sec. 301. Effective dates.

1     **TITLE I—HEALTH INSURANCE**  
 2                   **BILL OF RIGHTS**  
 3                   **Subtitle A—Access to Care**

4     **SEC. 101. 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 any benefits with respect to  
 9           emergency services (as defined in paragraph (2)(B)),  
 10          the plan or issuer shall cover emergency services fur-  
 11          nished under the plan or coverage—

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

14                           (B) whether or not the health care pro-  
 15                           vider furnishing such services is a participating  
 16                           provider 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 by a nonparticipating health care pro-  
 20                           vider—

21                                   (i) the participant, beneficiary, or en-  
 22                                   rollee is not liable for amounts that exceed  
 23                                   the amounts of liability that would be in-

1 curred if the services were provided by a  
 2 participating health care provider, and

3 (ii) the plan or issuer pays an amount  
 4 that is not less than the amount paid to a  
 5 participating health care provider for the  
 6 same services; and

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

16 (2) DEFINITIONS.—In this section:

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

1 condition described in clause (i), (ii), or (iii) of  
2 section 1867(e)(1)(A) of the Social Security  
3 Act.

4 (B) EMERGENCY SERVICES.—The term  
5 “emergency services” means—

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 an emergency medical  
13 condition (as defined in subparagraph  
14 (A)), and

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

20 (b) REIMBURSEMENT FOR MAINTENANCE CARE AND  
21 POST-STABILIZATION CARE.—In the case of services  
22 (other than emergency services) for which benefits are  
23 available under a group health plan, or under health insur-  
24 ance coverage offered by a health insurance issuer, the  
25 plan or issuer shall provide for reimbursement with re-

1 spect to such services provided to a participant, bene-  
2 ficiary, or enrollee other than through a participating  
3 health care provider in a manner consistent with sub-  
4 section (a)(1)(C) if the services are maintenance care or  
5 post-stabilization care covered under the guidelines estab-  
6 lished under section 1852(d)(2) of the Social Security Act  
7 (relating to promoting efficient and timely coordination of  
8 appropriate maintenance and post-stabilization care of an  
9 enrollee after an enrollee has been determined to be sta-  
10 ble), or, in the absence of guidelines under such section,  
11 such guidelines as the Secretary shall establish to carry  
12 out this subsection.

13 **SEC. 102. OFFERING OF CHOICE OF COVERAGE OPTIONS**  
14 **UNDER GROUP HEALTH PLANS.**

15 (a) REQUIREMENT.—

16 (1) OFFERING OF POINT-OF-SERVICE COV-  
17 ERAGE OPTION.—Except as provided in paragraph  
18 (2), if a group health plan (or health insurance cov-  
19 erage offered by a health insurance issuer in connec-  
20 tion with a group health plan) provides benefits only  
21 through participating health care providers, the plan  
22 or issuer shall offer the participant the option to  
23 purchase point-of-service coverage (as defined in  
24 subsection (b)) for all such benefits for which cov-  
25 erage is otherwise so limited. Such option shall be

1 made available to the participant at the time of en-  
2 rollment under the plan or coverage and at such  
3 other times as the plan or issuer offers the partici-  
4 pant a choice of coverage options.

5 (2) EXCEPTION.—Paragraph (1) shall not  
6 apply with respect to a participant in a group health  
7 plan if the plan offers the participant—

8 (A) a choice of health insurance coverage  
9 through more than one health insurance issuer;  
10 or

11 (B) two or more coverage options that dif-  
12 fer significantly with respect to the use of par-  
13 ticipating health care providers or the networks  
14 of such providers that are used.

15 (b) POINT-OF-SERVICE COVERAGE DEFINED.—In  
16 this section, the term “point-of-service coverage” means,  
17 with respect to benefits covered under a group health plan  
18 or health insurance issuer, coverage of such benefits when  
19 provided by a nonparticipating health care provider. Such  
20 coverage need not include coverage of providers that the  
21 plan or issuer excludes because of fraud, quality, or similar  
22 reasons.

23 (c) CONSTRUCTION.—Nothing in this section shall be  
24 construed—

1           (1) as requiring coverage for benefits for a par-  
2           ticular type of health care provider;

3           (2) as requiring an employer to pay any costs  
4           as a result of this section or to make equal contribu-  
5           tions with respect to different health coverage op-  
6           tions; or

7           (3) as preventing a group health plan or health  
8           insurance issuer from imposing higher premiums or  
9           cost-sharing on a participant for the exercise of a  
10          point-of-service coverage option.

11          (d) **NO REQUIREMENT FOR GUARANTEED AVAIL-**  
12 **ABILITY.**—If a health insurance issuer offers health insur-  
13 **ance coverage that includes point-of-service coverage with**  
14 **respect to an employer solely in order to meet the require-**  
15 **ment of subsection (a), nothing in section 2711(a)(1)(A)**  
16 **of the Public Health Service Act shall be construed as re-**  
17 **quiring the offering of such coverage with respect to an-**  
18 **other employer.**

19 **SEC. 103. CHOICE OF PROVIDERS.**

20          (a) **PRIMARY CARE.**—A group health plan, and a  
21 **health insurance issuer that offers health insurance cov-**  
22 **erage, shall permit each participant, beneficiary, and en-**  
23 **rollee to receive primary care from any participating pri-**  
24 **mary care provider who is available to accept such individ-**  
25 **ual.**



1 (b) SPECIALISTS.—

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

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

15 **SEC. 104. ACCESS TO SPECIALTY CARE.**

16 (a) OBSTETRICAL AND GYNECOLOGICAL CARE.—

17 (1) IN GENERAL.—If a group health plan, or a  
18 health insurance issuer in connection with the provi-  
19 sion of health insurance coverage, requires or pro-  
20 vides for a participant, beneficiary, or enrollee to  
21 designate a participating primary care provider—

22 (A) the plan or issuer shall permit such an  
23 individual who is a female to designate a par-  
24 ticipating physician who specializes in obstetrics

1 and gynecology as the individual's primary care  
2 provider; and

3 (B) if such an individual has not des-  
4 ignated such a provider as a primary care pro-  
5 vider, the plan or issuer—

6 (i) may not require authorization or a  
7 referral by the individual's primary care  
8 provider or otherwise for coverage of rou-  
9 tine gynecological care (such as preventive  
10 women's health examinations) and preg-  
11 nancy-related services provided by a par-  
12 ticipating health care professional who spe-  
13 cializes in obstetrics and gynecology to the  
14 extent such care is otherwise covered, and

15 (ii) may treat the ordering of other  
16 gynecological care by such a participating  
17 physician as the authorization of the pri-  
18 mary care provider with respect to such  
19 care under the plan or coverage.

20 (2) CONSTRUCTION.—Nothing in paragraph  
21 (1)(B)(ii) shall waive any requirements of coverage  
22 relating to medical necessity or appropriateness with  
23 respect to coverage of gynecological care so ordered.

24 (b) SPECIALTY CARE.—

1           (1) SPECIALTY CARE FOR COVERED SERV-  
2 ICES.—

3           (A) IN GENERAL.—If—

4                   (i) an individual is a participant or  
5 beneficiary under a group health plan or  
6 an enrollee who is covered under health in-  
7 surance coverage offered by a health insur-  
8 ance issuer,

9                   (ii) the individual has a condition or  
10 disease of sufficient seriousness and com-  
11 plexity to require treatment by a specialist,  
12 and

13                   (iii) benefits for such treatment are  
14 provided under the plan or coverage,

15 the plan or issuer shall make or provide for a  
16 referral to a specialist who is available and ac-  
17 cessible to provide the treatment for such condi-  
18 tion or disease.

19           (B) SPECIALIST DEFINED.—For purposes  
20 of this subsection, the term “specialist” means,  
21 with respect to a condition, a health care practi-  
22 tioner, facility, or center (such as a center of  
23 excellence) that has adequate expertise through  
24 appropriate training and experience (including,  
25 in the case of a child, appropriate pediatric ex-

1           pertise) to provide high quality care in treating  
2           the condition.

3                   (C) CARE UNDER REFERRAL.—A group  
4           health plan or health insurance issuer may re-  
5           quire that the care provided to an individual  
6           pursuant to such referral under subparagraph  
7           (A) be—

8                           (i) pursuant to a treatment plan, only  
9                           if the treatment plan is developed by the  
10                          specialist and approved by the plan or  
11                          issuer, in consultation with the designated  
12                          primary care provider or specialist and the  
13                          individual (or the individual’s designee),  
14                          and

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

18           Nothing in this subsection shall be construed as  
19           preventing such a treatment plan for an individ-  
20           ual from requiring a specialist to provide the  
21           primary care provider with regular updates on  
22           the specialty care provided, as well as all nec-  
23           essary medical information.

24                   (D) REFERRALS TO PARTICIPATING PRO-  
25           VIDERS.—A group health plan or health insur-

1           ance issuer is not required under subparagraph  
2           (A) to provide for a referral to a specialist that  
3           is not a participating provider, unless the plan  
4           or issuer does not have an appropriate specialist  
5           that is available and accessible to treat the indi-  
6           vidual's condition and that is a participating  
7           provider with respect to such treatment.

8                   (E) TREATMENT OF NONPARTICIPATING  
9           PROVIDERS.—If a plan or issuer refers an indi-  
10          vidual to a nonparticipating specialist pursuant  
11          to subparagraph (A), services provided pursu-  
12          ant to the approved treatment plan (if any)  
13          shall be provided at no additional cost to the in-  
14          dividual beyond what the individual would oth-  
15          erwise pay for services received by such a spe-  
16          cialist that is a participating provider.

17                   (2) SPECIALISTS AS PRIMARY CARE PROVID-  
18          ERS.—

19                   (A) IN GENERAL.—A group health plan, or  
20          a health insurance issuer, in connection with  
21          the provision of health insurance coverage, shall  
22          have a procedure by which an individual who is  
23          a participant, beneficiary, or enrollee and who  
24          has an ongoing special condition (as defined in  
25          subparagraph (C)) may receive a referral to a

1 specialist for such condition who shall be re-  
2 sponsible for and capable of providing and co-  
3 ordinating the individual's primary and spe-  
4 cialty care. If such an individual's care would  
5 most appropriately be coordinated by such a  
6 specialist, such plan or issuer shall refer the in-  
7 dividual to such specialist.

8 (B) TREATMENT AS PRIMARY CARE PRO-  
9 VIDER.—Such specialist shall be permitted to  
10 treat the individual without a referral from the  
11 individual's primary care provider and may au-  
12 thorize such referrals, procedures, tests, and  
13 other medical services as the individual's pri-  
14 mary care provider would otherwise be per-  
15 mitted to provide or authorize, subject to the  
16 terms of the treatment plan (referred to in  
17 paragraph (1)(C)(i)).

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

21 (i) is life-threatening, degenerative, or  
22 disabling, and

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

1 (D) TERMS OF REFERRAL.—The provi-  
2 sions of subparagraphs (C) through (E) of  
3 paragraph (1) apply with respect to referrals  
4 under subparagraph (A) of this paragraph in  
5 the same manner as they apply to referrals  
6 under paragraph (1)(A).

7 (3) STANDING REFERRALS.—

8 (A) IN GENERAL.—A group health plan,  
9 and a health insurance issuer in connection  
10 with the provision of health insurance coverage,  
11 shall have a procedure by which an individual  
12 who is a participant, beneficiary, or enrollee  
13 and who has a condition that requires ongoing  
14 care from a specialist may receive a standing  
15 referral to such specialist for treatment of such  
16 condition. If the plan or issuer, or if the pri-  
17 mary care provider in consultation with the  
18 medical director of the plan or issuer and the  
19 specialist (if any), determines that such a  
20 standing referral is appropriate, the plan or  
21 issuer shall make such a referral to such a spe-  
22 cialist.

23 (B) TERMS OF REFERRAL.—The provi-  
24 sions of subparagraphs (C) through (E) of  
25 paragraph (1) apply with respect to referrals

1           under subparagraph (A) of this paragraph in  
2           the same manner as they apply to referrals  
3           under paragraph (1)(A).

4 **SEC. 105. CONTINUITY OF CARE.**

5           (a) IN GENERAL.—

6           (1) TERMINATION OF PROVIDER.—If a contract  
7           between a group health plan, or a health insurance  
8           issuer in connection with the provision of health in-  
9           surance coverage, and a health care provider is ter-  
10          minated (as defined in paragraph (3)), or benefits or  
11          coverage provided by a health care provider are ter-  
12          minated because of a change in the terms of pro-  
13          vider participation in a group health plan, and an in-  
14          dividual who is a participant, beneficiary, or enrollee  
15          in the plan or coverage is undergoing a course of  
16          treatment from the provider at the time of such ter-  
17          mination, the plan or issuer shall—

18                   (A) notify the individual on a timely basis  
19                   of such termination, and

20                   (B) subject to subsection (c), permit the  
21                   individual to continue or be covered with re-  
22                   spect to the course of treatment with the pro-  
23                   vider during a transitional period (provided  
24                   under subsection (b)).



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

15           (3) TERMINATION.—In this section, the term  
16 “terminated” includes, with respect to a contract,  
17 the expiration or nonrenewal of the contract, but  
18 does not include a termination of the contract by the  
19 plan or issuer for failure to meet applicable quality  
20 standards or for fraud.

21 (b) TRANSITIONAL PERIOD.—

22           (1) IN GENERAL.—Except as provided in para-  
23 graphs (2) through (4), the transitional period under  
24 this subsection shall extend for at least 90 days from

1 the date of the notice described in subsection  
2 (a)(1)(A) of the provider's termination.

3 (2) INSTITUTIONAL CARE.—The transitional pe-  
4 riod under this subsection for institutional or inpa-  
5 tient care from a provider shall extend until the dis-  
6 charge or termination of the period of institutional-  
7 ization and also shall include institutional care pro-  
8 vided within a reasonable time of the date of termi-  
9 nation of the provider status if the care was sched-  
10 uled before the date of the announcement of the ter-  
11 mination of the provider status under subsection  
12 (a)(1)(A) or if the individual on such date was on  
13 an established waiting list or otherwise scheduled to  
14 have such care.

15 (3) PREGNANCY.—If—

16 (A) a participant, beneficiary, or enrollee  
17 has entered the second trimester of pregnancy  
18 at the time of a provider's termination of par-  
19 ticipation, and

20 (B) the provider was treating the preg-  
21 nancy before date of the termination,

22 the transitional period under this subsection with re-  
23 spect to provider's treatment of the pregnancy shall  
24 extend through the provision of post-partum care di-  
25 rectly related to the delivery.

1 (4) TERMINAL ILLNESS.—If—

2 (A) a participant, beneficiary, or enrollee  
3 was determined to be terminally ill (as deter-  
4 mined under section 1861(dd)(3)(A) of the So-  
5 cial Security Act) at the time of a provider’s  
6 termination of participation, and

7 (B) the provider was treating the terminal  
8 illness before the date of termination,  
9 the transitional period under this subsection shall  
10 extend for the remainder of the individual’s life for  
11 care directly related to the treatment of the terminal  
12 illness.

13 (c) PERMISSIBLE TERMS AND CONDITIONS.—A  
14 group health plan or health insurance issuer may condi-  
15 tion coverage of continued treatment by a provider under  
16 subsection (a)(1)(B) upon the provider agreeing to the fol-  
17 lowing terms and conditions:

18 (1) The provider agrees to accept reimburse-  
19 ment from the plan or issuer and individual involved  
20 (with respect to cost-sharing) at the rates applicable  
21 prior to the start of the transitional period as pay-  
22 ment in full (or, in the case described in subsection  
23 (a)(2), at the rates applicable under the replacement  
24 plan or issuer after the date of the termination of  
25 the contract with the health insurance issuer) and

1 not to impose cost-sharing with respect to the indi-  
2 vidual in an amount that would exceed the cost-shar-  
3 ing that could have been imposed if the contract re-  
4 ferred to in subsection (a)(1) had not been termi-  
5 nated.

6 (2) The provider agrees to adhere to the quality  
7 assurance standards of the plan or issuer responsible  
8 for payment under paragraph (1) and to provide to  
9 such plan or issuer necessary medical information  
10 related to the care provided.

11 (3) The provider agrees otherwise to adhere to  
12 such plan's or issuer's policies and procedures, in-  
13 cluding procedures regarding referrals and obtaining  
14 prior authorization and providing services pursuant  
15 to a treatment plan (if any) approved by the plan or  
16 issuer.

17 (d) CONSTRUCTION.—Nothing in this section shall be  
18 construed to require the coverage of benefits which would  
19 not have been covered if the provider involved remained  
20 a participating provider.

21 **SEC. 106. COVERAGE FOR INDIVIDUALS PARTICIPATING IN**  
22 **APPROVED CLINICAL TRIALS.**

23 (a) COVERAGE.—

24 (1) IN GENERAL.—If a group health plan, or  
25 health insurance issuer that is providing health in-

1       surance coverage, provides coverage to a qualified in-  
2       dividual (as defined in subsection (b)), the plan or  
3       issuer—

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

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

12              (C) may not discriminate against the indi-  
13      vidual on the basis of the enrollee's participa-  
14      tion in such trial.

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

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

1 will accept the individual as a participant in the  
2 trial.

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

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

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

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

18 (2) Either—

19 (A) the referring physician is a participat-  
20 ing health care professional and has concluded  
21 that the individual’s participation in such trial  
22 would be appropriate based upon the individual  
23 meeting the conditions described in paragraph  
24 (1); or

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

7 (c) PAYMENT.—

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

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

17 (A) a participating provider, the payment  
18 rate shall be at the agreed upon rate, or

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

23 (d) APPROVED CLINICAL TRIAL DEFINED.—

24 (1) IN GENERAL.—In this section, the term  
25 “approved clinical trial” means a clinical research

1 study or clinical investigation approved and funded  
2 (which may include funding through in-kind con-  
3 tributions) by one or more of the following:

4 (A) The National Institutes of Health.

5 (B) A cooperative group or center of the  
6 National Institutes of Health.

7 (C) Either of the following if the condi-  
8 tions described in paragraph (2) are met:

9 (i) The Department of Veterans Af-  
10 fairs.

11 (ii) The Department of Defense.

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

18 (A) to be comparable to the system of peer  
19 review of studies and investigations used by the  
20 National Institutes of Health, and

21 (B) assures unbiased review of the highest  
22 scientific standards by qualified individuals who  
23 have no interest in the outcome of the review.



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

4 **SEC. 107. ACCESS TO NEEDED PRESCRIPTION DRUGS.**

5 (a) IN GENERAL.—If a group health plan, or health  
6 insurance issuer that offers health insurance coverage,  
7 provides benefits with respect to prescription drugs but  
8 the coverage limits such benefits to drugs included in a  
9 formulary, the plan or issuer shall—

10 (1) ensure participation of participating physi-  
11 cians and pharmacists in the development of the for-  
12 mulary;

13 (2) disclose to providers and, disclose upon re-  
14 quest under section 121(c)(6) to participants, bene-  
15 ficiaries, and enrollees, the nature of the formulary  
16 restrictions; and

17 (3) consistent with the standards for a utiliza-  
18 tion review program under section 115, provide for  
19 exceptions from the formulary limitation when a  
20 non-formulary alternative is medically indicated.

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

23 (1) IN GENERAL.—A group health plan (or  
24 health insurance coverage offered in connection with  
25 such a plan) that provides any coverage of prescrip-

1       tion drugs or medical devices shall not deny coverage  
2       of such a drug or device on the basis that the use  
3       is investigational, if the use—

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

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

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

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

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

6 **SEC. 108. ADEQUACY OF PROVIDER NETWORK.**

7           (a) IN GENERAL.—Each group health plan, and each  
8           health insurance issuer offering health insurance coverage,  
9           that provides benefits, in whole or in part, through partici-  
10          pating health care providers shall have (in relation to the  
11          coverage) a sufficient number, distribution, and variety of  
12          qualified participating health care providers to ensure that  
13          all covered health care services, including specialty serv-  
14          ices, will be available and accessible in a timely manner  
15          to all participants, beneficiaries, and enrollees under the  
16          plan or coverage.

17          (b) TREATMENT OF CERTAIN PROVIDERS.—The  
18          qualified health care providers under subsection (a) may  
19          include Federally qualified health centers, rural health  
20          clinics, migrant health centers, and other essential com-  
21          munity providers located in the service area of the plan  
22          or issuer and shall include such providers if necessary to  
23          meet the standards established to carry out such sub-  
24          section.

1 **SEC. 109. NONDISCRIMINATION IN DELIVERY OF SERVICES.**

2 (a) APPLICATION TO DELIVERY OF SERVICES.—Sub-  
3 ject to subsection (b), a group health plan, and health in-  
4 surance issuer in relation to health insurance coverage,  
5 may not discriminate against a participant, beneficiary, or  
6 enrollee in the delivery of health care services consistent  
7 with the benefits covered under the plan or coverage or  
8 as required by law based on race, color, ethnicity, national  
9 origin, religion, sex, age, mental or physical disability, sex-  
10 ual orientation, genetic information, or source of payment.

11 (b) CONSTRUCTION.—Nothing in subsection (a) shall  
12 be construed as relating to the eligibility to be covered,  
13 or the offering (or guaranteeing the offer) of coverage,  
14 under a plan or health insurance coverage, the application  
15 of any pre-existing condition exclusion consistent with ap-  
16 plicable law, or premiums charged under such plan or cov-  
17 erage.

18 **Subtitle B—Quality Assurance**

19 **SEC. 111. INTERNAL QUALITY ASSURANCE PROGRAM.**

20 (a) REQUIREMENT.—A group health plan, and a  
21 health insurance issuer that offers health insurance cov-  
22 erage, shall establish and maintain an ongoing, internal  
23 quality assurance and continuous quality improvement  
24 program that meets the requirements of subsection (b).

1 (b) PROGRAM REQUIREMENTS.—The requirements of  
2 this subsection for a quality improvement program of a  
3 plan or issuer are as follows:

4 (1) ADMINISTRATION.—The plan or issuer has  
5 a separate identifiable unit with responsibility for  
6 administration of the program.

7 (2) WRITTEN PLAN.—The plan or issuer has a  
8 written plan for the program that is updated annu-  
9 ally and that specifies at least the following:

10 (A) The activities to be conducted.

11 (B) The organizational structure.

12 (C) The duties of the medical director.

13 (D) Criteria and procedures for the assess-  
14 ment of quality.

15 (3) SYSTEMATIC REVIEW.—The program pro-  
16 vides for systematic review of the type of health  
17 services provided, consistency of services provided  
18 with good medical practice, and patient outcomes.

19 (4) QUALITY CRITERIA.—The program—

20 (A) uses criteria that are based on per-  
21 formance and patient outcomes where feasible  
22 and appropriate;

23 (B) includes criteria that are directed spe-  
24 cifically at meeting the needs of at-risk popu-  
25 lations and covered individuals with chronic

1 conditions or severe illnesses, including gender-  
2 specific criteria and pediatric-specific criteria  
3 where available and appropriate;

4 (C) includes methods for informing covered  
5 individuals of the benefit of preventive care and  
6 what specific benefits with respect to preventive  
7 care are covered under the plan or coverage;  
8 and

9 (D) makes available to the public a de-  
10 scription of the criteria used under subpara-  
11 graph (A).

12 (5) SYSTEM FOR REPORTING.—The program  
13 has procedures for reporting of possible quality con-  
14 cerns by providers and enrollees and for remedial ac-  
15 tions to correct quality problems, including written  
16 procedures for responding to concerns and taking  
17 appropriate corrective action.

18 (6) DATA ANALYSIS.—The program provides,  
19 using data that include the data collected under sec-  
20 tion 112, for an analysis of the plan's or issuer's  
21 performance on quality measures.

22 (7) DRUG UTILIZATION REVIEW.—The program  
23 provides for a drug utilization review program in ac-  
24 cordance with section 114.

1 (c) DEEMING.—For purposes of subsection (a), the  
2 requirements of—

3 (1) subsection (b) (other than paragraph (5))  
4 are deemed to be met with respect to a health insur-  
5 ance issuer that is a qualified health maintenance  
6 organization (as defined in section 1310(c) of the  
7 Public Health Service Act); or

8 (2) subsection (b) are deemed to be met with  
9 respect to a health insurance issuer that is accred-  
10 ited by a national accreditation organization that the  
11 Secretary certifies as applying, as a condition of cer-  
12 tification, standards at least as stringent as those re-  
13 quired for a quality improvement program under  
14 subsection (b).

15 (d) VARIATION PERMITTED.—The Secretary may  
16 provide for variations in the application of the require-  
17 ments of this section to group health plans and health in-  
18 surance issuers based upon differences in the delivery sys-  
19 tem among such plans and issuers as the Secretary deems  
20 appropriate.

21 **SEC. 112. COLLECTION OF STANDARDIZED DATA.**

22 (a) IN GENERAL.—A group health plan and a health  
23 insurance issuer that offers health insurance coverage  
24 shall collect uniform quality data that include a minimum  
25 uniform data set described in subsection (b).

1 (b) MINIMUM UNIFORM DATA SET.—The Secretary  
2 shall specify (and may from time to time update) the data  
3 required to be included in the minimum uniform data set  
4 under subsection (a) and the standard format for such  
5 data. Such data shall include at least—

6 (1) aggregate utilization data;

7 (2) data on the demographic characteristics of  
8 participants, beneficiaries, and enrollees;

9 (3) data on disease-specific and age-specific  
10 mortality rates and (to the extent feasible) morbidity  
11 rates of such individuals;

12 (4) data on satisfaction of such individuals, in-  
13 cluding data on voluntary disenrollment and griev-  
14 ances; and

15 (5) data on quality indicators and health out-  
16 comes, including, to the extent feasible and appro-  
17 priate, data on pediatric cases and on a gender-spe-  
18 cific basis.

19 (c) AVAILABILITY.—A summary of the data collected  
20 under subsection (a) shall be disclosed under section  
21 121(b)(9). The Secretary shall be provided access to all  
22 the data so collected.

23 (d) VARIATION PERMITTED.—The Secretary may  
24 provide for variations in the application of the require-  
25 ments of this section to group health plans and health in-



1 surance issuers based upon differences in the delivery sys-  
2 tem among such plans and issuers as the Secretary deems  
3 appropriate.

4 **SEC. 113. PROCESS FOR SELECTION OF PROVIDERS.**

5 (a) IN GENERAL.—A group health plan and a health  
6 insurance issuer that offers health insurance coverage  
7 shall, if it provides benefits through participating health  
8 care professionals, have a written process for the selection  
9 of participating health care professionals, including mini-  
10 mum professional requirements.

11 (b) VERIFICATION OF BACKGROUND.—Such process  
12 shall include verification of a health care provider’s license  
13 and a history of suspension or revocation.

14 (c) RESTRICTION.—Such process shall not use a  
15 high-risk patient base or location of a provider in an area  
16 with residents with poorer health status as a basis for ex-  
17 cluding providers from participation.

18 (d) NONDISCRIMINATION BASED ON LICENSURE.—

19 (1) IN GENERAL.—Such process shall not dis-  
20 criminate with respect to participation or indem-  
21 nification as to any provider who is acting within the  
22 scope of the provider’s license or certification under  
23 applicable State law, solely on the basis of such li-  
24 cense or certification.

1           (2) CONSTRUCTION.—Paragraph (1) shall not  
2 be construed—

3           (A) as requiring the coverage under a plan  
4 or coverage of particular benefits or services or  
5 to prohibit a plan or issuer from including pro-  
6 viders only to the extent necessary to meet the  
7 needs of the plan’s or issuer’s participants,  
8 beneficiaries, or enrollees or from establishing  
9 any measure designed to maintain quality and  
10 control costs consistent with the responsibilities  
11 of the plan or issuer; or

12           (B) to override any State licensure or  
13 scope-of-practice law.

14 (e) GENERAL NONDISCRIMINATION.—

15           (1) IN GENERAL.—Subject to paragraph (2),  
16 such process shall not discriminate with respect to  
17 selection of a health care professional to be a partici-  
18 pating health care provider, or with respect to the  
19 terms and conditions of such participation, based on  
20 the professional’s race, color, religion, sex, national  
21 origin, age, sexual orientation, or disability (consist-  
22 ent with the Americans with Disabilities Act of  
23 1990).

24           (2) RULES.—The appropriate Secretary may  
25 establish such definitions, rules, and exceptions as

1        may be appropriate to carry out paragraph (1), tak-  
2        ing into account comparable definitions, rules, and  
3        exceptions in effect under employment-based non-  
4        discrimination laws and regulations that relate to  
5        each of the particular bases for discrimination de-  
6        scribed in such paragraph.

7        **SEC. 114. DRUG UTILIZATION PROGRAM.**

8        A group health plan, and a health insurance issuer  
9        that provides health insurance coverage, that includes ben-  
10        efits for prescription drugs shall establish and maintain,  
11        as part of its internal quality assurance and continuous  
12        quality improvement program under section 111, a drug  
13        utilization program which—

14                (1) encourages appropriate use of prescription  
15        drugs by participants, beneficiaries, and enrollees  
16        and providers, and

17                (2) takes appropriate action to reduce the inci-  
18        dence of improper drug use and adverse drug reac-  
19        tions and interactions.

20        **SEC. 115. STANDARDS FOR UTILIZATION REVIEW ACTIVI-**  
21                **TIES.**

22        (a) COMPLIANCE WITH REQUIREMENTS.—

23                (1) IN GENERAL.—A group health plan, and a  
24        health insurance issuer that provides health insur-  
25        ance coverage, shall conduct utilization review activi-

1 ties in connection with the provision of benefits  
2 under such plan or coverage only in accordance with  
3 a utilization review program that meets the require-  
4 ments of this section.

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

13 (3) UTILIZATION REVIEW DEFINED.—For pur-  
14 poses of this section, the terms “utilization review”  
15 and “utilization review activities” mean procedures  
16 used to monitor or evaluate the clinical necessity,  
17 appropriateness, efficacy, or efficiency of health care  
18 services, procedures or settings, and includes pro-  
19 spective review, concurrent review, second opinions,  
20 case management, discharge planning, or retrospec-  
21 tive review.

22 (b) WRITTEN POLICIES AND CRITERIA.—

23 (1) WRITTEN POLICIES.—A utilization review  
24 program shall be conducted consistent with written

1 policies and procedures that govern all aspects of the  
2 program.

3 (2) USE OF WRITTEN CRITERIA.—

4 (A) IN GENERAL.—Such a program shall  
5 utilize written clinical review criteria developed  
6 pursuant to the program with the input of ap-  
7 propriate physicians. Such criteria shall include  
8 written clinical review criteria described in sec-  
9 tion 111(b)(4)(B).

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

20 (c) CONDUCT OF PROGRAM ACTIVITIES.—

21 (1) ADMINISTRATION BY HEALTH CARE PRO-  
22 FESSIONALS.—A utilization review program shall be  
23 administered by qualified health care professionals  
24 who shall oversee review decisions. In this sub-  
25 section, the term “health care professional” means a

1 physician or other health care practitioner licensed,  
2 accredited, or certified to perform specified health  
3 services consistent with State law.

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

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

12 (B) PEER REVIEW OF SAMPLE OF AD-  
13 VERSE CLINICAL DETERMINATIONS.—Such a  
14 program shall provide that clinical peers (as de-  
15 fined in section 191(c)(2)) shall evaluate the  
16 clinical appropriateness of at least a sample of  
17 adverse clinical determinations.

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

1 (i) provides incentives, direct or indi-  
2 rect, for such persons to make inappropri-  
3 ate review decisions, or

4 (ii) is based, directly or indirectly, on  
5 the quantity or type of adverse determina-  
6 tions rendered.

7 (D) PROHIBITION OF CONFLICTS.—Such a  
8 program shall not permit a health care profes-  
9 sional who provides health care services to an  
10 individual to perform utilization review activi-  
11 ties in connection with the health care services  
12 being provided to the individual.

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

21 (4) LIMITS ON FREQUENCY.—Such a program  
22 shall not provide for the performance of utilization  
23 review activities with respect to a class of services  
24 furnished to an individual more frequently than is

1 reasonably required to assess whether the services  
2 under review are medically necessary or appropriate.

3 (5) LIMITATION ON INFORMATION REQUESTS.—

4 Under such a program, information shall be required  
5 to be provided by health care providers only to the  
6 extent it is necessary to perform the utilization re-  
7 view activity involved.

8 (6) REVIEW OF PRELIMINARY UTILIZATION RE-

9 VIEW DECISION.—Under such program a partici-  
10 pant, beneficiary, or enrollee or any provider acting  
11 on behalf of such an individual with the individual's  
12 consent, who is dissatisfied with a preliminary utili-  
13 zation review decision has the opportunity to discuss  
14 the decision with, and have such decision reviewed  
15 by, the medical director of the plan or issuer in-  
16 volved (or the director's designee) who has the au-  
17 thority to reverse the decision.

18 (d) DEADLINE FOR DETERMINATIONS.—

19 (1) PRIOR AUTHORIZATION SERVICES.—Except

20 as provided in paragraph (2), in the case of a utili-  
21 zation review activity involving the prior authoriza-  
22 tion of health care items and services for an individ-  
23 ual, the utilization review program shall make a de-  
24 termination concerning such authorization, and pro-  
25 vide notice of the determination to the individual or



1 the individual's designee and the individual's health  
2 care provider by telephone and in printed form, as  
3 soon as possible in accordance with the medical ex-  
4 igencies of the cases, and in no event later than 3  
5 business days after the date of receipt of information  
6 that is reasonably necessary to make such deter-  
7 mination.

8 (2) CONTINUED CARE.—In the case of a utiliza-  
9 tion review activity involving authorization for con-  
10 tinued or extended health care services for an indi-  
11 vidual, or additional services for an individual under-  
12 going a course of continued treatment prescribed by  
13 a health care provider, the utilization review pro-  
14 gram shall make a determination concerning such  
15 authorization, and provide notice of the determina-  
16 tion to the individual or the individual's designee  
17 and the individual's health care provider by tele-  
18 phone and in printed form, as soon as possible in ac-  
19 cordance with the medical exigencies of the cases,  
20 and in no event later than 1 business day after the  
21 date of receipt of information that is reasonably nec-  
22 essary to make such determination. Such notice shall  
23 include, with respect to continued or extended health  
24 care services, the number of extended services ap-

1 proved, the new total of approved services, the date  
2 of onset of services, and the next review date, if any.

3 (3) PREVIOUSLY PROVIDED SERVICES.—In the  
4 case of a utilization review activity involving retro-  
5 spective review of health care services previously pro-  
6 vided for an individual, the utilization review pro-  
7 gram shall make a determination concerning such  
8 services, and provide notice of the determination to  
9 the individual or the individual’s designee and the  
10 individual’s health care provider by telephone and in  
11 printed form, within 30 days of the date of receipt  
12 of information that is reasonably necessary to make  
13 such determination.

14 (4) REFERENCE TO SPECIAL RULES FOR EMER-  
15 GENCY SERVICES, MAINTENANCE CARE, AND POST-  
16 STABILIZATION CARE.—For waiver of prior author-  
17 ization requirements in certain cases involving emer-  
18 gency services and maintenance care and post-sta-  
19 bilization care, see subsections (a)(1) and (b) of sec-  
20 tion 101, respectively.

21 (e) NOTICE OF ADVERSE DETERMINATIONS.—

22 (1) IN GENERAL.—Notice of an adverse deter-  
23 mination under a utilization review program shall be  
24 provided in printed form and shall include—

1 (A) the reasons for the determination (in-  
2 cluding the clinical rationale);

3 (B) instructions on how to initiate an ap-  
4 peal under section 132; and

5 (C) notice of the availability, upon request  
6 of the individual (or the individual's designee)  
7 of the clinical review criteria relied upon to  
8 make such determination.

9 (2) SPECIFICATION OF ANY ADDITIONAL INFOR-  
10 MATION.—Such a notice shall also specify what (if  
11 any) additional necessary information must be pro-  
12 vided to, or obtained by, the person making the de-  
13 termination in order to make a decision on such an  
14 appeal.

15 **SEC. 116. HEALTH CARE QUALITY ADVISORY BOARD.**

16 (a) ESTABLISHMENT.—The President shall establish  
17 an advisory board to provide information to Congress and  
18 the administration on issues relating to quality monitoring  
19 and improvement in the health care provided under group  
20 health plans and health insurance coverage.

21 (b) NUMBER AND APPOINTMENT.—The advisory  
22 board shall be composed of the Secretary of Health and  
23 Human Services (or the Secretary's designee), the Sec-  
24 retary of Labor (or the Secretary's designee), and 20 addi-  
25 tional members appointed by the President, in consulta-

1 tion with the Majority and Minority Leaders of the Senate  
2 and House of Representatives. The members so appointed  
3 shall include individuals with expertise in—

4 (1) consumer needs;

5 (2) education and training of health profes-  
6 sionals;

7 (3) health care services;

8 (4) health plan management;

9 (5) health care accreditation, quality assurance,  
10 improvement, measurement, and oversight;

11 (6) medical practice, including practicing physi-  
12 cians;

13 (7) prevention and public health; and

14 (8) public and private group purchasing for  
15 small and large employers or groups.

16 (c) DUTIES.—The advisory board shall—

17 (1) identify, update, and disseminate measures  
18 of health care quality for group health plans and  
19 health insurance issuers, including network and non-  
20 network plans;

21 (2) advise the Secretary on the development  
22 and maintenance of the minimum data set in section  
23 112(b); and

1           (3) advise the Secretary on standardized for-  
2           mats for information on group health plans and  
3           health insurance coverage.

4 The measures identified under paragraph (1) may be used  
5 on a voluntary basis by such plans and issuers. In carrying  
6 out paragraph (1), the advisory board shall consult and  
7 cooperate with national health care standard setting bod-  
8 ies which define quality indicators, the Agency for Health  
9 Care Policy and Research, the Institute of Medicine, and  
10 other public and private entities that have expertise in  
11 health care quality.

12       (d) REPORT.—The advisory board shall provide an  
13 annual report to Congress and the President on the qual-  
14 ity of the health care in the United States and national  
15 and regional trends in health care quality. Such report  
16 shall include a description of determinants of health care  
17 quality and measurements of practice and quality varia-  
18 bility within the United States.

19       (e) SECRETARIAL CONSULTATION.—In serving on  
20 the advisory board, the Secretaries of Health and Human  
21 Services and Labor (or their designees) shall consult with  
22 the Secretaries responsible for other Federal health insur-  
23 ance and health care programs.

24       (f) VACANCIES.—Any vacancy on the board shall be  
25 filled in such manner as the original appointment. Mem-

1 bers of the board shall serve without compensation but  
2 shall be reimbursed for travel, subsistence, and other nec-  
3 essary expenses incurred by them in the performance of  
4 their duties. Administrative support, scientific support,  
5 and technical assistance for the advisory board shall be  
6 provided by the Secretary of Health and Human Services.

7 (g) CONTINUATION.—Section 14(a)(2)(B) of the  
8 Federal Advisory Committee Act (5 U.S.C. App.; relating  
9 to the termination of advisory committees) shall not apply  
10 to the advisory board.

## 11 **Subtitle C—Patient Information**

### 12 **SEC. 121. PATIENT INFORMATION.**

13 (a) DISCLOSURE REQUIREMENT.—

14 (1) GROUP HEALTH PLANS.—A group health  
15 plan shall—

16 (A) provide to participants and bene-  
17 ficiaries at the time of initial coverage under  
18 the plan (or the effective date of this section, in  
19 the case of individuals who are participants or  
20 beneficiaries as of such date), and at least an-  
21 nually thereafter, the information described in  
22 subsection (b) in printed form;

23 (B) provide to participants and bene-  
24 ficiaries, within a reasonable period (as speci-  
25 fied by the appropriate Secretary) before or

1 after the date of significant changes in the in-  
2 formation described in subsection (b), informa-  
3 tion in printed form on such significant  
4 changes; and

5 (C) upon request, make available to par-  
6 ticipants and beneficiaries, the applicable au-  
7 thority, and prospective participants and bene-  
8 ficiaries, the information described in sub-  
9 section (b) or (c) in printed form.

10 (2) HEALTH INSURANCE ISSUERS.—A health  
11 insurance issuer in connection with the provision of  
12 health insurance coverage shall—

13 (A) provide to individuals enrolled under  
14 such coverage at the time of enrollment, and at  
15 least annually thereafter, the information de-  
16 scribed in subsection (b) in printed form;

17 (B) provide to enrollees, within a reason-  
18 able period (as specified by the appropriate Sec-  
19 retary) before or after the date of significant  
20 changes in the information described in sub-  
21 section (b), information in printed form on such  
22 significant changes; and

23 (C) upon request, make available to the  
24 applicable authority, to individuals who are pro-  
25 spective enrollees, and to the public the infor-

1           mation described in subsection (b) or (c) in  
2           printed form.

3           (b) INFORMATION PROVIDED.—The information de-  
4           scribed in this subsection with respect to a group health  
5           plan or health insurance coverage offered by a health in-  
6           surance issuer includes the following:

7           (1) SERVICE AREA.—The service area of the  
8           plan or issuer.

9           (2) BENEFITS.—Benefits offered under the  
10          plan or coverage, including—

11           (A) covered benefits, including benefit lim-  
12           its and coverage exclusions;

13           (B) cost sharing, such as deductibles, coin-  
14           surance, and copayment amounts, including any  
15           liability for balance billing, any maximum limi-  
16           tations on out of pocket expenses, and the max-  
17           imum out of pocket costs for services that are  
18           provided by non participating providers or that  
19           are furnished without meeting the applicable  
20           utilization review requirements;

21           (C) the extent to which benefits may be ob-  
22           tained from nonparticipating providers;

23           (D) the extent to which a participant, ben-  
24           eficiary, or enrollee may select from among par-



1            participating providers and the types of providers  
2            participating in the plan or issuer network;

3            (E) process for determining experimental  
4            coverage; and

5            (F) use of a prescription drug formulary.

6            (3) ACCESS.—A description of the following:

7            (A) The number, mix, and distribution of  
8            providers under the plan or coverage.

9            (B) Out-of-network coverage (if any) pro-  
10            vided by the plan or coverage.

11            (C) Any point-of-service option (including  
12            any supplemental premium or cost-sharing for  
13            such option).

14            (D) The procedures for participants, bene-  
15            ficiaries, and enrollees to select, access, and  
16            change participating primary and specialty pro-  
17            viders.

18            (E) The rights and procedures for obtain-  
19            ing referrals (including standing referrals) to  
20            participating and nonparticipating providers.

21            (F) The name, address, and telephone  
22            number of participating health care providers  
23            and an indication of whether each such provider  
24            is available to accept new patients.

1           (G) Any limitations imposed on the selec-  
2           tion of qualifying participating health care pro-  
3           viders, including any limitations imposed under  
4           section 103(b)(2).

5           (H) How the plan or issuer addresses the  
6           needs of participants, beneficiaries, and enroll-  
7           ees and others who do not speak English or  
8           who have other special communications needs in  
9           accessing providers under the plan or coverage,  
10          including the provision of information described  
11          in this subsection and subsection (c) to such in-  
12          dividuals and including the provision of infor-  
13          mation in a language other than English if 5  
14          percent of the number of participants, bene-  
15          ficiaries, and enrollees communicate in that lan-  
16          guage instead of English.

17          (4) **OUT-OF-AREA COVERAGE.**—Out-of-area cov-  
18          erage provided by the plan or issuer.

19          (5) **EMERGENCY COVERAGE.**—Coverage of  
20          emergency services, including—

21                 (A) the appropriate use of emergency serv-  
22                 ices, including use of the 911 telephone system  
23                 or its local equivalent in emergency situations  
24                 and an explanation of what constitutes an  
25                 emergency situation;

1 (B) the process and procedures of the plan  
2 or issuer for obtaining emergency services; and

3 (C) the locations of (i) emergency depart-  
4 ments, and (ii) other settings, in which plan  
5 physicians and hospitals provide emergency  
6 services and post-stabilization care.

7 (6) PERCENTAGE OF PREMIUMS USED FOR  
8 BENEFITS (LOSS-RATIOS).—In the case of health in-  
9 surance coverage only (and not with respect to group  
10 health plans that do not provide coverage through  
11 health insurance coverage), a description of the over-  
12 all loss-ratio for the coverage (as defined in accord-  
13 ance with rules established or recognized by the Sec-  
14 retary of Health and Human Services).

15 (7) PRIOR AUTHORIZATION RULES.—Rules re-  
16 garding prior authorization or other review require-  
17 ments that could result in noncoverage or non-  
18 payment.

19 (8) GRIEVANCE AND APPEALS PROCEDURES.—  
20 All appeal or grievance rights and procedures under  
21 the plan or coverage, including the method for filing  
22 grievances and the time frames and circumstances  
23 for acting on grievances and appeals, who is the ap-  
24 plicable authority with respect to the plan or issuer,  
25 and the availability of assistance through an om-

1       budsman to individuals in relation to group health  
2       plans and health insurance coverage.

3               (9) QUALITY ASSURANCE.—A summary descrip-  
4       tion of the data on quality collected under section  
5       112(a), including a summary description of the data  
6       on satisfaction of participants, beneficiaries, and en-  
7       rollees (including data on individual voluntary  
8       disenrollment and grievances and appeals) described  
9       in section 112(b)(4).

10              (10) SUMMARY OF PROVIDER FINANCIAL IN-  
11       CENTIVES.—A summary description of the informa-  
12       tion on the types of financial payment incentives  
13       (described in section 1852(j)(4) of the Social Secu-  
14       rity Act) provided by the plan or issuer under the  
15       coverage.

16              (11) INFORMATION ON ISSUER.—Notice of ap-  
17       propriate mailing addresses and telephone numbers  
18       to be used by participants, beneficiaries, and enroll-  
19       ees in seeking information or authorization for treat-  
20       ment.

21              (12) AVAILABILITY OF INFORMATION ON RE-  
22       QUEST.—Notice that the information described in  
23       subsection (c) is available upon request.

1 (c) INFORMATION MADE AVAILABLE UPON RE-  
2 QUEST.—The information described in this subsection is  
3 the following:

4 (1) UTILIZATION REVIEW ACTIVITIES.—A de-  
5 scription of procedures used and requirements (in-  
6 cluding circumstances, time frames, and appeal  
7 rights) under any utilization review program under  
8 section 115, including under any drug formulary  
9 program under section 107.

10 (2) GRIEVANCE AND APPEALS INFORMATION.—  
11 Information on the number of grievances and ap-  
12 peals and on the disposition in the aggregate of such  
13 matters.

14 (3) METHOD OF PHYSICIAN COMPENSATION.—  
15 An overall summary description as to the method of  
16 compensation of participating physicians, including  
17 information on the types of financial payment incen-  
18 tives (described in section 1852(j)(4) of the Social  
19 Security Act) provided by the plan or issuer under  
20 the coverage.

21 (4) SPECIFIC INFORMATION ON CREDENTIALS  
22 OF PARTICIPATING PROVIDERS.—In the case of each  
23 participating provider, a description of the creden-  
24 tials of the provider.

1           (5) CONFIDENTIALITY POLICIES AND PROCE-  
2           DURES.—A description of the policies and proce-  
3           dures established to carry out section 122.

4           (6) FORMULARY RESTRICTIONS.—A description  
5           of the nature of any drug formula restrictions.

6           (7) PARTICIPATING PROVIDER LIST.—A list of  
7           current participating health care providers.

8           (d) FORM OF DISCLOSURE.—

9           (1) UNIFORMITY.—Information required to be  
10          disclosed under this section shall be provided in ac-  
11          cordance with uniform, national reporting standards  
12          specified by the Secretary, after consultation with  
13          applicable State authorities, so that prospective en-  
14          rollees may compare the attributes of different  
15          issuers and coverage offered within an area.

16          (2) INFORMATION INTO HANDBOOK.—Nothing  
17          in this section shall be construed as preventing a  
18          group health plan or health insurance issuer from  
19          making the information under subsections (b) and  
20          (c) available to participants, beneficiaries, and en-  
21          rollees through an enrollee handbook or similar pub-  
22          lication.

23          (3) UPDATING PARTICIPATING PROVIDER IN-  
24          FORMATION.—The information on participating  
25          health care providers described in subsection

1 (b)(3)(C) shall be updated within such reasonable  
2 period as determined appropriate by the Secretary.  
3 Nothing in this section shall prevent an issuer from  
4 changing or updating other information made avail-  
5 able under this section.

6 (e) CONSTRUCTION.—Nothing in this section shall be  
7 construed as requiring public disclosure of individual con-  
8 tracts or financial arrangements between a group health  
9 plan or health insurance issuer and any provider.

10 **SEC. 122. PROTECTION OF PATIENT CONFIDENTIALITY.**

11 Insofar as a group health plan, or a health insurance  
12 issuer that offers health insurance coverage, maintains  
13 medical records or other health information regarding par-  
14 ticipants, beneficiaries, and enrollees, the plan or issuer  
15 shall establish procedures—

16 (1) to safeguard the privacy of any individually  
17 identifiable enrollee information;

18 (2) to maintain such records and information in  
19 a manner that is accurate and timely, and

20 (3) to assure timely access of such individuals  
21 to such records and information.

22 **SEC. 123. HEALTH INSURANCE OMBUDSMEN.**

23 (a) IN GENERAL.—Each State that obtains a grant  
24 under subsection (c) shall provide for creation and oper-  
25 ation of a Health Insurance Ombudsman through a con-

1 tract with a not-for-profit organization that operates inde-  
2 pendent of group health plans and health insurance  
3 issuers. Such Ombudsman shall be responsible for at least  
4 the following:

5           (1) To assist consumers in the State in choos-  
6           ing among health insurance coverage or among cov-  
7           erage options offered within group health plans.

8           (2) To provide counseling and assistance to en-  
9           rollees dissatisfied with their treatment by health in-  
10          surance issuers and group health plans in regard to  
11          such coverage or plans and with respect to griev-  
12          ances and appeals regarding determinations under  
13          such coverage or plans.

14          (b) FEDERAL ROLE.—In the case of any State that  
15          does not provide for such an Ombudsman under sub-  
16          section (a), the Secretary shall provide for the creation  
17          and operation of a Health Insurance Ombudsman through  
18          a contract with a not-for-profit organization that operates  
19          independent of group health plans and health insurance  
20          issuers and that is responsible for carrying out with re-  
21          spect to that State the functions otherwise provided under  
22          subsection (a) by a Health Insurance Ombudsman.

23          (c) AUTHORIZATION OF APPROPRIATIONS.—There  
24          are authorized to be appropriated to the Secretary of  
25          Health and Human Services such amounts as may be nec-



1 essary to provide for grants to States for contracts for  
2 Health Insurance Ombudsmen under subsection (a) or  
3 contracts for such Ombudsmen under subsection (b).

4 (d) CONSTRUCTION.—Nothing in this section shall be  
5 construed to prevent the use of other forms of enrollee  
6 assistance.

## 7 **Subtitle D—Grievance and Appeals** 8 **Procedures**

### 9 **SEC. 131. ESTABLISHMENT OF GRIEVANCE PROCESS.**

10 (a) ESTABLISHMENT OF GRIEVANCE SYSTEM.—

11 (1) IN GENERAL.—A group health plan, and a  
12 health insurance issuer in connection with the provi-  
13 sion of health insurance coverage, shall establish and  
14 maintain a system to provide for the presentation  
15 and resolution of oral and written grievances  
16 brought by individuals who are participants, bene-  
17 ficiaries, or enrollees, or health care providers or  
18 other individuals acting on behalf of an individual  
19 and with the individual's consent, regarding any as-  
20 pect of the plan's or issuer's services.

21 (2) SCOPE.—The system shall include griev-  
22 ances regarding access to and availability of services,  
23 quality of care, choice and accessibility of providers,  
24 network adequacy, and compliance with the require-  
25 ments of this title.

1 (b) GRIEVANCE SYSTEM.—Such system shall include  
2 the following components with respect to individuals who  
3 are participants, beneficiaries, or enrollees:

4 (1) Written notification to all such individuals  
5 and providers of the telephone numbers and business  
6 addresses of the plan or issuer personnel responsible  
7 for resolution of grievances and appeals.

8 (2) A system to record and document, over a  
9 period of at least 3 previous years, all grievances  
10 and appeals made and their status.

11 (3) A process providing for timely processing  
12 and resolution of grievances.

13 (4) Procedures for follow-up action, including  
14 the methods to inform the person making the grievance  
15 of the resolution of the grievance.

16 (5) Notification to the continuous quality im-  
17 provement program under section 111(a) of all  
18 grievances and appeals relating to quality of care.

19 **SEC. 132. INTERNAL APPEALS OF ADVERSE DETERMINA-**  
20 **TIONS.**

21 (a) RIGHT OF APPEAL.—

22 (1) IN GENERAL.—A participant or beneficiary  
23 in a group health plan, and an enrollee in health in-  
24 surance coverage offered by a health insurance  
25 issuer, and any provider or other person acting on

1       behalf of such an individual with the individual's  
2       consent, may appeal any appealable decision (as de-  
3       fined in paragraph (2)) under the procedures de-  
4       scribed in this section and (to the extent applicable)  
5       section 133. Such individuals and providers shall be  
6       provided with a written explanation of the appeal  
7       process and the determination upon the conclusion  
8       of the appeals process and as provided in section  
9       121(b)(8).

10           (2) APPEALABLE DECISION DEFINED.—In this  
11       section, the term “appealable decision” means any of  
12       the following:

13           (A) Denial, reduction, or termination of, or  
14       failure to provide or make payment (in whole or  
15       in part) for, a benefit, including a failure to  
16       cover an item or service for which benefits are  
17       otherwise provided because it is determined to  
18       be experimental or investigational or not medi-  
19       cally necessary or appropriate.

20           (B) Failure to provide coverage of emer-  
21       gency services or reimbursement of mainte-  
22       nance care or post-stabilization care under sec-  
23       tion 101.

24           (C) Failure to provide a choice of provider  
25       under section 103.

1 (D) Failure to provide qualified health care  
2 providers under section 103.

3 (E) Failure to provide access to specialty  
4 and other care under section 104.

5 (F) Failure to provide continuation of care  
6 under section 105.

7 (G) Failure to provide coverage of routine  
8 patient costs in connection with an approval  
9 clinical trial under section 106.

10 (H) Failure to provide access to needed  
11 drugs under section 107(a)(3) or 107(b).

12 (I) Discrimination in delivery of services in  
13 violation of section 109.

14 (J) An adverse determination under a utili-  
15 zation review program under section 115.

16 (K) The imposition of a limitation that is  
17 prohibited under section 151.

18 (b) INTERNAL APPEAL PROCESS.—

19 (1) IN GENERAL.—Each group health plan and  
20 health insurance issuer shall establish and maintain  
21 an internal appeal process under which any partici-  
22 pant, beneficiary, enrollee, or provider acting on be-  
23 half of such an individual with the individual's con-  
24 sent, who is dissatisfied with any appealable decision  
25 has the opportunity to appeal the decision through

1 an internal appeal process. The appeal may be com-  
2 municated orally.

3 (2) CONDUCT OF REVIEW.—

4 (A) IN GENERAL.—The process shall in-  
5 clude a review of the decision by a physician or  
6 other health care professional (or professionals)  
7 who has been selected by the plan or issuer and  
8 who has not been involved in the appealable de-  
9 cision at issue in the appeal.

10 (B) AVAILABILITY AND PARTICIPATION OF  
11 CLINICAL PEERS.—The individuals conducting  
12 such review shall include one or more clinical  
13 peers (as defined in section 191(c)(2)) who have  
14 not been involved in the appealable decision at  
15 issue in the appeal.

16 (3) DEADLINE.—

17 (A) IN GENERAL.—Subject to subsection  
18 (c), the plan or issuer shall conclude each ap-  
19 peal as soon as possible after the time of the re-  
20 ceipt of the appeal in accordance with medical  
21 exigencies of the case involved, but in no event  
22 later than—

23 (i) 72 hours after the time of receipt  
24 of an expedited appeal, and

1 (ii) except as provided in subpara-  
2 graph (B), 15 business days after such  
3 time in the case of all other appeals.

4 (B) EXTENSION.—A group health plan or  
5 health insurance issuer may extend the deadline  
6 for an appeal that does not relate to a decision  
7 regarding an expedited appeal and that does  
8 not involve medical exigencies up to an addi-  
9 tional 10 business days where it can dem-  
10 onstrate to the applicable authority reasonable  
11 cause for the delay beyond its control and  
12 where it provides, within the original deadline  
13 under subparagraph (A), a written progress re-  
14 port and explanation for the delay to such au-  
15 thority and to the participant, beneficiary, or  
16 enrollee and provider involved.

17 (4) NOTICE.—If a plan or issuer denies an ap-  
18 peal, the plan or issuer shall provide the participant,  
19 beneficiary, or enrollee and provider involved with  
20 notice in printed form of the denial and the reasons  
21 therefore, together with a notice in printed form of  
22 rights to any further appeal.

23 (c) EXPEDITED REVIEW PROCESS.—

24 (1) IN GENERAL.—A group health plan, and a  
25 health insurance issuer, shall establish procedures in

1 writing for the expedited consideration of appeals  
2 under subsection (b) in situations in which the appli-  
3 cation of the normal timeframe for making a deter-  
4 mination could seriously jeopardize the life or health  
5 of the participant, beneficiary, or enrollee or such an  
6 individual's ability to regain maximum function.

7 (2) PROCESS.—Under such procedures—

8 (A) the request for expedited appeal may  
9 be submitted orally or in writing by an individ-  
10 ual or provider who is otherwise entitled to re-  
11 quest the appeal;

12 (B) all necessary information, including  
13 the plan's or issuer's decision, shall be trans-  
14 mitted between the plan or issuer and the re-  
15 quester by telephone, facsimile, or other simi-  
16 larly expeditious available method; and

17 (C) the plan or issuer shall expedite the  
18 appeal if the request for an expedited appeal is  
19 submitted under subparagraph (A) by a physi-  
20 cian and the request indicates that the situation  
21 described in paragraph (1) exists.

22 (d) DIRECT USE OF FURTHER APPEALS.—In the  
23 event that the plan or issuer fails to comply with any of  
24 the deadlines for completion of appeals under this section  
25 or in the event that the plan or issuer for any reason ex-

1 expressly waives its rights to an internal review of an appeal  
 2 under subsection (b), the participant, beneficiary, or en-  
 3 rollee involved and the provider involved shall be relieved  
 4 of any obligation to complete the appeal involved and may,  
 5 at such an individual's or provider's option, proceed di-  
 6 rectly to seek further appeal through any applicable exter-  
 7 nal appeals process.

8 **SEC. 133. EXTERNAL APPEALS OF ADVERSE DETERMINA-**  
 9 **TIONS.**

10 (a) **RIGHT TO EXTERNAL APPEAL.—**

11 (1) **IN GENERAL.—**A group health plan, and a  
 12 health insurance issuer offering group health insur-  
 13 ance coverage, shall provide for an external appeals  
 14 process that meets the requirements of this section  
 15 in the case of an externally appealable decision de-  
 16 scribed in paragraph (2). The appropriate Secretary  
 17 shall establish standards to carry out such require-  
 18 ments.

19 (2) **EXTERNALLY APPEALABLE DECISION DE-**  
 20 **FINED.—**For purposes of this section, the term “ex-  
 21 ternally appealable decision” means an appealable  
 22 decision (as defined in section 132(a)(2)) if—

23 (A) the amount involved exceeds a signifi-  
 24 cant threshold; or



1 (B) the patient's life or health is jeopard-  
2 ized as a consequence of the decision.

3 Such term does not include a denial of coverage for  
4 services that are specifically listed in plan or cov-  
5 erage documents as excluded from coverage.

6 (3) EXHAUSTION OF INTERNAL APPEALS PROC-  
7 ESS.—A plan or issuer may condition the use of an  
8 external appeal process in the case of an externally  
9 appealable decision upon completion of the internal  
10 review process provided under section 132, but only  
11 if the decision is made in a timely basis consistent  
12 with the deadlines provided under this subtitle.

13 (b) GENERAL ELEMENTS OF EXTERNAL APPEALS  
14 PROCESS.—

15 (1) CONTRACT WITH QUALIFIED EXTERNAL AP-  
16 PEAL ENTITY.—

17 (A) CONTRACT REQUIREMENT.—Subject to  
18 subparagraph (B), the external appeal process  
19 under this section of a plan or issuer shall be  
20 conducted under a contract between the plan or  
21 issuer and one or more qualified external appeal  
22 entities (as defined in subsection (c)).

23 (B) RESTRICTIONS ON QUALIFIED EXTER-  
24 NAL APPEAL ENTITY.—

1 (i) BY STATE FOR HEALTH INSUR-  
2 ANCE ISSUERS.—With respect to health in-  
3 surance issuers in a State, the State may  
4 provide for external review activities to be  
5 conducted by a qualified external appeal  
6 entity that is designated by the State or  
7 that is selected by the State in such a  
8 manner as to assure an unbiased deter-  
9 mination.

10 (ii) BY FEDERAL GOVERNMENT FOR  
11 GROUP HEALTH PLANS.—With respect to  
12 group health plans, the appropriate Sec-  
13 retary may exercise the same authority as  
14 a State may exercise with respect to health  
15 insurance issuers under clause (i). Such  
16 authority may include requiring the use of  
17 the qualified external appeal entity des-  
18 ignated or selected under such clause.

19 (iii) LIMITATION ON PLAN OR ISSUER  
20 SELECTION.—If an applicable authority  
21 permits more than one entity to qualify as  
22 a qualified external appeal entity with re-  
23 spect to a group health plan or health in-  
24 surance issuer and the plan or issuer may

1           select among such qualified entities, the  
2           applicable authority—

3                   (I) shall assure that the selection  
4                   process will not create any incentives  
5                   for external appeal entities to make a  
6                   decision in a biased manner, and

7                   (II) shall implement a procedures  
8                   for auditing a sample of decisions by  
9                   such entities to assure that no such  
10                  decisions are made in a biased man-  
11                  ner.

12                  (C) OTHER TERMS AND CONDITIONS.—  
13                  The terms and conditions of a contract under  
14                  this paragraph shall be consistent with the  
15                  standards the appropriate Secretary shall estab-  
16                  lish to assure there is no real or apparent con-  
17                  flict of interest in the conduct of external ap-  
18                  peal activities. Such contract shall provide that  
19                  the direct costs of the process (not including  
20                  costs of representation of a participant, bene-  
21                  ficiary, or enrollee) shall be paid by the plan or  
22                  issuer, and not by the participant, beneficiary,  
23                  or enrollee.

24                  (2) ELEMENTS OF PROCESS.—An external ap-  
25                  peal process shall be conducted consistent with

1 standards established by the appropriate Secretary  
2 that include at least the following:

3 (A) FAIR PROCESS; DE NOVO DETERMINA-  
4 TION.—The process shall provide for a fair, de  
5 novo determination.

6 (B) DETERMINATION CONCERNING EXTER-  
7 NALLY APPEALABLE DECISIONS.—A qualified  
8 external appeal entity shall determine whether a  
9 decision is an externally appealable decision and  
10 related decisions, including—

11 (i) whether such a decision involves an  
12 expedited appeal;

13 (ii) the appropriate deadlines for in-  
14 ternal review process required due to medi-  
15 cal exigencies in a case; and

16 (iii) whether such a process has been  
17 completed.

18 (C) OPPORTUNITY TO SUBMIT EVIDENCE,  
19 HAVE REPRESENTATION, AND MAKE ORAL  
20 PRESENTATION.—Each party to an externally  
21 appealable decision—

22 (i) may submit and review evidence  
23 related to the issues in dispute,

1           (ii) may use the assistance or rep-  
2           resentation of one or more individuals (any  
3           of whom may be an attorney), and

4           (iii) may make an oral presentation.

5           (D) PROVISION OF INFORMATION.—The  
6           plan or issuer involved shall provide timely ac-  
7           cess to all its records relating to the matter of  
8           the externally appealable decision and to all  
9           provisions of the plan or health insurance cov-  
10          erage (including any coverage manual) relating  
11          to the matter.

12          (E) TIMELY DECISIONS.—A determination  
13          by the external appeal entity on the decision  
14          shall—

15               (i) be made orally or in writing and,  
16               if it is made orally, shall be supplied to the  
17               parties in writing as soon as possible;

18               (ii) be binding on the plan or issuer;

19               (iii) be made in accordance with the  
20               medical exigencies of the case involved, but  
21               in no event later than 60 days (or 72  
22               hours in the case of an expedited appeal)  
23               from the date of completion of the filing of  
24               notice of external appeal of the decision;

1 (iv) state, in layperson’s language, the  
2 basis for the determination, including, if  
3 relevant, any basis in the terms or condi-  
4 tions of the plan or coverage; and

5 (v) inform the participant, beneficiary,  
6 or enrollee of the individual’s rights to seek  
7 further review by the courts (or other proc-  
8 ess) of the external appeal determination.

9 (c) QUALIFICATIONS OF EXTERNAL APPEAL ENTI-  
10 TIES.—

11 (1) IN GENERAL.—For purposes of this section,  
12 the term “qualified external appeal entity” means,  
13 in relation to a plan or issuer, an entity (which may  
14 be a governmental entity) that is certified under  
15 paragraph (2) as meeting the following require-  
16 ments:

17 (A) There is no real or apparent conflict of  
18 interest that would impede the entity conduct-  
19 ing external appeal activities independent of the  
20 plan or issuer.

21 (B) The entity conducts external appeal  
22 activities through clinical peers.

23 (C) The entity has sufficient medical, legal,  
24 and other expertise and sufficient staffing to  
25 conduct external appeal activities for the plan

1 or issuer on a timely basis consistent with sub-  
2 section (b)(3)(E).

3 (D) The entity meets such other require-  
4 ments as the appropriate Secretary may im-  
5 pose.

6 (2) CERTIFICATION OF EXTERNAL APPEAL EN-  
7 TITIES.—

8 (A) IN GENERAL.—In order to be treated  
9 as a qualified external appeal entity with re-  
10 spect to—

11 (i) a group health plan, the entity  
12 must be certified (and, in accordance with  
13 subparagraph (B), periodically recertified)  
14 as meeting the requirements of paragraph  
15 (1) by the Secretary of Labor (or under a  
16 process recognized or approved by the Sec-  
17 retary of Labor); or

18 (ii) a health insurance issuer operat-  
19 ing in a State, the entity must be certified  
20 (and, in accordance with subparagraph  
21 (B), periodically recertified) as meeting  
22 such requirements by the applicable State  
23 authority (or, if the States has not estab-  
24 lished an adequate certification and recer-  
25 tification process, by the Secretary of

1 Health and Human Services, or under a  
2 process recognized or approved by such  
3 Secretary).

4 (B) RECERTIFICATION PROCESS.—The ap-  
5 propriate Secretary shall develop standards for  
6 the recertification of external appeal entities.  
7 Such standards shall include a specification  
8 of—

9 (i) the information required to be sub-  
10 mitted as a condition of recertification on  
11 the entity's performance of external appeal  
12 activities, which information shall include  
13 the number of cases reviewed, a summary  
14 of the disposition of those cases, the length  
15 of time in making determinations on those  
16 cases, and such information as may be nec-  
17 essary to assure the independence of the  
18 entity from the plans or issuers for which  
19 external appeal activities are being con-  
20 ducted; and

21 (ii) the periodicity which recertifi-  
22 cation will be required.

23 (d) CONTINUING LEGAL RIGHTS OF ENROLLEES.—  
24 Nothing in this title shall be construed as removing any  
25 legal rights of participants, beneficiaries, enrollees, and



1 others under State or Federal law, including the right to  
2 file judicial actions to enforce rights.

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

5 **SEC. 141. PROHIBITION OF INTERFERENCE WITH CERTAIN**  
6 **MEDICAL COMMUNICATIONS.**

7 (a) PROHIBITION.—

8 (1) GENERAL RULE.—The provisions of any  
9 contract or agreement, or the operation of any con-  
10 tract or agreement, between a group health plan or  
11 health insurance issuer in relation to health insur-  
12 ance coverage (including any partnership, associa-  
13 tion, or other organization that enters into or ad-  
14 ministers such a contract or agreement) and a  
15 health care provider (or group of health care provid-  
16 ers) shall not prohibit or restrict the provider from  
17 engaging in medical communications with the pro-  
18 vider's patient.

19 (2) NULLIFICATION.—Any contract provision or  
20 agreement described in paragraph (1) shall be null  
21 and void.

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

24 (1) to prohibit the enforcement, as part of a  
25 contract or agreement to which a health care pro-

1 vider is a party, of any mutually agreed upon terms  
2 and conditions, including terms and conditions re-  
3 quiring a health care provider to participate in, and  
4 cooperate with, all programs, policies, and proce-  
5 dures developed or operated by a group health plan  
6 or health insurance issuer to assure, review, or im-  
7 prove the quality and effective utilization of health  
8 care services (if such utilization is according to  
9 guidelines or protocols that are based on clinical or  
10 scientific evidence and the professional judgment of  
11 the provider) but only if the guidelines or protocols  
12 under such utilization do not prohibit or restrict  
13 medical communications between providers and their  
14 patients; or

15 (2) to permit a health care provider to mis-  
16 represent the scope of benefits covered under the  
17 group health plan or health insurance coverage or to  
18 otherwise require a group health plan health insur-  
19 ance issuer to reimburse providers for benefits not  
20 covered under the plan or coverage.

21 (c) MEDICAL COMMUNICATION DEFINED.—In this  
22 section:

23 (1) IN GENERAL.—The term “medical commu-  
24 nication” means any communication made by a  
25 health care provider with a patient of the health care

1 provider (or the guardian or legal representative of  
2 such patient) with respect to—

3 (A) the patient’s health status, medical  
4 care, or treatment options;

5 (B) any utilization review requirements  
6 that may affect treatment options for the pa-  
7 tient; or

8 (C) any financial incentives that may af-  
9 fect the treatment of the patient.

10 (2) MISREPRESENTATION.—The term “medical  
11 communication” does not include a communication  
12 by a health care provider with a patient of the  
13 health care provider (or the guardian or legal rep-  
14 resentative of such patient) if the communication in-  
15 volves a knowing or willful misrepresentation by  
16 such provider.

17 **SEC. 142. PROHIBITION AGAINST TRANSFER OF INDEM-**  
18 **NIFICATION OR IMPROPER INCENTIVE AR-**  
19 **RANGEMENTS.**

20 (a) PROHIBITION OF TRANSFER OF INDEMNIFICA-  
21 TION.—

22 (1) IN GENERAL.—No contract or agreement  
23 between a group health plan or health insurance  
24 issuer (or any agent acting on behalf of such a plan  
25 or issuer) and a health care provider shall contain

1 any provision purporting to transfer to the health  
2 care provider by indemnification or otherwise any li-  
3 ability relating to activities, actions, or omissions of  
4 the plan, issuer, or agent (as opposed to the pro-  
5 vider).

6 (2) NULLIFICATION.—Any contract or agree-  
7 ment provision described in paragraph (1) shall be  
8 null and void.

9 (b) PROHIBITION OF IMPROPER PHYSICIAN INCEN-  
10 TIVE PLANS.—

11 (1) IN GENERAL.—A group health plan and a  
12 health insurance issuer offering health insurance  
13 coverage may not operate any physician incentive  
14 plan (as defined in subparagraph (B) of section  
15 1876(i)(8) of the Social Security Act) unless the re-  
16 quirements described in subparagraph (A) of such  
17 section are met with respect to such a plan.

18 (2) APPLICATION.—For purposes of carrying  
19 out paragraph (1), any reference in section  
20 1876(i)(8) of the Social Security Act to the Sec-  
21 retary, an eligible organization, or an individual en-  
22 rolled with the organization shall be treated as a ref-  
23 erence to the applicable authority, a group health  
24 plan or health insurance issuer, respectively, and a

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

3 **SEC. 143. ADDITIONAL RULES REGARDING PARTICIPATION**  
4 **OF HEALTH CARE PROFESSIONALS.**

5 (a) PROCEDURES.—Insofar as a group health plan,  
6 or health insurance issuer that offers health insurance cov-  
7 erage, provides benefits through participating health care  
8 professionals, the plan or issuer shall establish reasonable  
9 procedures relating to the participation (under an agree-  
10 ment between a professional and the plan or issuer) of  
11 such professionals under the plan or coverage. Such proce-  
12 dures shall include—

13 (1) providing notice of the rules regarding par-  
14 ticipation;

15 (2) providing written notice of participation de-  
16 cisions that are adverse to professionals; and

17 (3) providing a process within the plan or issuer  
18 for appealing such adverse decisions, including the  
19 presentation of information and views of the profes-  
20 sional regarding such decision.

21 (b) CONSULTATION IN MEDICAL POLICIES.—A group  
22 health plan, and health insurance issuer that offers health  
23 insurance coverage, shall consult with participating physi-  
24 cians (if any) regarding the plan's or issuer's medical pol-  
25 icy, quality, and medical management procedures.

1 **SEC. 144. PROTECTION FOR PATIENT ADVOCACY.**

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

12 (b) PROTECTION FOR QUALITY ADVOCACY BY  
13 HEALTH CARE PROFESSIONALS.—

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

18 (A) discloses information relating to the  
19 care, services, or conditions affecting one or  
20 more participants, beneficiaries, or enrollees of  
21 the plan or issuer to an appropriate public reg-  
22 ulatory agency, an appropriate private accredi-  
23 tation body, or appropriate management per-  
24 sonnel of the plan or issuer; or

25 (B) initiates, cooperates, or otherwise par-  
26 ticipates in an investigation or proceeding by

1           such an agency with respect to such care, serv-  
2           ices, or conditions.

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

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

22                   (A) the disclosure is made on the basis of  
23                   personal knowledge and is consistent with that  
24                   degree of learning and skill ordinarily possessed  
25                   by health care professionals with the same li-

1           censure or certification and the same experi-  
2           ence;

3           (B) the professional reasonably believes the  
4           information to be true;

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

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

17          (3) EXCEPTION AND SPECIAL RULE.—

18           (A) GENERAL EXCEPTION.—Paragraph (1)  
19           does not protect disclosures that would violate  
20           Federal or State law or diminish or impair the  
21           rights of any person to the continued protection  
22           of confidentiality of communications provided  
23           by such law.

24           (B) NOTICE OF INTERNAL PROCEDURES.—  
25           Subparagraph (D) of paragraph (2) shall not



1 apply unless the internal procedures involved  
2 are reasonably expected to be known to the  
3 health care professional involved. For purposes  
4 of this subparagraph, a health care professional  
5 is reasonably expected to know of internal pro-  
6 cedures if those procedures have been made  
7 available to the professional through distribu-  
8 tion or posting.

9 (C) INTERNAL PROCEDURE EXCEPTION.—

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

12 (i) the disclosure relates to an immi-  
13 nent hazard of loss of life or serious injury  
14 to a patient;

15 (ii) the disclosure is made to an ap-  
16 propriate private accreditation body pursu-  
17 ant to disclosure procedures established by  
18 the body; or

19 (iii) the disclosure is in response to an  
20 inquiry made in an investigation or pro-  
21 ceeding of an appropriate public regulatory  
22 agency and the information disclosed is  
23 limited to the scope of the investigation or  
24 proceeding.

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

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

16           (6) CONSTRUCTIONS.—

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

23           (B) ENFORCEMENT OF PEER REVIEW PRO-  
24 TOCOLS AND INTERNAL PROCEDURES.—Noth-  
25 ing in this subsection shall be construed to pro-

1           hibit a plan, issuer, or provider from establish-  
2           ing and enforcing reasonable peer review or uti-  
3           lization review protocols or determining whether  
4           a protected health care professional has com-  
5           plied with those protocols or from establishing  
6           and enforcing internal procedures for the pur-  
7           pose of addressing quality concerns.

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

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

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

23                 (B) with respect to an institutional health  
24                 care provider, is an employee of the provider or  
25                 has a contract or other arrangement with the

1 provider respecting the provision of health care  
2 services.

3 **Subtitle F—Promoting Good**  
4 **Medical Practice**

5 **SEC. 151. PROMOTING GOOD MEDICAL PRACTICE.**

6 (a) PROHIBITING ARBITRARY LIMITATIONS OR CON-  
7 DITIONS FOR THE PROVISION OF SERVICES.—

8 (1) IN GENERAL.—A group health plan, and a  
9 health insurance issuer in connection with the provi-  
10 sion of health insurance coverage, may not arbitrar-  
11 ily interfere with or alter the decision of the treating  
12 physician regarding the manner or setting in which  
13 particular services are delivered if the services are  
14 medically necessary or appropriate for treatment or  
15 diagnosis to the extent that such treatment or diag-  
16 nosis is otherwise a covered benefit.

17 (2) CONSTRUCTION.—Paragraph (1) shall not  
18 be construed as prohibiting a plan or issuer from  
19 limiting the delivery of services to one or more  
20 health care providers within a network of such pro-  
21 viders.

22 (b) NO CHANGE IN COVERAGE.—Subsection (a) shall  
23 not be construed as requiring coverage of particular serv-  
24 ices the coverage of which is otherwise not covered under

1 the terms of the plan or coverage or from conducting utili-  
 2 zation review activities consistent with this subsection.

3 (c) **MEDICAL NECESSITY OR APPROPRIATENESS DE-**  
 4 **FINED.**—In subsection (a), the term “medically necessary  
 5 or appropriate” means, with respect to a service or benefit,  
 6 a service or benefit which is consistent with generally ac-  
 7 cepted principles of professional medical practice.

8 **SEC. 152. STANDARDS RELATING TO BENEFITS FOR CER-**  
 9 **TAIN BREAST CANCER TREATMENT.**

10 (a) **REQUIREMENTS FOR MINIMUM HOSPITAL STAY**  
 11 **FOLLOWING MASTECTOMY OR LYMPH NODE DISSEC-**  
 12 **TION.**—

13 (1) **IN GENERAL.**—A group health plan, and a  
 14 health insurance issuer offering group health insur-  
 15 ance coverage, may not—

16 (A) except as provided in paragraph (2)—

17 (i) restrict benefits for any hospital  
 18 length of stay in connection with a mastec-  
 19 tomy for the treatment of breast cancer to  
 20 less than 48 hours, or

21 (ii) restrict benefits for any hospital  
 22 length of stay in connection with a lymph  
 23 node dissection for the treatment of breast  
 24 cancer to less than 24 hours, or

1           (B) require that a provider obtain author-  
2           ization from the plan or the issuer for prescrib-  
3           ing any length of stay required under subpara-  
4           graph (A) (without regard to paragraph (2)).

5           (2) EXCEPTION.—Paragraph (1)(A) shall not  
6           apply in connection with any group health plan or  
7           health insurance issuer in any case in which the de-  
8           cision to discharge the woman involved prior to the  
9           expiration of the minimum length of stay otherwise  
10          required under paragraph (1)(A) is made by the at-  
11          tending provider in consultation with the woman or  
12          in a case involving a partial mastectomy without  
13          lymph node dissection.

14          (b) PROHIBITIONS.—A group health plan, and a  
15          health insurance issuer offering group health insurance  
16          coverage in connection with a group health plan, may  
17          not—

18               (1) deny to a woman eligibility, or continued  
19               eligibility, to enroll or to renew coverage under the  
20               terms of the plan, solely for the purpose of avoiding  
21               the requirements of this section;

22               (2) provide monetary payments or rebates to  
23               women to encourage such women to accept less than  
24               the minimum protections available under this sec-  
25               tion;

1           (3) penalize or otherwise reduce or limit the re-  
2           imbursement of an attending provider because such  
3           provider provided care to an individual participant  
4           or beneficiary in accordance with this section;

5           (4) provide incentives (monetary or otherwise)  
6           to an attending provider to induce such provider to  
7           provide care to an individual participant or bene-  
8           ficiary in a manner inconsistent with this section; or

9           (5) subject to subsection (c)(3), restrict benefits  
10          for any portion of a period within a hospital length  
11          of stay required under subsection (a) in a manner  
12          which is less favorable than the benefits provided for  
13          any preceding portion of such stay.

14          (c) RULES OF CONSTRUCTION.—

15           (1) Nothing in this section shall be construed to  
16           require a woman who is a participant or bene-  
17           ficiary—

18                   (A) to undergo a mastectomy or lymph  
19                   node dissection in a hospital; or

20                   (B) to stay in the hospital for a fixed pe-  
21                   riod of time following a mastectomy or lymph  
22                   node dissection.

23           (2) This section shall not apply with respect to  
24           any group health plan, or any group health insur-  
25           ance coverage offered by a health insurance issuer,

1       which does not provide benefits for hospital lengths  
2       of stay in connection with a mastectomy or lymph  
3       node dissection for the treatment of breast cancer.

4           (3) Nothing in this section shall be construed as  
5       preventing a group health plan or issuer from impos-  
6       ing deductibles, coinsurance, or other cost-sharing in  
7       relation to benefits for hospital lengths of stay in  
8       connection with a mastectomy or lymph node dissec-  
9       tion for the treatment of breast cancer under the  
10      plan (or under health insurance coverage offered in  
11      connection with a group health plan), except that  
12      such coinsurance or other cost-sharing for any por-  
13      tion of a period within a hospital length of stay re-  
14      quired under subsection (a) may not be greater than  
15      such coinsurance or cost-sharing for any preceding  
16      portion of such stay.

17      (d) LEVEL AND TYPE OF REIMBURSEMENTS.—Noth-  
18      ing in this section shall be construed to prevent a group  
19      health plan or a health insurance issuer offering group  
20      health insurance coverage from negotiating the level and  
21      type of reimbursement with a provider for care provided  
22      in accordance with this section.

23      (e) EXCEPTION FOR HEALTH INSURANCE COVERAGE  
24      IN CERTAIN STATES.—



1           (1) IN GENERAL.—The requirements of this  
2 section shall not apply with respect to health insur-  
3 ance coverage if there is a State law (as defined in  
4 section 2723(d)(1) of the Public Health Service Act)  
5 for a State that regulates such coverage that is de-  
6 scribed in any of the following subparagraphs:

7           (A) Such State law requires such coverage  
8 to provide for at least a 48-hour hospital length  
9 of stay following a mastectomy performed for  
10 treatment of breast cancer and at least a 24-  
11 hour hospital length of stay following a lymph  
12 node dissection for treatment of breast cancer.

13           (B) Such State law requires, in connection  
14 with such coverage for surgical treatment of  
15 breast cancer, that the hospital length of stay  
16 for such care is left to the decision of (or re-  
17 quired to be made by) the attending provider in  
18 consultation with the woman involved.

19           (2) CONSTRUCTION.—Section 2723(a)(1) of the  
20 Public Health Service Act and section 731(a)(1) of  
21 the Employee Retirement Income Security Act of  
22 1974 shall not be construed as superseding a State  
23 law described in paragraph (1).

1 **SEC. 153. STANDARDS RELATING TO BENEFITS FOR RECON-**  
2 **STRUCTIVE BREAST SURGERY.**

3 (a) **REQUIREMENTS FOR RECONSTRUCTIVE BREAST**  
4 **SURGERY.—**

5 (1) **IN GENERAL.**—A group health plan, and a  
6 health insurance issuer offering group health insur-  
7 ance coverage, that provides coverage for breast sur-  
8 gery in connection with a mastectomy shall provide  
9 coverage for reconstructive breast surgery resulting  
10 from the mastectomy. Such coverage shall include  
11 coverage for all stages of reconstructive breast sur-  
12 gery performed on a nondiseased breast to establish  
13 symmetry with the diseased when reconstruction on  
14 the diseased breast is performed and coverage of  
15 prostheses and complications of mastectomy includ-  
16 ing lymphedema.

17 (2) **RECONSTRUCTIVE BREAST SURGERY DE-**  
18 **FINED.**—In this section, the term “reconstructive  
19 breast surgery” means surgery performed as a result  
20 of a mastectomy to reestablish symmetry between  
21 two breasts, and includes augmentation  
22 mammoplasty, reduction mammoplasty, and  
23 mastopexy.

24 (3) **MASTECTOMY DEFINED.**—In this section,  
25 the term “mastectomy” means the surgical removal  
26 of all or part of a breast.

1 (b) PROHIBITIONS.—

2 (1) DENIAL OF COVERAGE BASED ON COSMETIC  
3 SURGERY.—A group health plan, and a health insur-  
4 ance issuer offering group health insurance coverage  
5 in connection with a group health plan, may not  
6 deny coverage described in subsection (a)(1) on the  
7 basis that the coverage is for cosmetic surgery.

8 (2) APPLICATION OF SIMILAR PROHIBITIONS.—  
9 Paragraphs (2) through (5) of section 152 shall  
10 apply under this section in the same manner as they  
11 apply with respect to section 152.

12 (c) RULES OF CONSTRUCTION.—

13 (1) Nothing in this section shall be construed to  
14 require a woman who is a participant or beneficiary  
15 to undergo reconstructive breast surgery.

16 (2) This section shall not apply with respect to  
17 any group health plan, or any group health insur-  
18 ance coverage offered by a health insurance issuer,  
19 which does not provide benefits for mastectomies.

20 (3) Nothing in this section shall be construed as  
21 preventing a group health plan or issuer from impos-  
22 ing deductibles, coinsurance, or other cost-sharing in  
23 relation to benefits for reconstructive breast surgery  
24 under the plan (or under health insurance coverage  
25 offered in connection with a group health plan), ex-

1       cept that such coinsurance or other cost-sharing for  
2       any portion may not be greater than such coinsur-  
3       ance or cost-sharing that is otherwise applicable with  
4       respect to benefits for mastectomies.

5       (e) LEVEL AND TYPE OF REIMBURSEMENTS.—Noth-  
6       ing in this section shall be construed to prevent a group  
7       health plan or a health insurance issuer offering group  
8       health insurance coverage from negotiating the level and  
9       type of reimbursement with a provider for care provided  
10      in accordance with this section.

11      (f) EXCEPTION FOR HEALTH INSURANCE COVERAGE  
12      IN CERTAIN STATES.—

13           (1) IN GENERAL.—The requirements of this  
14      section shall not apply with respect to health insur-  
15      ance coverage if there is a State law (as defined in  
16      section 2723(d)(1) of the Public Health Service Act)  
17      for a State that regulates such coverage and that re-  
18      quires coverage of at least the coverage of recon-  
19      structive breast surgery otherwise required under  
20      this section.

21           (2) CONSTRUCTION.—Section 2723(a)(1) of the  
22      Public Health Service Act and section 731(a)(1) of  
23      the Employee Retirement Income Security Act of  
24      1974 shall not be construed as superseding a State  
25      law described in paragraph (1).

## 1                   **Subtitle G—Definitions**

### 2   **SEC. 191. DEFINITIONS.**

#### 3           (a) INCORPORATION OF GENERAL DEFINITIONS.—

4   The provisions of section 2971 of the Public Health Serv-  
5   ice Act shall apply for purposes of this title in the same  
6   manner as they apply for purposes of title XXVII of such  
7   Act.

8           (b) SECRETARY.—Except as otherwise provided, the  
9   term “Secretary” means the Secretary of Health and  
10   Human Services, in consultation with the Secretary of  
11   Labor and the Secretary of the Treasury and the term  
12   “appropriate Secretary” means the Secretary of Health  
13   and Human Services in relation to carrying out this title  
14   under sections 2706 and 2751 of the Public Health Serv-  
15   ice Act, the Secretary of Labor in relation to carrying out  
16   this title under section 713 of the Employee Retirement  
17   Income Security Act of 1974, and the Secretary of the  
18   Treasury in relation to carrying out this title under chap-  
19   ter 100 and section 4980D of the Internal Revenue Code  
20   of 1986.

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

23                   (1) APPLICABLE AUTHORITY.—The term “ap-  
24           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) CLINICAL PEER.—The term “clinical peer”  
13 means, with respect to a review or appeal, a physi-  
14 cian (allopathic or osteopathic) or other health care  
15 professional who holds a non-restricted license in a  
16 State and who is appropriately credentialed in the  
17 same or similar specialty as typically manages the  
18 medical condition, procedure, or treatment under re-  
19 view or appeal and includes a pediatric specialist  
20 where appropriate; except that only a physician may  
21 be a clinical peer with respect to the review or ap-  
22 peal of treatment rendered by a physician.

23 (3) HEALTH CARE PROVIDER.—The term  
24 “health care provider” includes a physician or other

1 health care professional, as well as an institutional  
2 provider of health care services.

3 (4) NONPARTICIPATING.—The term “non-  
4 participating” means, with respect to a health care  
5 provider that provides health care items and services  
6 to a participant, beneficiary, or enrollee under group  
7 health plan or health insurance coverage, a health  
8 care provider that is not a participating health care  
9 provider with respect to such items and services.

10 (5) PARTICIPATING.—The term “participating”  
11 mean, with respect to a health care provider that  
12 provides health care items and services to a partici-  
13 pant, beneficiary, or enrollee under group health  
14 plan or health insurance coverage offered by a  
15 health insurance issuer, a health care provider that  
16 furnishes such items and services under a contract  
17 or other arrangement with the plan or issuer.

18 **SEC. 192. PREEMPTION; STATE FLEXIBILITY; CONSTRUC-**  
19 **TION.**

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

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

1 solely relating to health insurance issuers in connec-  
2 tion with group health insurance coverage except to  
3 the extent that such standard or requirement pre-  
4 vents the application of a requirement of this title.

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

11 (b) RULES OF CONSTRUCTION.—Except as provided  
12 in sections 152 and 153, nothing in this title shall be con-  
13 strued as requiring a group health plan or health insur-  
14 ance coverage to provide specific benefits under the terms  
15 of such plan or coverage.

16 (c) DEFINITIONS.—For purposes of this section—

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

23 (2) STATE.—The term “State” includes a  
24 State, the Northern Mariana Islands, any political



1 subdivisions of a State or such Islands, or any agen-  
 2 cy or instrumentality of either.

3 **SEC. 193. REGULATIONS.**

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

12 **TITLE II—APPLICATION TO**  
 13 **GROUP HEALTH PLANS**  
 14 **UNDER THE INTERNAL REVE-**  
 15 **NUE CODE OF 1986**

16 **SEC. 201. AMENDMENTS TO THE INTERNAL REVENUE CODE**  
 17 **OF 1986.**

18 Subchapter B of chapter 100 of the Internal Revenue  
 19 Code of 1986 (as amended by section 1531(a) of the Tax-  
 20 payer Relief Act of 1997) is amended—

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

“Sec. 9813. Standard relating to patient freedom of choice.”;  
 and

1           (2) by inserting after section 9812 the follow-  
2           ing:

3   **“SEC. 9813. STANDARD RELATING TO PATIENTS’ BILL OF**  
4                                   **RIGHTS.**

5           “A group health plan shall comply with the require-  
6   ments of title I of the Patients’ Bill of Rights Act of 1998  
7   (as in effect as of the date of the enactment of such Act),  
8   and such requirements shall be deemed to be incorporated  
9   into this section.”.

10 **TITLE III—EFFECTIVE DATES;**  
11 **COORDINATION IN IMPLE-**  
12 **MENTATION**

13 **SEC. 301. EFFECTIVE DATES.**

14           (a) IN GENERAL.—Subject to subsection (b), the  
15   amendments made by section 201 (and title I insofar as  
16   it relates to such section) shall apply with respect to group  
17   health plans for plan years beginning on or after January  
18   1, 1999 (in this section referred to as the “general effec-  
19   tive date”) and also shall apply to portions of plan years  
20   occurring on and after such date.

21           (b) TREATMENT OF COLLECTIVE BARGAINING  
22   AGREEMENTS.—In the case of a group health plan main-  
23   tained pursuant to 1 or more collective bargaining agree-  
24   ments between employee representatives and 1 or more  
25   employers ratified before the date of enactment of this

1 Act, the amendments made by section 201 (and title I in-  
2 sofar as it relates to such section) shall not apply to plan  
3 years beginning before the later of—

4 (1) the date on which the last collective bar-  
5 gaining agreements relating to the plan terminates  
6 (determined without regard to any extension thereof  
7 agreed to after the date of enactment of this Act),  
8 or

9 (2) the general effective date.

10 For purposes of paragraph (1), any plan amendment made  
11 pursuant to a collective bargaining agreement relating to  
12 the plan which amends the plan solely to conform to any  
13 requirement added by this Act shall not be treated as a  
14 termination of such collective bargaining agreement.

○