^{108TH CONGRESS} 2D SESSION H.R. 4628

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

IN THE HOUSE OF REPRESENTATIVES

JUNE 21, 2004

Mr. DINGELL (for himself, Mr. ANDREWS, Mr. BERRY, Mr. STENHOLM, Mr. GEORGE MILLER of California, Mr. WAXMAN, Mr. STARK, Mr. RANGEL, Mr. BROWN of Ohio, Ms. PELOSI, Mr. HOYER, Mr. MENENDEZ, Mr. FROST, Mr. SANDLIN, Mr. EDWARDS, Mr. DAVIS of Florida, Mr. MEE-HAN, Mr. LAMPSON, Mr. HOLDEN, Mr. GREEN of Texas, Mr. BELL, Mr. MOORE, Mr. TURNER of Texas, Mr. PALLONE, Mrs. CAPPS, Mr. MEEKS of New York, Ms. Schakowsky, Mrs. Maloney, Ms. Delauro, Ms. WATERS, Mr. LARSON of Connecticut, Mr. JACKSON of Illinois, Mr. KEN-NEDY of Rhode Island, Ms. SLAUGHTER, Mr. SERRANO, Mr. LIPINSKI, Mr. Etheridge, Mr. Boswell, Mr. Strickland, Mr. Holt, Ms. Kap-TUR, Mr. ACKERMAN, Mr. HINCHEY, Mr. MCNULTY, Mr. GORDON, Ms. DEGETTE, Ms. KILPATRICK, Mr. SPRATT, Mr. SKELTON, Mr. CONYERS, Mr. Doyle, Mr. Oberstar, Mr. Stupak, Mr. Sherman, Mrs. McCar-THY of New York, Ms. LINDA T. SÁNCHEZ of California, and Mrs. TAUSCHER) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Education and the Workforce and Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

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

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

3 SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

- 4 (a) SHORT TITLE.—This Act may be cited as the
- 5 "Patients' Bill of Rights Act of 2004".
- 6 (b) TABLE OF CONTENTS.—The table of contents of
- 7 this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—IMPROVING MANAGED CARE

Subtitle A—Utilization review; claims; and internal and external appeals

- Sec. 101. Utilization review activities.
- Sec. 102. Procedures for initial claims for benefits and prior authorization determinations.
- Sec. 103. Internal appeals of claims denials.
- Sec. 104. Independent external appeals procedures.
- Sec. 105. Health Care Consumer Assistance Fund.

Subtitle B—Access to care

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

Subtitle C—Access to information

Sec. 121. Patient access to information.

Subtitle D—Protecting the doctor-patient relationship

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

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Sec. 135. Protection for patient advocacy.

Subtitle E—Definitions

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

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

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

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

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

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

- Sec. 401. Application of patient protection standards to group health plans and group health insurance coverage under the Employee Retirement Income Security Act of 1974.
- Sec. 402. Availability of civil remedies.
- Sec. 403. Cooperation between Federal and State authorities.

TITLE V—AMENDMENTS TO THE INTERNAL REVENUE CODE OF 1986

Subtitle A—Application of patient protection provisions

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

Subtitle B—Health care coverage access tax incentives

- Sec. 511. Credit for health insurance expenses of small businesses.
- Sec. 512. Certain grants by private foundations to qualified health benefit purchasing coalitions.
- Sec. 513. State grant program for market innovation.
- Sec. 514. Grant program to facilitate health benefits information for small employers.
- Sec. 515. State grant program for market innovation.

TITLE VI—EFFECTIVE DATES; COORDINATION IN IMPLEMENTATION

Sec. 601. Effective dates.

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Sec. 602. Coordination in implementation.

Sec. 603. Severability.

TITLE VII—MISCELLANEOUS PROVISIONS

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

TITLE I—IMPROVING MANAGED CARE Subtitle A—Utilization Review; Claims; and Internal and Exter- nal Appeals

6 SEC. 101. UTILIZATION REVIEW ACTIVITIES.

7 (a) COMPLIANCE WITH REQUIREMENTS.—

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

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

1	(3) UTILIZATION REVIEW DEFINED.—For pur-
2	poses of this section, the terms "utilization review"
3	and "utilization review activities" mean procedures
4	used to monitor or evaluate the use or coverage,
5	clinical necessity, appropriateness, efficacy, or effi-
6	ciency of health care services, procedures or settings,
7	and includes prospective review, concurrent review,
8	second opinions, case management, discharge plan-
9	ning, or retrospective review.
10	(b) WRITTEN POLICIES AND CRITERIA.—
11	(1) WRITTEN POLICIES.—A utilization review
12	program shall be conducted consistent with written
13	policies and procedures that govern all aspects of the
14	program.
15	(2) Use of written criteria.—
16	(A) IN GENERAL.—Such a program shall
17	utilize written clinical review criteria developed
18	with input from a range of appropriate actively
19	practicing health care professionals, as deter-
20	mined by the plan, pursuant to the program.
21	Such criteria shall include written clinical re-
22	view criteria that are based on valid clinical evi-
23	dence where available and that are directed spe-
24	cifically at meeting the needs of at-risk popu-
25	lations and covered individuals with chronic

conditions or severe illnesses, including genderspecific criteria and pediatric-specific criteria where available and appropriate.

4 (B) CONTINUING USE OF STANDARDS IN RETROSPECTIVE REVIEW.—If a health care 5 service has been specifically pre-authorized or 6 7 approved for a participant, beneficiary, or en-8 rollee under such a program, the program shall 9 not, pursuant to retrospective review, revise or 10 modify the specific standards, criteria, or proce-11 dures used for the utilization review for proce-12 dures, treatment, and services delivered to the 13 enrollee during the same course of treatment.

14 (C) REVIEW OF SAMPLE OF CLAIMS DENI15 ALS.—Such a program shall provide for a peri16 odic evaluation of the clinical appropriateness of
17 at least a sample of denials of claims for bene18 fits.

19 (c) CONDUCT OF PROGRAM ACTIVITIES.—

20 (1) ADMINISTRATION BY HEALTH CARE PRO21 FESSIONALS.—A utilization review program shall be
22 administered by qualified health care professionals
23 who shall oversee review decisions.

24 (2) USE OF QUALIFIED, INDEPENDENT PER25 SONNEL.—

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(A) IN GENERAL.—A utilization review

2 program shall provide for the conduct of utilization review activities only through personnel 3 4 who are qualified and have received appropriate training in the conduct of such activities under 5 6 the program. 7 (B) PROHIBITION OF CONTINGENT COM-8 PENSATION ARRANGEMENTS.—Such a program 9 shall not, with respect to utilization review ac-10 tivities, permit or provide compensation or any-11 thing of value to its employees, agents, or con-12 tractors in a manner that encourages denials of 13 claims for benefits. 14 (C) PROHIBITION OF CONFLICTS.—Such a 15 program shall not permit a health care profes-16 sional who is providing health care services to 17 an individual to perform utilization review ac-18 tivities in connection with the health care serv-19 ices being provided to the individual. 20 (3) ACCESSIBILITY OF REVIEW.—Such a pro-21 gram shall provide that appropriate personnel per-22 forming utilization review activities under the pro-23 gram, including the utilization review administrator, 24 are reasonably accessible by toll-free telephone dur-

ing normal business hours to discuss patient care

1 and allow response to telephone requests, and that 2 appropriate provision is made to receive and respond 3 promptly to calls received during other hours. 4 (4) LIMITS ON FREQUENCY.—Such a program 5 shall not provide for the performance of utilization 6 review activities with respect to a class of services 7 furnished to an individual more frequently than is 8 reasonably required to assess whether the services 9 under review are medically necessary and appro-10 priate. 11 SEC. 102. PROCEDURES FOR INITIAL CLAIMS FOR BENE-12 FITS AND PRIOR AUTHORIZATION DETER-13 **MINATIONS.** 14 (a) PROCEDURES OF INITIAL CLAIMS FOR BENE-15 FITS.— 16 (1) IN GENERAL.—A group health plan, and a 17 health insurance issuer offering health insurance 18 coverage, shall-19 (A) make a determination on an initial 20 claim for benefits by a participant, beneficiary, 21 or enrollee (or authorized representative) re-22 garding payment or coverage for items or serv-23 ices under the terms and conditions of the plan 24 or coverage involved, including any cost-sharing 25 amount that the participant, beneficiary, or enrollee is required to pay with respect to such claim for benefits; and

3 (B) notify a participant, beneficiary, or en-4 rollee (or authorized representative) and the 5 treating health care professional involved re-6 garding a determination on an initial claim for 7 benefits made under the terms and conditions 8 of the plan or coverage, including any cost-shar-9 ing amounts that the participant, beneficiary, 10 or enrollee may be required to make with re-11 spect to such claim for benefits, and of the 12 right of the participant, beneficiary, or enrollee 13 to an internal appeal under section 103.

14 (2) Access to information.—

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

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described in subparagraph (B) or (C) of subsection (b)(1), by such earlier time as may be necessary to comply with the applicable timeline under such subparagraph.

5 (B) LIMITED EFFECT OF FAILURE ON 6 PLAN OR ISSUER'S OBLIGATIONS.—Failure of 7 the participant, beneficiary, or enrollee to com-8 ply with the requirements of subparagraph (A) 9 shall not remove the obligation of the plan or 10 issuer to make a decision in accordance with 11 the medical exigencies of the case and as soon 12 as possible, based on the available information, 13 and failure to comply with the time limit estab-14 lished by this paragraph shall not remove the 15 obligation of the plan or issuer to comply with 16 the requirements of this section.

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

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1	timely manner on a form provided by the plan or
2	issuer. In the case of such an oral request for bene-
3	fits, the making of the request (and the timing of
4	such request) shall be treated as the making at that
5	time of a claim for such benefits without regard to
6	whether and when a written confirmation of such re-
7	quest is made.
8	(b) TIMELINE FOR MAKING DETERMINATIONS.—
9	(1) Prior Authorization determination.—
10	(A) IN GENERAL.—A group health plan,
11	and a health insurance issuer offering health in-
12	surance coverage, shall make a prior authoriza-
13	tion determination on a claim for benefits
14	(whether oral or written) in accordance with the
15	medical exigencies of the case and as soon as
16	possible, but in no case later than 14 days from
17	the date on which the plan or issuer receives in-
18	formation that is reasonably necessary to enable
19	the plan or issuer to make a determination on
20	the request for prior authorization and in no
21	case later than 28 days after the date of the
22	claim for benefits is received.
23	(B) EXPEDITED DETERMINATION.—Not-
24	withstanding subparagraph (A), a group health
25	plan, and a health insurance issuer offering

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

(I) IN GENERAL.—Subject to
clause (ii), in the case of a concurrent
review of ongoing care (including hospitalization), which results in a termi-

1	nation or reduction of such care, the
2	plan or issuer must provide by tele-
3	phone and in printed form notice of
4	the concurrent review determination
5	to the individual or the individual's
6	designee and the individual's health
7	care provider in accordance with the
8	medical exigencies of the case and as
9	soon as possible, with sufficient time
10	prior to the termination or reduction
11	to allow for an appeal under section
12	103(b)(3) to be completed before the
13	termination or reduction takes effect.
14	(II) CONTENTS OF NOTICE.—
15	Such notice shall include, with respect
16	to ongoing health care items and serv-
17	ices, the number of ongoing services
18	approved, the new total of approved
19	services, the date of onset of services,
20	and the next review date, if any, as
21	well as a statement of the individual's
22	rights to further appeal.
23	(ii) Rule of construction.—Clause
24	(i) shall not be construed as requiring
25	plans or issuers to provide coverage of care

that would exceed the coverage limitations
for such care.
(2) Retrospective determination.—A
group health plan, and a health insurance issuer of-
fering health insurance coverage, shall make a retro-
spective determination on a claim for benefits in ac-
cordance with the medical exigencies of the case and
as soon as possible, but not later than 30 days after
the date on which the plan or issuer receives infor-
mation that is reasonably necessary to enable the
plan or issuer to make a determination on the claim,
or, if earlier, 60 days after the date of receipt of the
claim for benefits.

(c) NOTICE OF A DENIAL OF A CLAIM FOR BENE-14 15 FITS.—Written notice of a denial made under an initial 16 claim for benefits shall be issued to the participant, bene-17 ficiary, or enrollee (or authorized representative) and the 18 treating health care professional in accordance with the 19 medical exigencies of the case and as soon as possible, but in no case later than 2 days after the date of the deter-20 mination (or, in the case described in subparagraph (B) 21 22 or (C) of subsection (b)(1), within the 72-hour or applicable period referred to in such subparagraph). 23

(d) REQUIREMENTS OF NOTICE OF DETERMINA-24 TIONS.—The written notice of a denial of a claim for bene-25

fits determination under subsection (c) shall be provided
 in printed form and written in a manner calculated to be
 understood by the participant, beneficiary, or enrollee and
 shall include—

5 (1) the specific reasons for the determination
6 (including a summary of the clinical or scientific evi7 dence used in making the determination);

8 (2) the procedures for obtaining additional in-9 formation concerning the determination; and

10 (3) notification of the right to appeal the deter11 mination and instructions on how to initiate an ap12 peal in accordance with section 103.

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

(1) AUTHORIZED REPRESENTATIVE.—The term
"authorized representative" means, with respect to
an individual who is a participant, beneficiary, or enrollee, any health care professional or other person
acting on behalf of the individual with the individual's consent or without such consent if the individual is medically unable to provide such consent.

(2) CLAIM FOR BENEFITS.—The term "claim
for benefits" means any request for coverage (including authorization of coverage), for eligibility, or
for payment in whole or in part, for an item or serv-

ice under a group health plan or health insurance
 coverage.

3 (3) DENIAL OF CLAIM FOR BENEFITS.—The
4 term "denial" means, with respect to a claim for
5 benefits, a denial (in whole or in part) of, or a fail6 ure to act on a timely basis upon, the claim for ben7 efits and includes a failure to provide benefits (in8 cluding items and services) required to be provided
9 under this title.

10 (4) TREATING HEALTH CARE PROFESSIONAL.—
11 The term "treating health care professional" means,
12 with respect to services to be provided to a partici13 pant, beneficiary, or enrollee, a health care profes14 sional who is primarily responsible for delivering
15 those services to the participant, beneficiary, or en16 rollee.

17 SEC. 103. INTERNAL APPEALS OF CLAIMS DENIALS.

18 (a) RIGHT TO INTERNAL APPEAL.—

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

23 (2) TIME FOR APPEAL.—

24 (A) IN GENERAL.—A group health plan,25 and a health insurance issuer offering health in-

1	surance coverage, shall ensure that a partici-
2	pant, beneficiary, or enrollee (or authorized rep-
3	resentative) has a period of not less than 180
4	days beginning on the date of a denial of a
5	claim for benefits under section 102 in which to
6	appeal such denial under this section.
7	(B) DATE OF DENIAL.—For purposes of
8	subparagraph (A), the date of the denial shall
9	be deemed to be the date as of which the partic-
10	ipant, beneficiary, or enrollee knew of the denial
11	of the claim for benefits.
12	(3) FAILURE TO ACT.—The failure of a plan or
13	issuer to issue a determination on a claim for bene-
14	fits under section 102 within the applicable timeline
15	established for such a determination under such sec-
16	tion is a denial of a claim for benefits for purposes
17	this subtitle as of the date of the applicable deadline.
18	(4) PLAN WAIVER OF INTERNAL REVIEW.—A
19	group health plan, or health insurance issuer offer-
20	ing health insurance coverage, may waive the inter-
21	nal review process under this section. In such case
22	the plan or issuer shall provide notice to the partici-
23	pant, beneficiary, or enrollee (or authorized rep-
24	resentative) involved, the participant, beneficiary, or
25	enrollee (or authorized representative) involved shall

be relieved of any obligation to complete the internal
 review involved, and may, at the option of such par ticipant, beneficiary, enrollee, or representative pro ceed directly to seek further appeal through external
 review under section 104 or otherwise.

6 (b) TIMELINES FOR MAKING DETERMINATIONS.—

7 (1) ORAL REQUESTS.—In the case of an appeal 8 of a denial of a claim for benefits under this section 9 that involves an expedited or concurrent determina-10 tion, a participant, beneficiary, or enrollee (or au-11 thorized representative) may request such appeal 12 orally. A group health plan, or health insurance 13 issuer offering health insurance coverage, may re-14 quire that the participant, beneficiary, or enrollee 15 (or authorized representative) provide written con-16 firmation of such request in a timely manner on a 17 form provided by the plan or issuer. In the case of 18 such an oral request for an appeal of a denial, the 19 making of the request (and the timing of such re-20 quest) shall be treated as the making at that time 21 of a request for an appeal without regard to whether 22 and when a written confirmation of such request is 23 made.

24 (2) Access to information.—

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

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

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1	obligation of the plan or issuer to comply with
2	the requirements of this section.
3	(3) Prior Authorization determina-
4	TIONS.—
5	(A) IN GENERAL.—Except as provided in
6	this paragraph or paragraph (4), a group
7	health plan, and a health insurance issuer offer-
8	ing health insurance coverage, shall make a de-
9	termination on an appeal of a denial of a claim
10	for benefits under this subsection in accordance
11	with the medical exigencies of the case and as
12	soon as possible, but in no case later than 14
13	days from the date on which the plan or issuer
14	receives information that is reasonably nec-
15	essary to enable the plan or issuer to make a
16	determination on the appeal and in no case
17	later than 28 days after the date the request
18	for the appeal is received.
19	(B) EXPEDITED DETERMINATION.—Not-
20	withstanding subparagraph (A), a group health
21	plan, and a health insurance issuer offering
22	health insurance coverage, shall expedite a prior

withstanding subparagraph (A), a group health plan, and a health insurance issuer offering health insurance coverage, shall expedite a prior authorization determination on an appeal of a denial of a claim for benefits described in subparagraph (A), when a request for such an ex-

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

17 (C) ONGOING CARE DETERMINATIONS.—

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

- 1 the individual or the individual's designee 2 and the individual's health care provider in 3 accordance with the medical exigencies of 4 the case and as soon as possible, with suf-5 ficient time prior to the termination or re-6 duction to allow for an external appeal 7 under section 104 to be completed before 8 the termination or reduction takes effect. 9 (ii) RULE OF CONSTRUCTION.—Clause
- (i) shall not be construed as requiring
 plans or issuers to provide coverage of care
 that would exceed the coverage limitations
 for such care.
- 14 (4)RETROSPECTIVE DETERMINATION.—A 15 group health plan, and a health insurance issuer of-16 fering health insurance coverage, shall make a retro-17 spective determination on an appeal of a denial of a 18 claim for benefits in no case later than 30 days after 19 the date on which the plan or issuer receives nec-20 essary information that is reasonably necessary to 21 enable the plan or issuer to make a determination on 22 the appeal and in no case later than 60 days after 23 the date the request for the appeal is received.
- 24 (c) CONDUCT OF REVIEW.—

1	(1) IN GENERAL.—A review of a denial of a
2	claim for benefits under this section shall be con-
3	ducted by an individual with appropriate expertise
4	who was not involved in the initial determination.
5	(2) PEER REVIEW OF MEDICAL DECISIONS BY
6	HEALTH CARE PROFESSIONALS.—A review of an ap-
7	peal of a denial of a claim for benefits that is based
8	on a lack of medical necessity and appropriateness,
9	or based on an experimental or investigational treat-
10	ment, or requires an evaluation of medical facts—
11	(A) shall be made by a physician
12	(allopathic or osteopathic); or
13	(B) in a claim for benefits provided by a
14	non-physician health professional, shall be made
15	by reviewer (or reviewers) including at least one
16	practicing non-physician health professional of
17	the same or similar specialty;
18	with appropriate expertise (including, in the case of
19	a child, appropriate pediatric expertise) and acting
20	within the appropriate scope of practice within the
21	State in which the service is provided or rendered,
22	who was not involved in the initial determination.
23	(d) Notice of Determination.—
24	(1) IN GENERAL.—Written notice of a deter-
25	mination made under an internal appeal of a denial

1	of a claim for benefits shall be issued to the partici-
2	pant, beneficiary, or enrollee (or authorized rep-
3	resentative) and the treating health care professional
4	in accordance with the medical exigencies of the case
5	and as soon as possible, but in no case later than
6	2 days after the date of completion of the review (or,
7	in the case described in subparagraph (B) or (C) of
8	subsection $(b)(3)$, within the 72-hour or applicable
9	period referred to in such subparagraph).
10	(2) FINAL DETERMINATION.—The decision by a
11	plan or issuer under this section shall be treated as
12	the final determination of the plan or issuer on a de-
13	nial of a claim for benefits. The failure of a plan or
14	issuer to issue a determination on an appeal of a de-
15	nial of a claim for benefits under this section within
16	the applicable timeline established for such a deter-
17	mination shall be treated as a final determination on
18	an appeal of a denial of a claim for benefits for pur-
19	poses of proceeding to external review under section
20	104.
01	(2) DROUTDRUTT OR NOTION With more of

(3) REQUIREMENTS OF NOTICE.—With respect
to a determination made under this section, the notice described in paragraph (1) shall be provided in
printed form and written in a manner calculated to

1	be understood by the participant, beneficiary, or en-
2	rollee and shall include—
3	(A) the specific reasons for the determina-
4	tion (including a summary of the clinical or sci-
5	entific evidence used in making the determina-
6	tion);
7	(B) the procedures for obtaining additional
8	information concerning the determination; and
9	(C) notification of the right to an inde-
10	pendent external review under section 104 and
11	instructions on how to initiate such a review.
12	SEC. 104. INDEPENDENT EXTERNAL APPEALS PROCE-
13	DURES.
13 14	DURES. (a) RIGHT TO EXTERNAL APPEAL.—A group health
14	(a) RIGHT TO EXTERNAL APPEAL.—A group health
14 15	(a) RIGHT TO EXTERNAL APPEAL.—A group health plan, and a health insurance issuer offering health insur-
14 15 16 17	(a) RIGHT TO EXTERNAL APPEAL.—A group health plan, and a health insurance issuer offering health insur- ance coverage, shall provide in accordance with this sec-
14 15 16 17	(a) RIGHT TO EXTERNAL APPEAL.—A group health plan, and a health insurance issuer offering health insur- ance coverage, shall provide in accordance with this sec- tion participants, beneficiaries, and enrollees (or author-
14 15 16 17 18	(a) RIGHT TO EXTERNAL APPEAL.—A group health plan, and a health insurance issuer offering health insur- ance coverage, shall provide in accordance with this sec- tion participants, beneficiaries, and enrollees (or author- ized representatives) with access to an independent exter-
14 15 16 17 18 19	(a) RIGHT TO EXTERNAL APPEAL.—A group health plan, and a health insurance issuer offering health insur- ance coverage, shall provide in accordance with this sec- tion participants, beneficiaries, and enrollees (or author- ized representatives) with access to an independent exter- nal review for any denial of a claim for benefits.
 14 15 16 17 18 19 20 	 (a) RIGHT TO EXTERNAL APPEAL.—A group health plan, and a health insurance issuer offering health insurance coverage, shall provide in accordance with this section participants, beneficiaries, and enrollees (or authorized representatives) with access to an independent external review for any denial of a claim for benefits. (b) INITIATION OF THE INDEPENDENT EXTERNAL
 14 15 16 17 18 19 20 21 	 (a) RIGHT TO EXTERNAL APPEAL.—A group health plan, and a health insurance issuer offering health insurance coverage, shall provide in accordance with this section participants, beneficiaries, and enrollees (or authorized representatives) with access to an independent external review for any denial of a claim for benefits. (b) INITIATION OF THE INDEPENDENT EXTERNAL REVIEW PROCESS.—
 14 15 16 17 18 19 20 21 22 	 (a) RIGHT TO EXTERNAL APPEAL.—A group health plan, and a health insurance issuer offering health insurance coverage, shall provide in accordance with this section participants, beneficiaries, and enrollees (or authorized representatives) with access to an independent external review for any denial of a claim for benefits. (b) INITIATION OF THE INDEPENDENT EXTERNAL REVIEW PROCESS.— (1) TIME TO FILE.—A request for an inde-

1	or enrollee receives notice of the denial under section
2	103(d) or notice of waiver of internal review under
3	section $103(a)(4)$ or the date on which the plan or
4	issuer has failed to make a timely decision under
5	section $103(d)(2)$ and notifies the participant or
6	beneficiary that it has failed to make a timely deci-
7	sion and that the beneficiary must file an appeal
8	with an external review entity within 180 days if the
9	participant or beneficiary desires to file such an ap-
10	peal.
11	(2) FILING OF REQUEST.—
12	(A) IN GENERAL.—Subject to the suc-
13	ceeding provisions of this subsection, a group
14	health plan, or health insurance issuer offering
15	health insurance coverage, may—
16	(i) except as provided in subparagraph
17	(B)(i), require that a request for review be
18	in writing;
19	(ii) limit the filing of such a request
20	to the participant, beneficiary, or enrollee
21	involved (or an authorized representative);
22	(iii) except if waived by the plan or
23	issuer under section $103(a)(4)$, condition
24	access to an independent external review
25	under this section upon a final determina-

1	tion of a denial of a claim for benefits
2	under the internal review procedure under
3	section 103;
4	(iv) except as provided in subpara-
5	graph (B)(ii), require payment of a filing
6	fee to the plan or issuer of a sum that does
7	not exceed \$25; and
8	(v) require that a request for review
9	include the consent of the participant, ben-
10	eficiary, or enrollee (or authorized rep-
11	resentative) for the release of necessary
12	medical information or records of the par-
13	ticipant, beneficiary, or enrollee to the
14	qualified external review entity only for
15	purposes of conducting external review ac-
16	tivities.
17	(B) REQUIREMENTS AND EXCEPTION RE-
18	LATING TO GENERAL RULE.—
19	(i) Oral requests permitted in
20	EXPEDITED OR CONCURRENT CASES.—In
21	the case of an expedited or concurrent ex-
22	ternal review as provided for under sub-
23	section (e), the request for such review
24	may be made orally. A group health plan,
25	or health insurance issuer offering health

insurance coverage, may require that the participant, beneficiary, or enrollee (or authorized representative) provide written confirmation of such request in a timely manner on a form provided by the plan or issuer. Such written confirmation shall be treated as a consent for purposes of subparagraph (A)(v). In the case of such an oral request for such a review, the making of the request (and the timing of such request) shall be treated as the making at that time of a request for such a review without regard to whether and when a written confirmation of such request is made.

16 (ii) EXCEPTION TO FILING FEE RE17 QUIREMENT.—

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

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1	indigent (as defined in such guide-
2	lines).
3	(II) FEE NOT REQUIRED.—Pay-
4	ment of a filing fee shall not be re-
5	quired under subparagraph (A)(iv) if
6	the plan or issuer waives the internal
7	appeals process under section
8	103(a)(4).
9	(III) Refunding of fee.—The
10	filing fee paid under subparagraph
11	(A)(iv) shall be refunded if the deter-
12	mination under the independent exter-
13	nal review is to reverse or modify the
14	denial which is the subject of the re-
15	view.
16	(IV) Collection of filing
17	FEE.—The failure to pay such a filing
18	fee shall not prevent the consideration
19	of a request for review but, subject to
20	the preceding provisions of this clause,
21	shall constitute a legal liability to pay.
22	(c) Referral to Qualified External Review
23	Entity Upon Request.—
24	(1) IN GENERAL.—Upon the filing of a request
25	for independent external review with the group

health plan, or health insurance issuer offering
health insurance coverage, the plan or issuer shall
immediately refer such request, and forward the
plan or issuer's initial decision (including the information described in section 103(d)(3)(A)), to a
qualified external review entity selected in accordance with this section.

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

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

1	(A) IN GENERAL.—With respect to a re-
2	quest referred to a qualified external review en-
3	tity under paragraph (1) relating to a denial of
4	a claim for benefits, the entity shall refer such
5	request for the conduct of an independent med-
6	ical review unless the entity determines that—
7	(i) any of the conditions described in
8	clauses (ii) or (iii) of subsection $(b)(2)(A)$
9	have not been met;
10	(ii) the denial of the claim for benefits
11	does not involve a medically reviewable de-
12	cision under subsection $(d)(2)$;
13	(iii) the denial of the claim for bene-
14	fits relates to a decision regarding whether
15	an individual is a participant, beneficiary,
16	or enrollee who is enrolled under the terms
17	and conditions of the plan or coverage (in-
18	cluding the applicability of any waiting pe-
19	riod under the plan or coverage); or
20	(iv) the denial of the claim for bene-
21	fits is a decision as to the application of
22	cost-sharing requirements or the applica-
23	tion of a specific exclusion or express limi-
24	tation on the amount, duration, or scope of
25	coverage of items or services under the

1	terms and conditions of the plan or cov-
2	erage unless the decision is a denial de-
3	scribed in subsection $(d)(2)$.
4	Upon making a determination that any of
5	clauses (i) through (iv) applies with respect to
6	the request, the entity shall determine that the
7	denial of a claim for benefits involved is not eli-
8	gible for independent medical review under sub-
9	section (d), and shall provide notice in accord-
10	ance with subparagraph (C).
11	(B) PROCESS FOR MAKING DETERMINA-
12	TIONS.—
13	(i) NO DEFERENCE TO PRIOR DETER-
14	MINATIONS.—In making determinations
15	under subparagraph (A), there shall be no
16	deference given to determinations made by
17	the plan or issuer or the recommendation
18	of a treating health care professional (if
19	any).
20	(ii) USE OF APPROPRIATE PER-
21	SONNEL.—A qualified external review enti-
22	ty shall use appropriately qualified per-
23	sonnel to make determinations under this
24	section.

1	(C) NOTICES AND GENERAL TIMELINES
2	FOR DETERMINATION.—
3	(i) NOTICE IN CASE OF DENIAL OF

 $(\mathbf{1})$ 4 REFERRAL.—If the entity under this para-5 graph does not make a referral to an inde-6 pendent medical reviewer, the entity shall provide notice to the plan or issuer, the 7 participant, beneficiary, or enrollee (or au-8 9 thorized representative) filing the request, 10 and the treating health care professional 11 (if any) that the denial is not subject to 12 independent medical review. Such notice— 13 (I) shall be written (and, in addi-14

14tion, may be provided orally) in a15manner calculated to be understood16by a participant or enrollee;

17 (II) shall include the reasons for18 the determination;

19(III) include any relevant terms20and conditions of the plan or cov-21erage; and

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

1	(ii) GENERAL TIMELINE FOR DETER-
2	MINATIONS.—Upon receipt of information
3	under paragraph (2), the qualified external
4	review entity, and if required the inde-
5	pendent medical reviewer, shall make a de-
6	termination within the overall timeline that
7	is applicable to the case under review as
8	described in subsection (e), except that if
9	the entity determines that a referral to an
10	independent medical reviewer is not re-
11	quired, the entity shall provide notice of
12	such determination to the participant, ben-
13	eficiary, or enrollee (or authorized rep-
14	resentative) within such timeline and with-
15	in 2 days of the date of such determina-
16	tion.
17	(d) INDEPENDENT MEDICAL REVIEW.—
18	(1) IN GENERAL.—If a qualified external review
19	entity determines under subsection (c) that a denial
20	of a claim for benefits is eligible for independent
21	medical review, the entity shall refer the denial in-
22	volved to an independent medical reviewer for the
23	conduct of an independent medical review under this
24	subsection.

1	(2) Medically reviewable decisions.—A
2	denial of a claim for benefits is eligible for inde-
3	pendent medical review if the benefit for the item or
4	service for which the claim is made would be a cov-
5	ered benefit under the terms and conditions of the
6	plan or coverage but for one (or more) of the fol-
7	lowing determinations:
8	(A) DENIALS BASED ON MEDICAL NECES-
9	SITY AND APPROPRIATENESS.—A determination
10	that the item or service is not covered because
11	it is not medically necessary and appropriate or
12	based on the application of substantially equiva-
13	lent terms.
14	(B) DENIALS BASED ON EXPERIMENTAL
15	OR INVESTIGATIONAL TREATMENT.—A deter-
16	mination that the item or service is not covered
17	because it is experimental or investigational or
18	based on the application of substantially equiva-
19	lent terms.
20	(C) DENIALS OTHERWISE BASED ON AN
21	EVALUATION OF MEDICAL FACTS.—A deter-
22	mination that the item or service or condition
23	is not covered based on grounds that require an
24	evaluation of the medical facts by a health care
25	professional in the specific case involved to de-

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1	termine the coverage and extent of coverage of
2	the item or service or condition.
3	(3) INDEPENDENT MEDICAL REVIEW DETER-
4	MINATION.—
5	(A) IN GENERAL.—An independent med-
6	ical reviewer under this section shall make a
7	new independent determination with respect to
8	whether or not the denial of a claim for a ben-
9	efit that is the subject of the review should be
10	upheld, reversed, or modified.
11	(B) STANDARD FOR DETERMINATION.—
12	The independent medical reviewer's determina-
13	tion relating to the medical necessity and ap-
14	propriateness, or the experimental or investiga-
15	tional nature, or the evaluation of the medical
16	facts, of the item, service, or condition involved
17	shall be based on the medical condition of the
18	participant, beneficiary, or enrollee (including
19	the medical records of the participant, bene-
20	ficiary, or enrollee) and valid, relevant scientific
21	evidence and clinical evidence, including peer-re-
22	viewed medical literature or findings and in-
23	cluding expert opinion.
24	(C) NO COVERAGE FOR EXCLUDED BENE-
25	FITS.—Nothing in this subsection shall be con-

1	strued to permit an independent medical re-
2	viewer to require that a group health plan, or
3	health insurance issuer offering health insur-
4	ance coverage, provide coverage for items or
5	services for which benefits are specifically ex-
6	cluded or expressly limited under the plan or
7	coverage in the plain language of the plan docu-
8	ment (and which are disclosed under section
9	121(b)(1)(C)). Notwithstanding any other pro-
10	vision of this Act, any exclusion of an exact
11	medical procedure, any exact time limit on the
12	duration or frequency of coverage, and any
13	exact dollar limit on the amount of coverage
14	that is specifically enumerated and defined (in
15	the plain language of the plan or coverage docu-
16	ments) under the plan or coverage offered by a
17	group health plan or health insurance issuer of-
18	fering health insurance coverage and that is
19	disclosed under section $121(b)(1)$ shall be con-
20	sidered to govern the scope of the benefits that
21	may be required: <i>Provided</i> , That the terms and
22	conditions of the plan or coverage relating to
23	such an exclusion or limit are in compliance
24	with the requirements of law.

1	(D) EVIDENCE AND INFORMATION TO BE
2	USED IN MEDICAL REVIEWS.—In making a de-
3	termination under this subsection, the inde-
4	pendent medical reviewer shall also consider ap-
5	propriate and available evidence and informa-
6	tion, including the following:
7	(i) The determination made by the
8	plan or issuer with respect to the claim
9	upon internal review and the evidence,
10	guidelines, or rationale used by the plan or
11	issuer in reaching such determination.
12	(ii) The recommendation of the treat-
13	ing health care professional and the evi-
14	dence, guidelines, and rationale used by
15	the treating health care professional in
16	reaching such recommendation.
17	(iii) Additional relevant evidence or
18	information obtained by the reviewer or
19	submitted by the plan, issuer, participant,
20	beneficiary, or enrollee (or an authorized
21	representative), or treating health care
22	professional.
23	(iv) The plan or coverage document.
24	(E) INDEPENDENT DETERMINATION.—In
25	making determinations under this section, a

1 qualified external review entity and an inde-2 pendent medical reviewer shall— (i) consider the claim under review 3 4 without deference to the determinations 5 made by the plan or issuer or the rec-6 ommendation of the treating health care 7 professional (if any); and 8 (ii) consider, but not be bound by, the 9 definition used by the plan or issuer of "medically necessary and appropriate", or 10 11 "experimental or investigational", or other 12 substantially equivalent terms that are 13 used by the plan or issuer to describe med-14 ical necessity and appropriateness or ex-15 perimental or investigational nature of the 16 treatment. 17 (F) DETERMINATION OF INDEPENDENT 18 MEDICAL REVIEWER.—An independent medical 19 reviewer shall, in accordance with the deadlines 20 described in subsection (e), prepare a written 21 determination to uphold, reverse, or modify the 22 denial under review. Such written determination 23 shall include— 24 (i) the determination of the reviewer;

1	(ii) the specific reasons of the re-
2	viewer for such determination, including a
3	summary of the clinical or scientific evi-
4	dence used in making the determination;
5	and
6	(iii) with respect to a determination to
7	reverse or modify the denial under review,
8	a timeframe within which the plan or
9	issuer must comply with such determina-
10	tion.
11	(G) Nonbinding nature of additional
12	RECOMMENDATIONS.—In addition to the deter-
13	mination under subparagraph (F), the reviewer
14	may provide the plan or issuer and the treating
15	health care professional with additional rec-
16	ommendations in connection with such a deter-
17	mination, but any such recommendations shall
18	not affect (or be treated as part of) the deter-
19	mination and shall not be binding on the plan
20	or issuer.
21	(e) TIMELINES AND NOTIFICATIONS.—
22	(1) TIMELINES FOR INDEPENDENT MEDICAL
23	REVIEW.—
24	(A) Prior authorization determina-
25	TION.—

1	(i) IN GENERAL.—The independent
2	medical reviewer (or reviewers) shall make
3	a determination on a denial of a claim for
4	benefits that is referred to the reviewer
5	under subsection $(c)(3)$ in accordance with
6	the medical exigencies of the case and as
7	soon as possible, but in no case later than
8	14 days after the date of receipt of infor-
9	mation under subsection $(c)(2)$ if the re-
10	view involves a prior authorization of items
11	or services and in no case later than 21
12	days after the date the request for external
13	review is received.
14	(ii) EXPEDITED DETERMINATION.—
15	Notwithstanding clause (i) and subject to
16	clause (iii), the independent medical re-
17	viewer (or reviewers) shall make an expe-
18	dited determination on a denial of a claim
19	for benefits described in clause (i), when a
20	request for such an expedited determina-
21	tion is made by a participant, beneficiary,
22	or enrollee (or authorized representative)
23	at any time during the process for making
24	a determination, and a health care profes-
25	sional certifies, with the request, that a de-

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

13 (iii) ONGOING CARE DETERMINA-TION.—Notwithstanding clause (i), in the 14 15 case of a review described in such clause 16 that involves a termination or reduction of 17 care, the notice of the determination shall 18 be completed not later than 24 hours after 19 the time the request for external review is 20 received by the qualified external review 21 entity and before the end of the approved 22 period of care.

23 (B) RETROSPECTIVE DETERMINATION.—
24 The independent medical reviewer (or review25 ers) shall complete a review in the case of a ret-

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

9 (2) NOTIFICATION OF DETERMINATION.—The 10 external review entity shall ensure that the plan or 11 issuer, the participant, beneficiary, or enrollee (or 12 authorized representative) and the treating health 13 care professional (if any) receives a copy of the writ-14 ten determination of the independent medical re-15 viewer prepared under subsection (d)(3)(F). Nothing 16 in this paragraph shall be construed as preventing 17 an entity or reviewer from providing an initial oral 18 notice of the reviewer's determination.

19 (3) FORM OF NOTICES.—Determinations and
20 notices under this subsection shall be written in a
21 manner calculated to be understood by a participant.
22 (f) COMPLIANCE.—

23 (1) APPLICATION OF DETERMINATIONS.—
24 (A) EXTERNAL REVIEW DETERMINATIONS
25 BINDING ON PLAN.—The determinations of an

1	external review entity and an independent med-
2	ical reviewer under this section shall be binding
3	upon the plan or issuer involved.
4	(B) COMPLIANCE WITH DETERMINA-
5	TION.—If the determination of an independent
6	medical reviewer is to reverse or modify the de-
7	nial, the plan or issuer, upon the receipt of such
8	determination, shall authorize coverage to com-
9	ply with the medical reviewer's determination in
10	accordance with the timeframe established by
11	the medical reviewer.
12	(2) Failure to comply.—
13	(A) IN GENERAL.—If a plan or issuer fails
14	to comply with the timeframe established under
15	paragraph (1)(B) with respect to a participant,
16	beneficiary, or enrollee, where such failure to
17	comply is caused by the plan or issuer, the par-
18	ticipant, beneficiary, or enrollee may obtain the
19	items or services involved (in a manner con-
20	sistent with the determination of the inde-
21	pendent external reviewer) from any provider
22	regardless of whether such provider is a partici-
23	pating provider under the plan or coverage.

24 (B) REIMBURSEMENT.—

1	(i) IN GENERAL.—Where a partici-
2	pant, beneficiary, or enrollee obtains items
3	or services in accordance with subpara-
4	graph (A), the plan or issuer involved shall
5	provide for reimbursement of the costs of
6	such items or services. Such reimburse-
7	ment shall be made to the treating health
8	care professional or to the participant, ben-
9	eficiary, or enrollee (in the case of a partic-
10	ipant, beneficiary, or enrollee who pays for
11	the costs of such items or services).
12	(ii) Amount.—The plan or issuer
13	shall fully reimburse a professional, partici-
14	pant, beneficiary, or enrollee under clause
15	(i) for the total costs of the items or serv-
16	ices provided (regardless of any plan limi-
17	tations that may apply to the coverage of
18	such items or services) so long as the items
19	or services were provided in a manner con-
20	sistent with the determination of the inde-
21	pendent medical reviewer.
22	(C) FAILURE TO REIMBURSE.—Where a
23	plan or issuer fails to provide reimbursement to
24	a professional, participant, beneficiary, or en-
25	rollee in accordance with this paragraph, the

1	professional, participant, beneficiary, or enrollee
2	may commence a civil action (or utilize other
3	remedies available under law) to recover only
4	the amount of any such reimbursement that is
5	owed by the plan or issuer and any necessary
6	legal costs or expenses (including attorney's
7	fees) incurred in recovering such reimburse-
8	ment.
9	(D) AVAILABLE REMEDIES.—The remedies
10	provided under this paragraph are in addition
11	to any other available remedies.
12	(3) Penalties against authorized offi-
13	CIALS FOR REFUSING TO AUTHORIZE THE DETER-
14	MINATION OF AN EXTERNAL REVIEW ENTITY.—
15	(A) MONETARY PENALTIES.—
16	(i) IN GENERAL.—In any case in
17	which the determination of an external re-
18	view entity is not followed by a group
19	health plan, or by a health insurance issuer
20	offering health insurance coverage, any
21	person who, acting in the capacity of au-
22	thorizing the benefit, causes such refusal
23	may, in the discretion of a court of com-
24	petent jurisdiction, be liable to an ag-
25	grieved participant, beneficiary, or enrollee

1	for a civil penalty in an amount of up to
2	\$1,000 a day from the date on which the
3	determination was transmitted to the plan
4	or issuer by the external review entity until
5	the date the refusal to provide the benefit
6	is corrected.
7	(ii) Additional penalty for fail-
8	ING TO FOLLOW TIMELINE.—In any case
9	in which treatment was not commenced by
10	the plan in accordance with the determina-
11	tion of an independent external reviewer,
12	the Secretary shall assess a civil penalty of
13	\$10,000 against the plan and the plan
14	shall pay such penalty to the participant,
15	beneficiary, or enrollee involved.
16	(B) CEASE AND DESIST ORDER AND
17	ORDER OF ATTORNEY'S FEESIn any action
18	described in subparagraph (A) brought by a
19	participant, beneficiary, or enrollee with respect
20	to a group health plan, or a health insurance
21	issuer offering health insurance coverage, in
22	which a plaintiff alleges that a person referred
23	to in such subparagraph has taken an action re-
24	sulting in a refusal of a benefit determined by
25	an external appeal entity to be covered, or has

1	failed to take an action for which such person
2	is responsible under the terms and conditions of
3	the plan or coverage and which is necessary
4	under the plan or coverage for authorizing a
5	benefit, the court shall cause to be served on
6	the defendant an order requiring the defend-
7	ant—
8	(i) to cease and desist from the al-
9	leged action or failure to act; and
10	(ii) to pay to the plaintiff a reasonable
11	attorney's fee and other reasonable costs
12	relating to the prosecution of the action on
13	the charges on which the plaintiff prevails.
14	(C) Additional civil penalties.—
15	(i) IN GENERAL.—In addition to any
16	penalty imposed under subparagraph (A)
17	or (B), the appropriate Secretary may as-
18	sess a civil penalty against a person acting
19	in the capacity of authorizing a benefit de-
20	termined by an external review entity for
21	one or more group health plans, or health
22	insurance issuers offering health insurance
23	coverage, for—
24	(I) any pattern or practice of re-
25	peated refusal to authorize a benefit

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1	determined by an external appeal enti-
2	ty to be covered; or
3	(II) any pattern or practice of re-
4	peated violations of the requirements
5	of this section with respect to such
6	plan or coverage.
7	(ii) Standard of proof and
8	AMOUNT OF PENALTY.—Such penalty shall
9	be payable only upon proof by clear and
10	convincing evidence of such pattern or
11	practice and shall be in an amount not to
12	exceed the lesser of—
13	(I) 25 percent of the aggregate
14	value of benefits shown by the appro-
15	priate Secretary to have not been pro-
16	vided, or unlawfully delayed, in viola-
17	tion of this section under such pattern
18	or practice; or
19	(II) \$ 500,000.
20	(D) REMOVAL AND DISQUALIFICATION.—
21	Any person acting in the capacity of author-
22	izing benefits who has engaged in any such pat-
23	tern or practice described in subparagraph
24	(C)(i) with respect to a plan or coverage, upon
25	the petition of the appropriate Secretary, may

1	be removed by the court from such position,
2	and from any other involvement, with respect to
3	such a plan or coverage, and may be precluded
4	from returning to any such position or involve-
5	ment for a period determined by the court.
6	(4) PROTECTION OF LEGAL RIGHTS.—Nothing
7	in this subsection or subtitle shall be construed as
8	altering or eliminating any cause of action or legal
9	rights or remedies of participants, beneficiaries, en-
10	rollees, and others under State or Federal law (in-
11	cluding sections 502 and 503 of the Employee Re-
12	tirement Income Security Act of 1974), including
13	the right to file judicial actions to enforce rights.
14	(g) Qualifications of Independent Medical
15	Reviewers.—
16	(1) IN GENERAL.—In referring a denial to 1 or
17	more individuals to conduct independent medical re-
18	view under subsection (c), the qualified external re-
19	view entity shall ensure that—
20	(A) each independent medical reviewer
21	meets the qualifications described in paragraphs
22	(2) and (3);
23	(B) with respect to each review at least 1
24	such reviewer meets the requirements described
25	in paragraphs (4) and (5); and

1	(C) compensation provided by the entity to
2	the reviewer is consistent with paragraph (6).
3	(2) LICENSURE AND EXPERTISE.—Each inde-
4	pendent medical reviewer shall be a physician
5	(allopathic or osteopathic) or health care profes-
6	sional who—
7	(A) is appropriately credentialed or li-
8	censed in 1 or more States to deliver health
9	care services; and
10	(B) typically treats the condition, makes
11	the diagnosis, or provides the type of treatment
12	under review.
13	(3) INDEPENDENCE.—
14	(A) IN GENERAL.—Subject to subpara-
15	graph (B), each independent medical reviewer
16	in a case shall—
17	(i) not be a related party (as defined
18	in paragraph (7));
19	(ii) not have a material familial, fi-
20	nancial, or professional relationship with
21	such a party; and
22	(iii) not otherwise have a conflict of
23	interest with such a party (as determined
24	under regulations).

1	(B) EXCEPTION.—Nothing in subpara-
2	graph (A) shall be construed to—
3	(i) prohibit an individual, solely on the
4	basis of affiliation with the plan or issuer,
5	from serving as an independent medical re-
6	viewer if—
7	(I) a non-affiliated individual is
8	not reasonably available;
9	(II) the affiliated individual is
10	not involved in the provision of items
11	or services in the case under review;
12	(III) the fact of such an affili-
13	ation is disclosed to the plan or issuer
14	and the participant, beneficiary, or
15	enrollee (or authorized representative)
16	and neither party objects; and
17	(IV) the affiliated individual is
18	not an employee of the plan or issuer
19	and does not provide services exclu-
20	sively or primarily to or on behalf of
21	the plan or issuer;
22	(ii) prohibit an individual who has
23	staff privileges at the institution where the
24	treatment involved takes place from serv-
25	ing as an independent medical reviewer

1	merely on the basis of such affiliation if
2	the affiliation is disclosed to the plan or
3	issuer and the participant, beneficiary, or
4	enrollee (or authorized representative), and
5	neither party objects; or
6	(iii) prohibit receipt of compensation
7	by an independent medical reviewer from
8	an entity if the compensation is provided
9	consistent with paragraph (6).
10	(4) PRACTICING HEALTH CARE PROFESSIONAL
11	IN SAME FIELD.—
12	(A) IN GENERAL.—In a case involving
13	treatment, or the provision of items or serv-
14	ices—
15	(i) by a physician, a reviewer shall be
16	a practicing physician (allopathic or osteo-
17	pathic) of the same or similar specialty, as
18	a physician who, acting within the appro-
19	priate scope of practice within the State in
20	which the service is provided or rendered,
21	typically treats the condition, makes the
22	diagnosis, or provides the type of treat-
23	ment under review; or
24	(ii) by a non-physician health care
25	professional, a reviewer (or reviewers) shall

1 include at least one practicing non-physi-2 cian health care professional of the same 3 or similar specialty as the non-physician 4 health care professional who, acting within the appropriate scope of practice within 5 6 the State in which the service is provided 7 or rendered, typically treats the condition, 8 makes the diagnosis, or provides the type 9 of treatment under review.

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

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

19 (6) LIMITATIONS ON REVIEWER COMPENSA20 TION.—Compensation provided by a qualified exter21 nal review entity to an independent medical reviewer
22 in connection with a review under this section
23 shall—

24 (A) not exceed a reasonable level; and

1	(B) not be contingent on the decision ren-
2	dered by the reviewer.
3	(7) Related party defined.—For purposes
4	of this section, the term "related party" means, with
5	respect to a denial of a claim under a plan or cov-
6	erage relating to a participant, beneficiary, or en-
7	rollee, any of the following:
8	(A) The plan, plan sponsor, or issuer in-
9	volved, or any fiduciary, officer, director, or em-
10	ployee of such plan, plan sponsor, or issuer.
11	(B) The participant, beneficiary, or en-
12	rollee (or authorized representative).
13	(C) The health care professional that pro-
14	vides the items or services involved in the de-
15	nial.
16	(D) The institution at which the items or
17	services (or treatment) involved in the denial
18	are provided.
19	(E) The manufacturer of any drug or
20	other item that is included in the items or serv-
21	ices involved in the denial.
22	(F) Any other party determined under any
23	regulations to have a substantial interest in the
24	denial involved.
25	(h) QUALIFIED EXTERNAL REVIEW ENTITIES.—

1	(1) Selection of qualified external re-
2	VIEW ENTITIES.—
3	(A) LIMITATION ON PLAN OR ISSUER SE-
4	LECTION.—The appropriate Secretary shall im-
5	plement procedures—
6	(i) to assure that the selection process
7	among qualified external review entities
8	will not create any incentives for external
9	review entities to make a decision in a bi-
10	ased manner; and
11	(ii) for auditing a sample of decisions
12	by such entities to assure that no such de-
13	cisions are made in a biased manner.
14	No such selection process under the procedures
15	implemented by the appropriate Secretary may
16	give either the patient or the plan or issuer any
17	ability to determine or influence the selection of
18	a qualified external review entity to review the
19	case of any participant, beneficiary, or enrollee.
20	(B) STATE AUTHORITY WITH RESPECT TO
21	QUALIFIED EXTERNAL REVIEW ENTITIES FOR
22	HEALTH INSURANCE ISSUERS.—With respect to
23	health insurance issuers offering health insur-
24	ance coverage in a State, the State may provide
25	for external review activities to be conducted by

1	a qualified external appeal entity that is des-
2	ignated by the State or that is selected by the
3	State in a manner determined by the State to
4	assure an unbiased determination.
5	(2) Contract with qualified external re-
6	VIEW ENTITY.—Except as provided in paragraph
7	(1)(B), the external review process of a plan or
8	issuer under this section shall be conducted under a
9	contract between the plan or issuer and 1 or more
10	qualified external review entities (as defined in para-
11	graph $(4)(A)$).
12	(3) TERMS AND CONDITIONS OF CONTRACT.—
13	The terms and conditions of a contract under para-
14	graph (2) shall—
15	(A) be consistent with the standards the
16	appropriate Secretary shall establish to assure
17	there is no real or apparent conflict of interest
18	in the conduct of external review activities; and
19	(B) provide that the costs of the external
20	review process shall be borne by the plan or
21	issuer.
22	Subparagraph (B) shall not be construed as apply-
23	ing to the imposition of a filing fee under subsection
24	(b)(2)(A)(iv) or costs incurred by the participant,
25	beneficiary, or enrollee (or authorized representative)

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or treating health care professional (if any) in sup-
port of the review, including the provision of addi-
tional evidence or information.
(4) QUALIFICATIONS.—
(A) IN GENERAL.—In this section, the
term "qualified external review entity" means,
in relation to a plan or issuer, an entity that is
initially certified (and periodically recertified)
under subparagraph (C) as meeting the fol-
lowing requirements:
(i) The entity has (directly or through
contracts or other arrangements) sufficient
medical, legal, and other expertise and suf-
ficient staffing to carry out duties of a
qualified external review entity under this
section on a timely basis, including making
determinations under subsection $(b)(2)(A)$
and providing for independent medical re-
views under subsection (d).
(ii) The entity is not a plan or issuer
or an affiliate or a subsidiary of a plan or
issuer, and is not an affiliate or subsidiary
of a professional or trade association of
plans or issuers or of health care providers.

1	(iii) The entity has provided assur-
2	ances that it will conduct external review
3	activities consistent with the applicable re-
4	quirements of this section and standards
5	specified in subparagraph (C), including
6	that it will not conduct any external review
7	activities in a case unless the independence
8	requirements of subparagraph (B) are met
9	with respect to the case.
10	(iv) The entity has provided assur-
11	ances that it will provide information in a
12	timely manner under subparagraph (D).
13	(v) The entity meets such other re-
14	quirements as the appropriate Secretary
15	provides by regulation.
16	(B) INDEPENDENCE REQUIREMENTS.—
17	(i) IN GENERAL.—Subject to clause
18	(ii), an entity meets the independence re-
19	quirements of this subparagraph with re-
20	spect to any case if the entity—
21	(I) is not a related party (as de-
22	fined in subsection $(g)(7)$;
23	(II) does not have a material fa-
24	milial, financial, or professional rela-
25	tionship with such a party; and

1	(III) does not otherwise have a
2	conflict of interest with such a party
3	(as determined under regulations).
4	(ii) EXCEPTION FOR REASONABLE
5	COMPENSATION.—Nothing in clause (i)
6	shall be construed to prohibit receipt by a
7	qualified external review entity of com-
8	pensation from a plan or issuer for the
9	conduct of external review activities under
10	this section if the compensation is provided
11	consistent with clause (iii).
12	(iii) LIMITATIONS ON ENTITY COM-
13	PENSATION.—Compensation provided by a
14	plan or issuer to a qualified external review
15	entity in connection with reviews under
16	this section shall—
17	(I) not exceed a reasonable level;
18	and
19	(II) not be contingent on any de-
20	cision rendered by the entity or by
21	any independent medical reviewer.
22	(C) CERTIFICATION AND RECERTIFICATION
23	PROCESS.—

(i) IN GENERAL.—The initial certifi-1 2 cation and recertification of a qualified external review entity shall be made— 3 4 (I) under a process that is recog-5 nized or approved by the appropriate 6 Secretary; or 7 (II) by a qualified private stand-8 ard-setting organization that is ap-9 proved by the appropriate Secretary 10 under clause (iii). 11 In taking action under subclause (I), the 12 appropriate Secretary shall give deference 13 to entities that are under contract with the 14 Federal Government or with an applicable 15 State authority to perform functions of the 16 type performed by qualified external review 17 entities.

(ii) PROCESS.—The appropriate Secretary shall not recognize or approve a
process under clause (i)(I) unless the process applies standards (as promulgated in
regulations) that ensure that a qualified
external review entity—

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

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1	the responsibilities of such an entity
2	in accordance with this section, in-
3	cluding meeting applicable deadlines;
4	(II) will meet (and has met, in
5	the case of recertification) appropriate
6	indicators of fiscal integrity;
7	(III) will maintain (and has
8	maintained, in the case of recertifi-
9	cation) appropriate confidentiality
10	with respect to individually identifi-
11	able health information obtained in
12	the course of conducting external re-
13	view activities; and
14	(IV) in the case of recertification,
15	shall review the matters described in
16	clause (iv).
17	(iii) Approval of qualified pri-
18	VATE STANDARD-SETTING ORGANIZA-
19	TIONS.—For purposes of clause (i)(II), the
20	appropriate Secretary may approve a quali-
21	fied private standard-setting organization
22	if such Secretary finds that the organiza-
23	tion only certifies (or recertifies) external
24	review entities that meet at least the
25	standards required for the certification (or

1	recertification) of external review entities
2	under clause (ii).
3	(iv) Considerations in recertifi-
4	CATIONS.—In conducting recertifications of
5	a qualified external review entity under
6	this paragraph, the appropriate Secretary
7	or organization conducting the recertifi-
8	cation shall review compliance of the entity
9	with the requirements for conducting ex-
10	ternal review activities under this section,
11	including the following:
12	(I) Provision of information
13	under subparagraph (D).
14	(II) Adherence to applicable
15	deadlines (both by the entity and by
16	independent medical reviewers it re-
17	fers cases to).
18	(III) Compliance with limitations
19	on compensation (with respect to both
20	the entity and independent medical re-
21	viewers it refers cases to).
22	(IV) Compliance with applicable
23	independence requirements.
24	(V) Compliance with the require-
25	ment of subsection $(d)(1)$ that only

1	medically reviewable decisions shall be
2	the subject of independent medical re-
3	view and with the requirement of sub-
4	section $(d)(3)$ that independent med-
5	ical reviewers may not require cov-
6	erage for specifically excluded bene-
7	fits.
8	(v) Period of certification or re-
9	CERTIFICATION.—A certification or recer-
10	tification provided under this paragraph
11	shall extend for a period not to exceed 2
12	years.
13	(vi) REVOCATION.—A certification or
14	recertification under this paragraph may
15	be revoked by the appropriate Secretary or
16	by the organization providing such certifi-
17	cation upon a showing of cause. The Sec-
18	retary, or organization, shall revoke a cer-
19	tification or deny a recertification with re-
20	spect to an entity if there is a showing that
21	the entity has a pattern or practice of or-
22	dering coverage for benefits that are spe-
23	cifically excluded under the plan or cov-
24	erage.

1	(vii) Petition for denial or with-
2	DRAWAL.—An individual may petition the
3	Secretary, or an organization providing the
4	certification involves, for a denial of recer-
5	tification or a withdrawal of a certification
6	with respect to an entity under this sub-
7	paragraph if there is a pattern or practice
8	of such entity failing to meet a require-
9	ment of this section.
10	(viii) SUFFICIENT NUMBER OF ENTI-
11	TIES.—The appropriate Secretary shall
12	certify and recertify a number of external
13	review entities which is sufficient to ensure
14	the timely and efficient provision of review
15	services.
16	(D) PROVISION OF INFORMATION.—
17	(i) IN GENERAL.—A qualified external
18	review entity shall provide to the appro-
19	priate Secretary, in such manner and at
20	such times as such Secretary may require,
21	such information (relating to the denials
22	which have been referred to the entity for
23	the conduct of external review under this
24	section) as such Secretary determines ap-
25	propriate to assure compliance with the

1	independence and other requirements of
2	this section to monitor and assess the qual-
3	ity of its external review activities and lack
4	of bias in making determinations. Such in-
5	formation shall include information de-
6	scribed in clause (ii) but shall not include
7	individually identifiable medical informa-
8	tion.
9	(ii) INFORMATION TO BE IN-
10	CLUDED.—The information described in
11	this subclause with respect to an entity is
12	as follows:
13	(I) The number and types of de-
14	nials for which a request for review
15	has been received by the entity.
16	(II) The disposition by the entity
17	of such denials, including the number
18	referred to a independent medical re-
19	viewer and the reasons for such dis-
20	positions (including the application of
21	exclusions), on a plan or issuer-spe-
22	cific basis and on a health care spe-
23	cialty-specific basis.

- 1 (III) The length of time in mak-2 ing determinations with respect to 3 such denials. 4 (IV) Updated information on the 5 information required to be submitted 6 as a condition of certification with re-7 spect to the entity's performance of 8 external review activities. 9 (iii) INFORMATION TO BE PROVIDED 10 TO CERTIFYING ORGANIZATION.-11 (I) IN GENERAL.—In the case of 12 qualified external review entity a 13 is certified (or recertified) which 14 under this subsection by a qualified 15 private standard-setting organization, 16 at the request of the organization, the 17 entity shall provide the organization 18 with the information provided to the 19 appropriate Secretary under clause 20 (i). 21 (\mathbf{II}) Additional INFORMA-22 TION.—Nothing in this subparagraph 23 shall be construed as preventing such
- 25 tional information as a condition of

an organization from requiring addi-

1certification or recertification of an2entity.

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

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

1	(5) REPORT.—Not later than 12 months after
2	the general effective date referred to in section 601,
3	the General Accounting Office shall prepare and
4	submit to the appropriate committees of Congress a
5	report concerning—
6	(A) the information that is provided under
7	paragraph (3)(D);
8	(B) the number of denials that have been
9	upheld by independent medical reviewers and
10	the number of denials that have been reversed
11	by such reviewers; and
12	(C) the extent to which independent med-
13	ical reviewers are requiring coverage for bene-
14	fits that are specifically excluded under the plan
15	or coverage.
16	SEC. 105. HEALTH CARE CONSUMER ASSISTANCE FUND.
17	(a) GRANTS.—
18	(1) IN GENERAL.—The Secretary of Health and
19	Human Services (referred to in this section as the
20	"Secretary") shall establish a fund, to be known as
21	the "Health Care Consumer Assistance Fund", to be
22	used to award grants to eligible States to carry out
23	consumer assistance activities (including programs
24	established by States prior to the enactment of this

1	Act) designed to provide information, assistance, and
2	referrals to consumers of health insurance products.
3	(2) STATE ELIGIBILITY.—To be eligible to re-
4	ceive a grant under this subsection a State shall pre-
5	pare and submit to the Secretary an application at
6	such time, in such manner, and containing such in-
7	formation as the Secretary may require, including a
8	State plan that describes—
9	(A) the manner in which the State will en-
10	sure that the health care consumer assistance
11	office (established under paragraph (4)) will
12	educate and assist health care consumers in ac-
13	cessing needed care;
14	(B) the manner in which the State will co-
15	ordinate and distinguish the services provided
16	by the health care consumer assistance office
17	with the services provided by Federal, State and
18	local health-related ombudsman, information,
19	protection and advocacy, insurance, and fraud
20	and abuse programs;
21	(C) the manner in which the State will
22	provide information, outreach, and services to
23	underserved, minority populations with limited
24	English proficiency and populations residing in
25	rural areas;

1	(D) the manner in which the State will
2	oversee the health care consumer assistance of-
3	fice, its activities, product materials and evalu-
4	ate program effectiveness;
5	(E) the manner in which the State will en-
6	sure that funds made available under this sec-
7	tion will be used to supplement, and not sup-
8	plant, any other Federal, State, or local funds
9	expended to provide services for programs de-
10	scribed under this section and those described
11	in subparagraphs (C) and (D);
12	(F) the manner in which the State will en-
13	sure that health care consumer office personnel
14	have the professional background and training
15	to carry out the activities of the office; and
16	(G) the manner in which the State will en-
17	sure that consumers have direct access to con-
18	sumer assistance personnel during regular busi-
19	ness hours.
20	(3) Amount of grant.—
21	(A) IN GENERAL.—From amounts appro-
22	priated under subsection (b) for a fiscal year,
23	the Secretary shall award a grant to a State in
24	an amount that bears the same ratio to such
25	amounts as the number of individuals within

the State covered under a group health plan or

under health insurance coverage offered by a health insurance issuer bears to the total number of individuals so covered in all States (as determined by the Secretary). Any amounts provided to a State under this subsection that are not used by the State shall be remitted to the Secretary and reallocated in accordance with this subparagraph.

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

16 (C) NON-FEDERAL CONTRIBUTIONS.—A
17 State will provide for the collection of non-Fed18 eral contributions for the operation of the office
19 in an amount that is not less than 25 percent
20 of the amount of Federal funds provided to the
21 State under this section.

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

24 (A) IN GENERAL.—From amounts pro25 vided under a grant under this subsection, a

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1	State shall, directly or through a contract with
2	an independent, nonprofit entity with dem-
3	onstrated experience in serving the needs of
4	health care consumers, provide for the estab-
5	lishment and operation of a State health care
6	consumer assistance office.
7	(B) ELIGIBILITY OF ENTITY.—To be eligi-
8	ble to enter into a contract under subparagraph
9	(A), an entity shall demonstrate that it has the
10	technical, organizational, and professional ca-
11	pacity to deliver the services described in sub-
12	section (b) to all public and private health in-
13	surance participants, beneficiaries, enrollees, or
14	prospective enrollees.
15	(C) EXISTING STATE ENTITY.—Nothing in
16	this section shall prevent the funding of an ex-
17	isting health care consumer assistance program
18	that otherwise meets the requirements of this
19	section.
20	(b) Use of Funds.—
21	(1) By STATE.—A State shall use amounts pro-
22	vided under a grant awarded under this section to
23	carry out consumer assistance activities directly or
24	by contract with an independent, non-profit organi-
25	zation. An eligible entity may use some reasonable

1	amount of such grant to ensure the adequate train-
2	ing of personnel carrying out such activities. To re-
3	ceive amounts under this subsection, an eligible enti-
4	ty shall provide consumer assistance services, includ-
5	ing—
6	(A) the operation of a toll-free telephone
7	hotline to respond to consumer requests;
8	(B) the dissemination of appropriate edu-
9	cational materials on available health insurance
10	products and on how best to access health care
11	and the rights and responsibilities of health
12	care consumers;
13	(C) the provision of education on effective
14	methods to promptly and efficiently resolve
15	questions, problems, and grievances;
16	(D) the coordination of educational and
17	outreach efforts with health plans, health care
18	providers, payers, and governmental agencies;
19	(E) referrals to appropriate private and
20	public entities to resolve questions, problems
21	and grievances; and
22	(F) the provision of information and as-
23	sistance, including acting as an authorized rep-
24	resentative, regarding internal, external, or ad-
25	ministrative grievances or appeals procedures in

1	nonlitigative settings to appeal the denial, ter-
2	mination, or reduction of health care services,
3	or the refusal to pay for such services, under a
4	group health plan or health insurance coverage
5	offered by a health insurance issuer.
6	(2) Confidentiality and access to infor-
7	MATION.—
8	(A) STATE ENTITY.—With respect to a
9	State that directly establishes a health care con-
10	sumer assistance office, such office shall estab-
11	lish and implement procedures and protocols in
12	accordance with applicable Federal and State
13	laws.
14	(B) CONTRACT ENTITY.—With respect to a
15	State that, through contract, establishes a
16	health care consumer assistance office, such of-
17	fice shall establish and implement procedures
18	and protocols, consistent with applicable Fed-
19	eral and State laws, to ensure the confiden-
20	tiality of all information shared by a partici-
21	pant, beneficiary, enrollee, or their personal
22	representative and their health care providers,
23	group health plans, or health insurance insurers
24	with the office and to ensure that no such infor-

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

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

1	dividual's health insurance coverage or prospective
2	coverage, including individuals covered under a
3	group health plan or health insurance coverage of-
4	fered by a health insurance issuer, the medicare or
5	medicaid programs under title XVIII or XIX of the
6	Social Security Act (42 U.S.C. 1395 and 1396 et
7	seq.), or under any other Federal or State health
8	care program.
9	(4) Designation of responsibilities.—
10	(A) WITHIN EXISTING STATE ENTITY.—If
11	the health care consumer assistance office of a
12	State is located within an existing State regu-
13	latory agency or office of an elected State offi-
14	cial, the State shall ensure that—
15	(i) there is a separate delineation of
16	the funding, activities, and responsibilities
17	of the office as compared to the other
18	funding, activities, and responsibilities of
19	the agency; and
20	(ii) the office establishes and imple-
21	ments procedures and protocols to ensure
22	the confidentiality of all information
23	shared by a participant, beneficiary, or en-
24	rollee or their personal representative and
25	their health care providers, group health

- plans, or health insurance issuers with the office and to ensure that no information is disclosed to the State agency or office without the written authorization of the individual or their personal representative in accordance with paragraph (2).
 (B) CONTRACT ENTITY.—In the case of an entity that enters into a contract with a State under subsection (a)(3), the entity shall provide assurances that the entity has no conflict of interest in carrying out the activities of the office and that the entity is independent of group health plans, health insurance issuers, providers, payers, and regulators of health care.
- (5) SUBCONTRACTS.—The health care consumer assistance office of a State may carry out activities and provide services through contracts entered into with 1 or more nonprofit entities so long
 as the office can demonstrate that all of the requirements of this section are complied with by the office.

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

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

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

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

8 Subtitle B—Access to Care

9 SEC. 111. CONSUMER CHOICE OPTION.

10 (a) IN GENERAL.—If—

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

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

sionals and providers who have entered into a contract with the plan to provide such services,

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

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

(c) OPEN SEASON.—An enrollee, participant, or beneficiary, may change to the offering provided under this
section only during a time period determined by the health

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

3 SEC. 112. CHOICE OF HEALTH CARE PROFESSIONAL.

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

12 (b) Specialists.—

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

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

1 CONSTRUCTION.—Nothing in this sub-(3)2 section shall be construed as affecting the applica-3 tion of section 114 (relating to access to specialty 4 care). 5 SEC. 113. ACCESS TO EMERGENCY CARE. 6 (a) COVERAGE OF EMERGENCY SERVICES.— 7 (1) IN GENERAL.—If a group health plan, or 8 health insurance coverage offered by a health insur-9 ance issuer, provides or covers any benefits with re-10 spect to services in an emergency department of a 11 hospital, the plan or issuer shall cover emergency 12 services (as defined in paragraph (2)(B))— 13 (A) without the need for any prior author-14 ization determination; 15 (B) whether the health care provider fur-16 nishing such services is a participating provider 17 with respect to such services; 18 (C) in a manner so that, if such services 19 are provided to a participant, beneficiary, or en-20 rollee----21 (i) by a nonparticipating health care 22 provider with or without prior authoriza-23 tion, or 24 (ii) by a participating health care pro-25 vider without prior authorization,

the participant, beneficiary, or enrollee is not liable for amounts that exceed the amounts of liability that would be incurred if the services were provided by a participating health care provider with prior authorization; and (D) without regard to any other term or condition of such coverage (other than exclusion or coordination of benefits, or an affiliation or waiting period, permitted under section 2701 of the Public Health Service Act, section 701 of the Employee Retirement Income Security Act of 1974, or section 9801 of the Internal Revenue Code of 1986, and other than applicable cost-sharing).

15 (2) DEFINITIONS.—In this section:

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

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1	section $1867(e)(1)(A)$ of the Social Security
2	Act.
3	(B) Emergency services.—The term
4	"emergency services" means, with respect to an
5	emergency medical condition—
6	(i) a medical screening examination
7	(as required under section 1867 of the So-
8	cial Security Act) that is within the capa-
9	bility of the emergency department of a
10	hospital, including ancillary services rou-
11	tinely available to the emergency depart-
12	ment to evaluate such emergency medical
13	condition, and
14	(ii) within the capabilities of the staff
15	and facilities available at the hospital, such
16	further medical examination and treatment
17	as are required under section 1867 of such
18	Act to stabilize the patient.
19	(C) STABILIZE.—The term "to stabilize",
20	with respect to an emergency medical condition
21	(as defined in subparagraph (A)), has the
22	meaning given in section $1867(e)(3)$ of the So-
23	cial Security Act (42 U.S.C. 1395dd(e)(3)).
24	(b) Reimbursement for Maintenance Care and

 $25\,$ Post-Stabilization Care.—A group health plan, and

health insurance coverage offered by a health insurance 1 issuer, must provide reimbursement for maintenance care 2 3 and post-stabilization care in accordance with the require-4 ments of section 1852(d)(2) of the Social Security Act (42) 5 U.S.C. 1395w-22(d)(2)). Such reimbursement shall be provided in a manner consistent with subsection (a)(1)(C). 6 7 (c) COVERAGE OF EMERGENCY AMBULANCE SERV-8 ICES.—

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

(2) EMERGENCY AMBULANCE SERVICES.—For
purposes of this subsection, the term "emergency
ambulance services" means ambulance services (as
defined for purposes of section 1861(s)(7) of the Social Security Act) furnished to transport an individual who has an emergency medical condition (as
defined in subsection (a)(2)(A)) to a hospital for the

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

11 SEC. 114. TIMELY ACCESS TO SPECIALISTS.

12 (a) TIMELY ACCESS.—

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

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

23 (A) to require the coverage under a group
24 health plan or health insurance coverage of ben25 efits or services;

1	(B) to prohibit a plan or issuer from in-
2	cluding providers in the network only to the ex-
3	tent necessary to meet the needs of the plan's
4	or issuer's participants, beneficiaries, or enroll-
5	ees; or
6	(C) to override any State licensure or
7	scope-of-practice law.
8	(3) Access to certain providers.—
9	(A) IN GENERAL.—With respect to spe-
10	cialty care under this section, if a participating
11	specialist is not available and qualified to pro-
12	vide such care to the participant, beneficiary, or
13	enrollee, the plan or issuer shall provide for cov-
14	erage of such care by a nonparticipating spe-
15	cialist.
16	(B) TREATMENT OF NONPARTICIPATING
17	PROVIDERS.—If a participant, beneficiary, or
18	enrollee receives care from a nonparticipating
19	specialist pursuant to subparagraph (A), such
20	specialty care shall be provided at no additional
21	cost to the participant, beneficiary, or enrollee
22	beyond what the participant, beneficiary, or en-
23	rollee would otherwise pay for such specialty
24	care if provided by a participating specialist.
25	(b) Referrals.—

1	(1) AUTHORIZATION.—Subject to subsection
2	(a)(1), a group health plan or health insurance
3	issuer may require an authorization in order to ob-
4	tain coverage for specialty services under this sec-
5	tion. Any such authorization—
6	(A) shall be for an appropriate duration of
7	time or number of referrals, including an au-
8	thorization for a standing referral where appro-
9	priate; and
10	(B) may not be refused solely because the
11	authorization involves services of a nonpartici-
12	pating specialist (described in subsection
13	(a)(3)).
14	(2) Referrals for ongoing special condi-
15	TIONS.—
16	(A) IN GENERAL.—Subject to subsection
17	(a)(1), a group health plan and a health insur-
18	ance issuer shall permit a participant, bene-
19	ficiary, or enrollee who has an ongoing special
20	condition (as defined in subparagraph (B)) to
21	receive a referral to a specialist for the treat-
22	ment of such condition and such specialist may
23	authorize such referrals, procedures, tests, and
24	other medical services with respect to such con-
25	dition, or coordinate the care for such condi-

1	tion, subject to the terms of a treatment plan
2	(if any) referred to in subsection (c) with re-
3	spect to the condition.
4	(B) ONGOING SPECIAL CONDITION DE-
5	FINED.—In this subsection, the term "ongoing
6	special condition" means a condition or disease
7	that—
8	(i) is life-threatening, degenerative,
9	potentially disabling, or congenital; and
10	(ii) requires specialized medical care
11	over a prolonged period of time.
12	(c) TREATMENT PLANS.—
13	(1) IN GENERAL.—A group health plan or
14	health insurance issuer may require that the spe-
15	cialty care be provided—
16	(A) pursuant to a treatment plan, but only
17	if the treatment plan—
18	(i) is developed by the specialist, in
19	consultation with the case manager or pri-
20	mary care provider, and the participant,
21	beneficiary, or enrollee, and
22	(ii) is approved by the plan or issuer
23	in a timely manner, if the plan or issuer
24	requires such approval; and

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

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

10 (d) SPECIALIST DEFINED.—For purposes of this sec-11 tion, the term "specialist" means, with respect to the con-12 dition of the participant, beneficiary, or enrollee, a health 13 care professional, facility, or center that has adequate expertise through appropriate training and experience (in-14 15 cluding, in the case of a child, appropriate pediatric expertise) to provide high quality care in treating the condition. 16 17 SEC. 115. PATIENT ACCESS TO OBSTETRICAL AND GYNECO-

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LOGICAL CARE.

19 (a) GENERAL RIGHTS.—

(1) DIRECT ACCESS.—A group health plan, and
a health insurance issuer offering health insurance
coverage, described in subsection (b) may not require authorization or referral by the plan, issuer, or
any person (including a primary care provider described in subsection (b)(2)) in the case of a female

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

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

(b) APPLICATION OF SECTION.—A group health plan,
or health insurance issuer offering health insurance coverage, described in this subsection is a group health plan
or coverage that—

19 (1) provides coverage for obstetric or20 gynecologic care; and

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

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

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

5 (2) preclude the group health plan or health in6 surance issuer involved from requiring that the ob7 stetrical or gynecological provider notify the primary
8 care health care professional or the plan or issuer of
9 treatment decisions.

10 SEC. 116. ACCESS TO PEDIATRIC CARE.

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

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

1 SEC. 117. CONTINUITY OF CARE.

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2 (a) TERMINATION OF PROVIDER.—

(1) IN GENERAL.—If—

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

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

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

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

1	minated, but only with respect to benefits that are
2	covered under the plan after the contract termi-
3	nation.
4	(3) REQUIREMENTS.—The requirements of this
5	paragraph are that the plan or issuer—
6	(A) notify the continuing care patient in-
7	volved, or arrange to have the patient notified
8	pursuant to subsection $(d)(2)$, on a timely basis
9	of the termination described in paragraph (1)
10	(or paragraph (2), if applicable) and the right
11	to elect continued transitional care from the
12	provider under this section;
13	(B) provide the patient with an oppor-
14	tunity to notify the plan or issuer of the pa-
15	tient's need for transitional care; and
16	(C) subject to subsection (c), permit the
17	patient to elect to continue to be covered with
18	respect to the course of treatment by such pro-
19	vider with the provider's consent during a tran-
20	sitional period (as provided for under subsection
21	(b)).
22	(4) Continuing care patient.—For purposes
23	of this section, the term "continuing care patient"
24	means a participant, beneficiary, or enrollee who-

1	(A) is undergoing a course of treatment
2	for a serious and complex condition from the
3	provider at the time the plan or issuer receives
4	or provides notice of provider, benefit, or cov-
5	erage termination described in paragraph (1)
6	(or paragraph (2), if applicable);
7	(B) is undergoing a course of institutional
8	or inpatient care from the provider at the time
9	of such notice;
10	(C) is scheduled to undergo non-elective
11	surgery from the provider at the time of such
12	notice;
13	(D) is pregnant and undergoing a course
14	of treatment for the pregnancy from the pro-
15	vider at the time of such notice; or
16	(E) is or was determined to be terminally
17	ill (as determined under section 1861(dd)(3)(A)
18	of the Social Security Act) at the time of such
19	notice, but only with respect to a provider that
20	was treating the terminal illness before the date
21	of such notice.
22	(b) TRANSITIONAL PERIODS.—
23	(1) Serious and complex conditions.—The
24	transitional period under this subsection with re-
25	spect to a continuing care patient described in sub-

1	section $(a)(4)(A)$ shall extend for up to 90 days (as
2	determined by the treating health care professional)
3	from the date of the notice described in subsection
4	(a)(3)(A).
5	(2) INSTITUTIONAL OR INPATIENT CARE.—The
6	transitional period under this subsection for a con-
7	tinuing care patient described in subsection
8	(a)(4)(B) shall extend until the earlier of—
9	(A) the expiration of the 90-day period be-
10	ginning on the date on which the notice under
11	subsection (a)(3)(A) is provided; or
12	(B) the date of discharge of the patient
13	from such care or the termination of the period
14	of institutionalization, or, if later, the date of
15	completion of reasonable follow-up care.
16	(3) Scheduled non-elective surgery.—
17	The transitional period under this subsection for a
18	continuing care patient described in subsection
19	(a)(4)(C) shall extend until the completion of the
20	surgery involved and post-surgical follow-up care re-
21	lating to the surgery and occurring within 90 days
22	after the date of the surgery.
23	(4) PREGNANCY.—The transitional period
24	under this subsection for a continuing care patient
25	described in subsection $(a)(4)(D)$ shall extend

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

3 (5) TERMINAL ILLNESS.—The transitional pe4 riod under this subsection for a continuing care pa5 tient described in subsection (a)(4)(E) shall extend
6 for the remainder of the patient's life for care that
7 is directly related to the treatment of the terminal
8 illness or its medical manifestations.

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

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

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

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

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

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

20 (2) with respect to the termination of a con21 tract under subsection (a) to prevent a group health
22 plan or health insurance issuer from requiring that
23 the health care provider—

24 (A) notify participants, beneficiaries, or en25 rollees of their rights under this section; or

1	(B) provide the plan or issuer with the
2	name of each participant, beneficiary, or en-
3	rollee who the provider believes is a continuing
4	care patient.
5	(e) DEFINITIONS.—In this section:
6	(1) CONTRACT.—The term "contract" includes,
7	with respect to a plan or issuer and a treating
8	health care provider, a contract between such plan
9	or issuer and an organized network of providers that
10	includes the treating health care provider, and (in
11	the case of such a contract) the contract between the
12	treating health care provider and the organized net-
13	work.
14	(2) HEALTH CARE PROVIDER.—The term
15	"health care provider" or "provider" means—
16	(A) any individual who is engaged in the
17	delivery of health care services in a State and
18	who is required by State law or regulation to be
19	licensed or certified by the State to engage in
20	the delivery of such services in the State; and
21	(B) any entity that is engaged in the deliv-
22	ery of health care services in a State and that,
23	if it is required by State law or regulation to be
24	licensed or certified by the State to engage in

1	the delivery of such services in the State, is so
2	licensed.
3	(3) Serious and complex condition.—The
4	term "serious and complex condition" means, with
5	respect to a participant, beneficiary, or enrollee
6	under the plan or coverage—
7	(A) in the case of an acute illness, a condi-
8	tion that is serious enough to require special-
9	ized medical treatment to avoid the reasonable
10	possibility of death or permanent harm; or
11	(B) in the case of a chronic illness or con-
12	dition, is an ongoing special condition (as de-
13	fined in section $114(b)(2)(B)$).
14	(4) TERMINATED.—The term "terminated" in-
15	cludes, with respect to a contract, the expiration or
16	nonrenewal of the contract, but does not include a
17	termination of the contract for failure to meet appli-
18	cable quality standards or for fraud.
19	SEC. 118. ACCESS TO NEEDED PRESCRIPTION DRUGS.
20	(a) IN GENERAL.—To the extent that a group health
21	plan, or health insurance coverage offered by a health in-
22	surance issuer, provides coverage for benefits with respect
23	to prescription drugs, and limits such coverage to drugs
24	included in a formulary, the plan or issuer shall—

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

4 (2) provide for disclosure of the formulary to5 providers; and

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

14 (b) COVERAGE OF APPROVED DRUGS AND MEDICAL15 DEVICES.—

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

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

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1	section 505 of the Federal Food, Drug,
2	and Cosmetic Act, without regard to any
3	postmarketing requirements that may
4	apply under such Act; or
5	(ii) is included in the labeling author-
6	ized by the application in effect for the
7	drug under section 351 of the Public
8	Health Service Act, without regard to any
9	postmarketing requirements that may
10	apply pursuant to such section; or
11	(B) in the case of a medical device, is in-
12	cluded in the labeling authorized by a regula-
13	tion under subsection (d) or (3) of section 513
14	of the Federal Food, Drug, and Cosmetic Act,
15	an order under subsection (f) of such section, or
16	an application approved under section 515 of
17	such Act, without regard to any postmarketing
18	requirements that may apply under such Act.
19	(2) CONSTRUCTION.—Nothing in this sub-
20	section shall be construed as requiring a group
21	health plan (or health insurance coverage offered in
22	connection with such a plan) to provide any coverage
23	of prescription drugs or medical devices.

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SEC. 119. COVERAGE FOR INDIVIDUALS PARTICIPATING IN
APPROVED CLINICAL TRIALS.
(a) COVERAGE.—
(1) IN GENERAL.—If a group health plan, or
health insurance issuer that is providing health in-
surance coverage, provides coverage to a qualified in-
dividual (as defined in subsection (b)), the plan or
issuer—

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

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

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

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

25 (3) Use of in-network providers.—If one 26 or more participating providers is participating in a •HR 4628 IH

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

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

13 (1)(A) The individual has a life-threatening or
14 serious illness for which no standard treatment is ef15 fective.

(B) The individual is eligible to participate in
an approved clinical trial according to the trial protocol with respect to treatment of such illness.

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

(2) Either—

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23 (A) the referring physician is a partici24 pating health care professional and has con25 cluded that the individual's participation in

1	such trial would be appropriate based upon the
2	individual meeting the conditions described in
3	paragraph (1); or
4	(B) the participant, beneficiary, or enrollee
5	provides medical and scientific information es-
6	tablishing that the individual's participation in
7	such trial would be appropriate based upon the
8	individual meeting the conditions described in
9	paragraph (1).
10	(c) PAYMENT.—
11	(1) IN GENERAL.—Under this section a group
12	health plan and a health insurance issuer shall pro-
13	vide for payment for routine patient costs described
14	in subsection $(a)(2)$ but is not required to pay for
15	costs of items and services that are reasonably ex-
16	pected (as determined by the appropriate Secretary)
17	to be paid for by the sponsors of an approved clin-
18	ical trial.
19	(2) PAYMENT RATE.—In the case of covered
20	items and services provided by—
21	(A) a participating provider, the payment
22	rate shall be at the agreed upon rate; or
23	(B) a nonparticipating provider, the pay-
24	ment rate shall be at the rate the plan or issuer

1	would normally pay for comparable services
2	under subparagraph (A).
3	(d) Approved Clinical Trial Defined.—
4	(1) IN GENERAL.—In this section, the term
5	"approved clinical trial" means a clinical research
6	study or clinical investigation—
7	(A) approved and funded (which may in-
8	clude funding through in-kind contributions) by
9	one or more of the following:
10	(i) the National Institutes of Health;
11	(ii) a cooperative group or center of
12	the National Institutes of Health, includ-
13	ing a qualified nongovernmental research
14	entity to which the National Cancer Insti-
15	tute has awarded a center support grant;
16	(iii) either of the following if the con-
17	ditions described in paragraph (2) are
18	met—
19	(I) the Department of Veterans
20	Affairs;
21	(II) the Department of Defense;
22	or
23	(B) approved by the Food and Drug Ad-
24	ministration.

1	(2) Conditions for departments.—The
2	conditions described in this paragraph, for a study
3	or investigation conducted by a Department, are
4	that the study or investigation has been reviewed
5	and approved through a system of peer review that
6	the appropriate Secretary determines—
7	(A) to be comparable to the system of peer
8	review of studies and investigations used by the
9	National Institutes of Health; and
10	(B) assures unbiased review of the highest
11	ethical standards by qualified individuals who
12	have no interest in the outcome of the review.
13	(e) CONSTRUCTION.—Nothing in this section shall be
14	construed to limit a plan's or issuer's coverage with re-
15	spect to clinical trials.
16	SEC. 120. REQUIRED COVERAGE FOR MINIMUM HOSPITAL
17	STAY FOR MASTECTOMIES AND LYMPH NODE
18	DISSECTIONS FOR THE TREATMENT OF
19	BREAST CANCER AND COVERAGE FOR SEC-
20	ONDARY CONSULTATIONS.
21	(a) INPATIENT CARE.—
22	(1) IN GENERAL.—A group health plan, and a
23	health insurance issuer providing health insurance
24	coverage, that provides medical and surgical benefits
25	shall ensure that inpatient coverage with respect to

1	the treatment of breast cancer is provided for a pe-
2	riod of time as is determined by the attending physi-
3	cian, in consultation with the patient, to be medi-
4	cally necessary and appropriate following—
5	(A) a mastectomy;
6	(B) a lumpectomy; or
7	(C) a lymph node dissection for the treat-
8	ment of breast cancer.
9	(2) EXCEPTION.—Nothing in this section shall
10	be construed as requiring the provision of inpatient
11	coverage if the attending physician and patient de-
12	termine that a shorter period of hospital stay is
13	medically appropriate.
14	(b) Prohibition on Certain Modifications.—In
15	implementing the requirements of this section, a group
16	health plan, and a health insurance issuer providing health
17	insurance coverage, may not modify the terms and condi-
18	tions of coverage based on the determination by a partici-
19	pant, beneficiary, or enrollee to request less than the min-
20	imum coverage required under subsection (a).
21	(c) Secondary Consultations.—
22	(1) IN GENERAL.—A group health plan, and a
23	health insurance issuer providing health insurance
24	coverage, that provides coverage with respect to
25	medical and surgical services provided in relation to

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

(2) EXCEPTION.—Nothing in paragraph (1)
shall be construed as requiring the provision of secondary consultations where the patient determines
not to seek such a consultation.

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

4 (1) penalize or otherwise reduce or limit the re5 imbursement of a provider or specialist because the
6 provider or specialist provided care to a participant,
7 beneficiary, or enrollee in accordance with this sec8 tion;

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

(3) provide financial or other incentives to a
physician or specialist to induce the physician or
specialist to refrain from referring a participant,
beneficiary, or enrollee for a secondary consultation
that would otherwise be covered by the plan or coverage involved under subsection (c).

22 Subtitle C—Access to Information

23 SEC. 121. PATIENT ACCESS TO INFORMATION.

24 (a) REQUIREMENT.—

25 (1) DISCLOSURE.—

1	(A) IN GENERAL.—A group health plan,
2	and a health insurance issuer that provides cov-
3	erage in connection with health insurance cov-
4	erage, shall provide for the disclosure to partici-
5	pants, beneficiaries, and enrollees—
6	(i) of the information described in
7	subsection (b) at the time of the initial en-
8	rollment of the participant, beneficiary, or
9	enrollee under the plan or coverage;
10	(ii) of such information on an annual
11	basis—
12	(I) in conjunction with the elec-
13	tion period of the plan or coverage if
14	the plan or coverage has such an elec-
15	tion period; or
16	(II) in the case of a plan or cov-
17	erage that does not have an election
18	period, in conjunction with the begin-
19	ning of the plan or coverage year; and
20	(iii) of information relating to any
21	material reduction to the benefits or infor-
22	mation described in such subsection or
23	subsection (c), in the form of a notice pro-
24	vided not later than 30 days before the
25	date on which the reduction takes effect.

1	(B) PARTICIPANTS, BENEFICIARIES, AND
2	ENROLLEES.—The disclosure required under
3	subparagraph (A) shall be provided—
4	(i) jointly to each participant, bene-
5	ficiary, and enrollee who reside at the same
6	address; or
7	(ii) in the case of a beneficiary or en-
8	rollee who does not reside at the same ad-
9	dress as the participant or another en-
10	rollee, separately to the participant or
11	other enrollees and such beneficiary or en-
12	rollee.
13	(2) Provision of information.—Information
14	shall be provided to participants, beneficiaries, and
15	enrollees under this section at the last known ad-
16	dress maintained by the plan or issuer with respect
17	to such participants, beneficiaries, or enrollees, to
18	the extent that such information is provided to par-
19	ticipants, beneficiaries, or enrollees via the United
20	States Postal Service or other private delivery serv-
21	ice.
22	(b) REQUIRED INFORMATION.—The informational
23	materials to be distributed under this section shall include
24	for each option available under the group health plan or

health insurance coverage the following:

1	(1) BENEFITS.—A description of the covered
2	benefits, including—
3	(A) any in- and out-of-network benefits;
4	(B) specific preventive services covered
5	under the plan or coverage if such services are
6	covered;
7	(C) any specific exclusions or express limi-
8	tations of benefits described in section
9	104(d)(3)(C);
10	(D) any other benefit limitations, including
11	any annual or lifetime benefit limits and any
12	monetary limits or limits on the number of vis-
13	its, days, or services, and any specific coverage
14	exclusions; and
15	(E) any definition of medical necessity
16	used in making coverage determinations by the
17	plan, issuer, or claims administrator.
18	(2) Cost sharing.—A description of any cost-
19	sharing requirements, including—
20	(A) any premiums, deductibles, coinsur-
21	ance, copayment amounts, and liability for bal-
22	ance billing, for which the participant, bene-
23	ficiary, or enrollee will be responsible under
24	each option available under the plan;

1	(B) any maximum out-of-pocket expense
2	for which the participant, beneficiary, or en-
3	rollee may be liable;
4	(C) any cost-sharing requirements for out-
5	of-network benefits or services received from
6	nonparticipating providers; and
7	(D) any additional cost-sharing or charges
8	for benefits and services that are furnished
9	without meeting applicable plan or coverage re-
10	quirements, such as prior authorization or
11	precertification.
12	(3) DISENROLLMENT.—Information relating to
13	the disenrollment of a participant, beneficiary, or en-
14	rollee.
15	(4) SERVICE AREA.—A description of the plan
16	or issuer's service area, including the provision of
17	any out-of-area coverage.
18	(5) PARTICIPATING PROVIDERS.—A directory of
19	participating providers (to the extent a plan or
20	issuer provides coverage through a network of pro-
21	viders) that includes, at a minimum, the name, ad-
22	dress, and telephone number of each participating
23	provider, and information about how to inquire
24	whether a participating provider is currently accept-
25	ing new patients.

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

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

(8) EXPERIMENTAL AND INVESTIGATIONAL
TREATMENTS.—A description of the process for determining whether a particular item, service, or
treatment is considered experimental or investigational, and the circumstances under which such
treatments are covered by the plan or issuer.

(9) SPECIALTY CARE.—A description of the requirements and procedures to be used by participants, beneficiaries, and enrollees in accessing specialty care and obtaining referrals to participating
and nonparticipating specialists, including any limi-

tations on choice of health care professionals referred to in section 112(b)(2) and the right to timely
access to specialists care under section 114 if such
section applies.

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

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

(12) EMERGENCY SERVICES.—A summary of
the rules and procedures for accessing emergency
services, including the right of a participant, beneficiary, or enrollee to obtain emergency services
under the prudent layperson standard under section

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

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

17 (14) ADVANCE DIRECTIVES AND ORGAN DONA18 TION.—A description of procedures for advance di19 rectives and organ donation decisions if the plan or
20 issuer maintains such procedures.

(15) INFORMATION ON PLANS AND ISSUERS.—
The name, mailing address, and telephone number
or numbers of the plan administrator and the issuer
to be used by participants, beneficiaries, and enrollees seeking information about plan or coverage bene-

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fits and services, payment of a claim, or authorization for services and treatment. Notice of whether
the benefits under the plan or coverage are provided
under a contract or policy of insurance issued by an
issuer, or whether benefits are provided directly by
the plan sponsor who bears the insurance risk.

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

(17) ACCREDITATION INFORMATION.—Any information that is made public by accrediting organizations in the process of accreditation if the plan or
issuer is accredited, or any additional quality indicators (such as the results of enrollee satisfaction surveys) that the plan or issuer makes public or makes
available to participants, beneficiaries, and enrollees.

(18) NOTICE OF REQUIREMENTS.—A description of any rights of participants, beneficiaries, and
enrollees that are established by the Patients' Bill of
Rights Act of 2004 (excluding those described in

1 paragraphs (1) through (17) if such sections apply. 2 The description required under this paragraph may 3 be combined with the notices of the type described 4 in sections 711(d), 713(b), or 606(a)(1) of the Em-5 ployee Retirement Income Security Act of 1974 and 6 with any other notice provision that the appropriate 7 Secretary determines may be combined, so long as 8 such combination does not result in any reduction in 9 the information that would otherwise be provided to 10 the recipient.

(19) AVAILABILITY OF ADDITIONAL INFORMATION.—A statement that the information described
in subsection (c), and instructions on obtaining such
information (including telephone numbers and, if
available, Internet websites), shall be made available
upon request.

17 (20) DESIGNATED DECISIONMAKERS.—A de18 scription of the participants and beneficiaries with
19 respect to whom each designated decisionmaker
20 under the plan has assumed liability under section
21 502(o) of the Employee Retirement Income Security
22 Act of 1974 and the name and address of each such
23 decisionmaker.

24 (c) ADDITIONAL INFORMATION.—The informational25 materials to be provided upon the request of a participant,

beneficiary, or enrollee shall include for each option avail able under a group health plan or health insurance cov erage the following:

4 (1) STATUS OF PROVIDERS.—The State licen5 sure status of the plan or issuer's participating
6 health care professionals and participating health
7 care facilities, and, if available, the education, train8 ing, specialty qualifications or certifications of such
9 professionals.

10 (2) Compensation Methods.—A summary 11 description by category of the applicable methods 12 (such as capitation, fee-for-service, salary, bundled 13 payments, per diem, or a combination thereof) used 14 for compensating prospective or treating health care 15 professionals (including primary care providers and 16 specialists) and facilities in connection with the pro-17 vision of health care under the plan or coverage.

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

(4) UTILIZATION REVIEW ACTIVITIES.—A description of procedures used and requirements (including circumstances, timeframes, and appeals
rights) under any utilization review program under

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

3 (5) EXTERNAL APPEALS INFORMATION.—Ag4 gregate information on the number and outcomes of
5 external medical reviews, relative to the sample size
6 (such as the number of covered lives) under the plan
7 or under the coverage of the issuer.

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

(e) RULES OF CONSTRUCTION.—Nothing in this section shall be construed to prohibit a group health plan,
or a health insurance issuer in connection with health insurance coverage, from—

(1) distributing any other additional information determined by the plan or issuer to be important or necessary in assisting participants, beneficiaries, and enrollees in the selection of a health
plan or health insurance coverage; and

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

1	(A) the disclosure of such information in
2	such form is in accordance with requirements
3	as the appropriate Secretary may impose, and
4	(B) in connection with any such disclosure
5	of information through the Internet or other
6	electronic media—
7	(i) the recipient has affirmatively con-
8	sented to the disclosure of such informa-
9	tion in such form,
10	(ii) the recipient is capable of access-
11	ing the information so disclosed on the re-
12	cipient's individual workstation or at the
13	recipient's home,
14	(iii) the recipient retains an ongoing
15	right to receive paper disclosure of such in-
16	formation and receives, in advance of any
17	attempt at disclosure of such information
18	to him or her through the Internet or
19	other electronic media, notice in printed
20	form of such ongoing right and of the
21	proper software required to view informa-
22	tion so disclosed, and
23	(iv) the plan administrator appro-
24	priately ensures that the intended recipient
25	is receiving the information so disclosed

and provides the information in printed
 form if the information is not received.
 Subtitle D—Protecting the Doctor patient Relationship
 SEC. 131. PROHIBITION OF INTERFERENCE WITH CERTAIN

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MEDICAL COMMUNICATIONS.

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

(b) NULLIFICATION.—Any contract provision or
agreement that restricts or prohibits medical communications in violation of subsection (a) shall be null and void.

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VIDERS BASED ON LICENSURE.

3 (a) IN GENERAL.—A group health plan, and a health
4 insurance issuer with respect to health insurance coverage,
5 shall not discriminate with respect to participation or in6 demnification as to any provider who is acting within the
7 scope of the provider's license or certification under appli8 cable State law, solely on the basis of such license or cer9 tification.

10 (b) CONSTRUCTION.—Subsection (a) shall not be con11 strued—

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

21 (2) to override any State licensure or scope-of22 practice law; or

(3) as requiring a plan or issuer that offers network coverage to include for participation every willing provider who meets the terms and conditions of
the plan or issuer.

3 (a) IN GENERAL.—A group health plan and a health
4 insurance issuer offering health insurance coverage may
5 not operate any physician incentive plan (as defined in
6 subparagraph (B) of section 1852(j)(4) of the Social Secu7 rity Act) unless the requirements described in clauses (i),
8 (ii)(I), and (iii) of subparagraph (A) of such section are
9 met with respect to such a plan.

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

(c) CONSTRUCTION.—Nothing in this section shall be
construed as prohibiting all capitation and similar arrangements or all provider discount arrangements.

21 SEC. 134. PAYMENT OF CLAIMS.

A group health plan, and a health insurance issuer
offering health insurance coverage, shall provide for
prompt payment of claims submitted for health care services or supplies furnished to a participant, beneficiary, or
enrollee with respect to benefits covered by the plan or
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issuer, in a manner that is no less protective than the pro visions of section 1842(c)(2) of the Social Security Act
 (42 U.S.C. 1395u(c)(2)).

4 SEC. 135. PROTECTION FOR PATIENT ADVOCACY.

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

15 (b) PROTECTION FOR QUALITY ADVOCACY BY16 HEALTH CARE PROFESSIONALS.—

17 (1) IN GENERAL.—A group health plan and a
18 health insurance issuer may not retaliate or dis19 criminate against a protected health care profes20 sional because the professional in good faith—

(A) discloses information relating to the
care, services, or conditions affecting one or
more participants, beneficiaries, or enrollees of
the plan or issuer to an appropriate public regulatory agency, an appropriate private accredi-

1	tation body, or appropriate management per-
2	sonnel of the plan or issuer; or
3	(B) initiates, cooperates, or otherwise par-
4	ticipates in an investigation or proceeding by
5	such an agency with respect to such care, serv-
6	ices, or conditions.
7	If an institutional health care provider is a partici-
8	pating provider with such a plan or issuer or other-
9	wise receives payments for benefits provided by such
10	a plan or issuer, the provisions of the previous sen-
11	tence shall apply to the provider in relation to care,
12	services, or conditions affecting one or more patients
13	within an institutional health care provider in the
14	same manner as they apply to the plan or issuer in
15	relation to care, services, or conditions provided to
16	one or more participants, beneficiaries, or enrollees;
17	and for purposes of applying this sentence, any ref-
18	erence to a plan or issuer is deemed a reference to
19	the institutional health care provider.
20	(2) GOOD FAITH ACTION.—For purposes of
21	paragraph (1), a protected health care professional
22	is considered to be acting in good faith with respect
23	to disclosure of information or participation if, with
24	respect to the information disclosed as part of the

25 action—

1	(A) the disclosure is made on the basis of
2	personal knowledge and is consistent with that
3	degree of learning and skill ordinarily possessed
4	by health care professionals with the same li-
5	censure or certification and the same experi-
6	ence;
7	(B) the professional reasonably believes the
8	information to be true;
9	(C) the information evidences either a vio-
10	lation of a law, rule, or regulation, of an appli-
11	cable accreditation standard, or of a generally
12	recognized professional or clinical standard or
13	that a patient is in imminent hazard of loss of
14	life or serious injury; and
15	(D) subject to subparagraphs (B) and (C)
16	of paragraph (3), the professional has followed
17	reasonable internal procedures of the plan,
18	issuer, or institutional health care provider es-
19	tablished for the purpose of addressing quality
20	concerns before making the disclosure.
21	(3) EXCEPTION AND SPECIAL RULE.—
22	(A) GENERAL EXCEPTION.—Paragraph (1)
23	does not protect disclosures that would violate
24	Federal or State law or diminish or impair the
25	rights of any person to the continued protection

of confidentiality of communications provided by such law.

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

13 (C) INTERNAL PROCEDURE EXCEPTION.—
14 Subparagraph (D) of paragraph (2) also shall
15 not apply if—

16 (i) the disclosure relates to an immi17 nent hazard of loss of life or serious injury
18 to a patient;

19 (ii) the disclosure is made to an ap20 propriate private accreditation body pursu21 ant to disclosure procedures established by
22 the body; or

23 (iii) the disclosure is in response to an
24 inquiry made in an investigation or pro25 ceeding of an appropriate public regulatory

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

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

(5) NOTICE.—A group health plan, health insurance issuer, and institutional health care provider
shall post a notice, to be provided or approved by
the Secretary of Labor, setting forth excerpts from,
or summaries of, the pertinent provisions of this
subsection and information pertaining to enforcement of such provisions.

19 (6) CONSTRUCTIONS.—

20 (A) DETERMINATIONS OF COVERAGE.—
21 Nothing in this subsection shall be construed to
22 prohibit a plan or issuer from making a deter23 mination not to pay for a particular medical
24 treatment or service or the services of a type of
25 health care professional.

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

(C) RELATION TO OTHER RIGHTS.—Nothing in this subsection shall be construed to
abridge rights of participants, beneficiaries, enrollees, and protected health care professionals
under other applicable Federal or State laws.

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

(A) with respect to a group health plan or
health insurance issuer, is an employee of the
plan or issuer or has a contract with the plan
or issuer for provision of services for which benefits are available under the plan or issuer; or

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

6 Subtitle E—Definitions

7 SEC. 151. DEFINITIONS.

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

13 (b) SECRETARY.—Except as otherwise provided, the term "Secretary" means the Secretary of Health and 14 15 Human Services, in consultation with the Secretary of Labor and the term "appropriate Secretary" means the 16 Secretary of Health and Human Services in relation to 17 carrying out this title under sections 2706 and 2751 of 18 the Public Health Service Act and the Secretary of Labor 19 20 in relation to carrying out this title under section 714 of 21 the Employee Retirement Income Security Act of 1974. 22 (c) ADDITIONAL DEFINITIONS.—For purposes of this 23 title:

24 (1) APPLICABLE AUTHORITY.—The term "ap25 plicable authority" means—

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

(2) ENROLLEE.—The term "enrollee" means,
with respect to health insurance coverage offered by
a health insurance issuer, an individual enrolled with
the issuer to receive such coverage.

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

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

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

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

12 (6) NETWORK.—The term "network" means,
13 with respect to a group health plan or health insur14 ance issuer offering health insurance coverage, the
15 participating health care professionals and providers
16 through whom the plan or issuer provides health
17 care items and services to participants, beneficiaries,
18 or enrollees.

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

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

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

14 (10) TERMS AND CONDITIONS.—The term
15 "terms and conditions" includes, with respect to a
16 group health plan or health insurance coverage, re17 quirements imposed under this title with respect to
18 the plan or coverage.

19sec. 152. preemption; state flexibility; construction20tion.

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

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

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

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

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

19 (b) APPLICATION OF SUBSTANTIALLY COMPLIANT20 STATE LAWS.—

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

1	complies (within the meaning of subsection (c)) with
2	a patient protection requirement (as defined in para-
3	graph (3)) and does not prevent the application of
4	other requirements under this Act (except in the
5	case of other substantially compliant requirements),
6	in applying the requirements of this title under sec-
7	tion 2707 and 2753 (as applicable) of the Public
8	Health Service Act (as added by title II), subject to
9	subsection $(a)(2)$ —
10	(A) the State law shall not be treated as
11	being superseded under subsection (a); and
12	(B) the State law shall apply instead of the
13	patient protection requirement otherwise appli-
14	cable with respect to health insurance coverage
15	and non-Federal governmental plans.
16	(2) LIMITATION.—In the case of a group health
17	plan covered under title I of the Employee Retire-
18	ment Income Security Act of 1974, paragraph (1)
19	shall be construed to apply only with respect to the
20	health insurance coverage (if any) offered in connec-
21	tion with the plan.
22	(3) DEFINITIONS.—In this section:
23	(A) PATIENT PROTECTION REQUIRE-
24	MENT.—The term "patient protection require-
25	ment" means a requirement under this title,

1 and includes (as a single requirement) a group 2 or related set of requirements under a section or similar unit under this title. 3 4 (B) SUBSTANTIALLY COMPLIANT.—The 5 terms "substantially compliant", substantially 6 complies", or "substantial compliance" with re-7 spect to a State law, mean that the State law 8 has the same or similar features as the patient 9 protection requirements and has a similar ef-10 fect. 11 (c) DETERMINATIONS OF SUBSTANTIAL COMPLI-12 ANCE.— 13 (1) CERTIFICATION BY STATES.—A State may 14 submit to the Secretary a certification that a State 15 law provides for patient protections that are at least 16 substantially compliant with one or more patient 17 protection requirements. Such certification shall be 18 accompanied by such information as may be re-19 quired to permit the Secretary to make the deter-20 mination described in paragraph (2)(A). 21 (2) REVIEW.— 22 (A) IN GENERAL.—The Secretary shall 23 promptly review a certification submitted under 24 paragraph (1) with respect to a State law to de-25 termine if the State law substantially complies

1	with the patient protection requirement (or re-
2	quirements) to which the law relates.
3	(B) Approval deadlines.—
4	(i) INITIAL REVIEW.—Such a certifi-
5	cation is considered approved unless the
6	Secretary notifies the State in writing,
7	within 90 days after the date of receipt of
8	the certification, that the certification is
9	disapproved (and the reasons for dis-
10	approval) or that specified additional infor-
11	mation is needed to make the determina-
12	tion described in subparagraph (A).
13	(ii) Additional information.—
14	With respect to a State that has been noti-
15	fied by the Secretary under clause (i) that
16	specified additional information is needed
17	to make the determination described in
18	subparagraph (A), the Secretary shall
19	make the determination within 60 days
20	after the date on which such specified ad-
21	ditional information is received by the Sec-
22	retary.
23	(3) Approval.—

1	(A) IN GENERAL.—The Secretary shall ap-
2	prove a certification under paragraph (1) un-
3	less—
4	(i) the State fails to provide sufficient
5	information to enable the Secretary to
6	make a determination under paragraph
7	(2)(A); or
8	(ii) the Secretary determines that the
9	State law involved does not provide for pa-
10	tient protections that substantially comply
11	with the patient protection requirement (or
12	requirements) to which the law relates.
13	(B) STATE CHALLENGE.—A State that has
14	a certification disapproved by the Secretary
15	under subparagraph (A) may challenge such
16	disapproval in the appropriate United States
17	district court.
18	(C) Deference to states.—With re-
19	spect to a certification submitted under para-
20	graph (1), the Secretary shall give deference to
21	the State's interpretation of the State law in-
22	volved with respect to the patient protection in-
23	volved.
24	(D) PUBLIC NOTIFICATION.—The Sec-
25	retary shall—

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1	(i) provide a State with a notice of the
2	determination to approve or disapprove a
3	certification under this paragraph;
4	(ii) promptly publish in the Federal
5	Register a notice that a State has sub-
6	mitted a certification under paragraph (1) ;
7	(iii) promptly publish in the Federal
8	Register the notice described in clause (i)
9	with respect to the State; and
10	(iv) annually publish the status of all
11	States with respect to certifications.
12	(4) CONSTRUCTION.—Nothing in this sub-
13	section shall be construed as preventing the certifi-
14	cation (and approval of certification) of a State law
15	under this subsection solely because it provides for
16	greater protections for patients than those protec-
17	tions otherwise required to establish substantial
18	compliance.
19	(5) Petitions.—
20	(A) PETITION PROCESS.—Effective on the
21	date on which the provisions of this Act become
22	effective, as provided for in section 601, a
23	group health plan, health insurance issuer, par-
24	ticipant, beneficiary, or enrollee may submit a
25	petition to the Secretary for an advisory opinion

1	as to whether or not a standard or requirement
2	under a State law applicable to the plan, issuer,
3	participant, beneficiary, or enrollee that is not
4	the subject of a certification under this sub-
5	section, is superseded under subsection $(a)(1)$
6	because such standard or requirement prevents
7	the application of a requirement of this title.
8	(B) Opinion.—The Secretary shall issue
9	an advisory opinion with respect to a petition
10	submitted under subparagraph (A) within the
11	60-day period beginning on the date on which
12	such petition is submitted.
13	(d) DEFINITIONS.—For purposes of this section:
14	(1) STATE LAW.—The term "State law" in-
15	cludes all laws, decisions, rules, regulations, or other
16	State action having the effect of law, of any State.
17	A law of the United States applicable only to the
18	District of Columbia shall be treated as a State law
19	rather than a law of the United States.
20	(2) STATE.—The term "State" includes a
21	State, the District of Columbia, Puerto Rico, the
22	Virgin Islands, Guam, American Samoa, the North-
23	ern Mariana Islands, any political subdivisions of
24	such, or any agency or instrumentality of such.

1 SEC. 153. EXCLUSIONS.

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

9 (b) EXCLUSION FROM ACCESS TO CARE MANAGED10 CARE PROVISIONS FOR FEE-FOR-SERVICE COVERAGE.—

(1) IN GENERAL.—The provisions of sections
11 (1) IN GENERAL.—The provisions of sections
12 111 through 117 shall not apply to a group health
13 plan or health insurance coverage if the only cov14 erage offered under the plan or coverage is fee-for15 service coverage (as defined in paragraph (2)).

16 (2) FEE-FOR-SERVICE COVERAGE DEFINED.—
17 For purposes of this subsection, the term "fee-for18 service coverage" means coverage under a group
19 health plan or health insurance coverage that—

20 (A) reimburses hospitals, health profes21 sionals, and other providers on a fee-for-service
22 basis without placing the provider at financial
23 risk;

24 (B) does not vary reimbursement for such25 a provider based on an agreement to contract

1	terms and conditions or the utilization of health
2	care items or services relating to such provider;
3	(C) allows access to any provider that is
4	lawfully authorized to provide the covered serv-
5	ices and that agrees to accept the terms and
6	conditions of payment established under the
7	plan or by the issuer; and
8	(D) for which the plan or issuer does not
9	require prior authorization before providing for
10	any health care services.
11	SEC. 154. TREATMENT OF EXCEPTED BENEFITS.
12	(a) IN GENERAL.—The requirements of this title and
13	the provisions of sections $502(a)(1)(C)$, $502(n)$, and

(a)(1)(0),14 514(d) of the Employee Retirement Income Security Act 15 of 1974 (added by section 402) shall not apply to excepted benefits (as defined in section 733(c) of such Act), other 16 than benefits described in section 733(c)(2)(A) of such 17 18 Act, in the same manner as the provisions of part 7 of 19 subtitle B of title I of such Act do not apply to such benefits under subsections (b) and (c) of section 732 of such 20 21 Act.

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

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

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

6 (2) Section 733(c)(2)(A) of the Employee Re7 tirement Income Security Act of 1974.

8 (3) Section 9832(c)(2)(A) of the Internal Rev9 enue Code of 1986.

10 SEC. 155. REGULATIONS.

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

19 SEC. 156. INCORPORATION INTO PLAN OR COVERAGE DOC-

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UMENTS.

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

3 SEC. 157. PRESERVATION OF PROTECTIONS.

4 (a) IN GENERAL.—The rights under this Act (includ5 ing the right to maintain a civil action and any other
6 rights under the amendments made by this Act) may not
7 be waived, deferred, or lost pursuant to any agreement
8 not authorized under this Act.

9 (b) EXCEPTION.—Subsection (a) shall not apply to 10 an agreement providing for arbitration or participation in 11 any other nonjudicial procedure to resolve a dispute if the 12 agreement—

(1) is entered into knowingly and voluntarily by
the parties involved after the dispute has arisen; or
(2) is pursuant to the terms of a collective bargaining agreement.

17 Nothing in this subsection shall be construed to permit18 the waiver of the requirements of sections 103 and 10419 (relating to internal and external review).

II—APPLICATION TITLE OF 1 QUALITY CARE **STANDARDS** 2 GROUP HEALTH TO PLANS 3 AND HEALTH INSURANCE 4 **COVERAGE UNDER THE PUB-**5 LIC HEALTH SERVICE ACT 6 7 SEC. 201. APPLICATION TO GROUP HEALTH PLANS AND

SEC. 201. AFFLICATION TO GROUP HEALTH FLANS AN

GROUP HEALTH INSURANCE COVERAGE.

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

12 "SEC. 2707. PATIENT PROTECTION STANDARDS.

13 "Each group health plan shall comply with patient 14 protection requirements under title I of the Patients' Bill 15 of Rights Act of 2004, and each health insurance issuer 16 shall comply with patient protection requirements under 17 such title with respect to group health insurance coverage 18 it offers, and such requirements shall be deemed to be in-19 corporated into this subsection.".

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

3 Part B of title XXVII of the Public Health Service
4 Act is amended by inserting after section 2752 the fol5 lowing new section:

6 "SEC. 2753. PATIENT PROTECTION STANDARDS.

7 "Each health insurance issuer shall comply with pa8 tient protection requirements under title I of the Patients'
9 Bill of Rights Act of 2004 with respect to individual health
10 insurance coverage it offers, and such requirements shall
11 be deemed to be incorporated into this subsection.".

12 SEC. 203. COOPERATION BETWEEN FEDERAL AND STATE 13 AUTHORITIES.

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

17 "SEC. 2793. COOPERATION BETWEEN FEDERAL AND STATE 18 AUTHORITIES.

19 "(a) AGREEMENT WITH STATES.—A State may 20 enter into an agreement with the Secretary for the delega-21 tion to the State of some or all of the Secretary's authority 22 under this title to enforce the requirements applicable 23 under title I of the Patients' Bill of Rights Act of 2004 24 with respect to health insurance coverage offered by a 25 health insurance issuer and with respect to a group health 26 plan that is a non-Federal governmental plan.

1 "(b) DELEGATIONS.—Any department, agency, or in-2 strumentality of a State to which authority is delegated 3 pursuant to an agreement entered into under this section 4 may, if authorized under State law and to the extent con-5 sistent with such agreement, exercise the powers of the Secretary under this title which relate to such authority.". 6 TITLE III—APPLICATION OF PA-7 PROTECTION TIENT **STAND-**8 ARDS TO FEDERAL HEALTH 9 **INSURANCE PROGRAMS** 10 11 SEC. 301. APPLICATION OF PATIENT PROTECTION STAND-12 ARDS TO FEDERAL HEALTH INSURANCE PRO-13 GRAMS. 14 (a) SENSE OF CONGRESS.—It is the sense of Con-

15 gress that enrollees in Federal health insurance programs 16 should have the same rights and privileges as those af-17 forded under title I and under the amendments made by 18 title IV to participants and beneficiaries under group 19 health plans.

(b) CONFORMING FEDERAL HEALTH INSURANCE
PROGRAMS.—It is the sense of Congress that the President should require, by executive order, the Federal official with authority over each Federal health insurance program, to the extent feasible, to take such steps as are nec-

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

3 (c) GAO REPORT ON ADDITIONAL STEPS RE-4 QUIRED.—Not later than 1 year after the date of the en-5 actment of this Act, the Comptroller General of the United 6 States shall submit to Congress a report on statutory 7 changes that are required to implement such rights and 8 privileges in a manner that is consistent with the missions 9 of the Federal health insurance programs and that avoids unnecessary duplication or disruption of such programs. 10 11 (d) FEDERAL HEALTH INSURANCE PROGRAM.—In 12 this section, the term "Federal health insurance program"

13 means a Federal program that provides creditable cov14 erage (as defined in section 2701(c)(1) of the Public
15 Health Service Act) and includes a health program of the
16 Department of Veterans Affairs.

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

4 SEC. 401. APPLICATION OF PATIENT PROTECTION STAND5 ARDS TO GROUP HEALTH PLANS AND GROUP
6 HEALTH INSURANCE COVERAGE UNDER THE
7 EMPLOYEE RETIREMENT INCOME SECURITY
8 ACT OF 1974.

9 Subpart B of part 7 of subtitle B of title I of the
10 Employee Retirement Income Security Act of 1974 is
11 amended by adding at the end the following new section:
12 "SEC. 714. PATIENT PROTECTION STANDARDS.

13 "(a) IN GENERAL.—Subject to subsection (b), a 14 group health plan (and a health insurance issuer offering 15 group health insurance coverage in connection with such a plan) shall comply with the requirements of title I of 16 the Patients' Bill of Rights Act of 2004 (as in effect as 17 18 of the date of the enactment of such Act), and such re-19 quirements shall be deemed to be incorporated into this 20 subsection.

21 "(b) Plan Satisfaction of Certain Require-22 Ments.—

23 "(1) SATISFACTION OF CERTAIN REQUIRE24 MENTS THROUGH INSURANCE.—For purposes of
25 subsection (a), insofar as a group health plan pro-

1	vides benefits in the form of health insurance cov-
2	erage through a health insurance issuer, the plan
3	shall be treated as meeting the following require-
4	ments of title I of the Patients' Bill of Rights Act
5	of 2004 with respect to such benefits and not be
6	considered as failing to meet such requirements be-
7	cause of a failure of the issuer to meet such require-
8	ments so long as the plan sponsor or its representa-
9	tives did not cause such failure by the issuer:
10	"(A) Section 111 (relating to consumer
11	choice option).
12	"(B) Section 112 (relating to choice of
13	health care professional).
14	"(C) Section 113 (relating to access to
15	emergency care).
16	"(D) Section 114 (relating to timely access
17	to specialists).
18	"(E) Section 115 (relating to patient ac-
19	cess to obstetrical and gynecological care).
20	"(F) Section 116 (relating to access to pe-
21	diatric care).
22	"(G) Section 117 (relating to continuity of
23	care), but only insofar as a replacement issuer
24	assumes the obligation for continuity of care.

1	"(H) Section 118 (relating to access to
2	needed prescription drugs).
3	"(I) Section 119 (relating to coverage for
4	individuals participating in approved clinical
5	trials).
6	"(J) Section 120 (relating to required cov-
7	erage for minimum hospital stay for
8	mastectomies and lymph node dissections for
9	the treatment of breast cancer and coverage for
10	secondary consultations).
11	"(K) Section 134 (relating to payment of
12	claims).
13	"(2) INFORMATION.—With respect to informa-
14	tion required to be provided or made available under
15	section 121 of the Patients' Bill of Rights Act of
16	2004, in the case of a group health plan that pro-
17	vides benefits in the form of health insurance cov-
18	erage through a health insurance issuer, the Sec-
19	retary shall determine the circumstances under
20	which the plan is not required to provide or make
21	available the information (and is not liable for the
22	issuer's failure to provide or make available the in-
23	formation), if the issuer is obligated to provide and
24	make available (or provides and makes available)
25	such information.

1 "(3) INTERNAL APPEALS.—With respect to the 2 internal appeals process required to be established 3 under section 103 of such Act, in the case of a 4 group health plan that provides benefits in the form 5 of health insurance coverage through a health insur-6 ance issuer, the Secretary shall determine the cir-7 cumstances under which the plan is not required to 8 provide for such process and system (and is not lia-9 ble for the issuer's failure to provide for such proc-10 ess and system), if the issuer is obligated to provide 11 for (and provides for) such process and system.

"(4) EXTERNAL APPEALS.—Pursuant to rules 12 13 of the Secretary, insofar as a group health plan en-14 ters into a contract with a qualified external appeal 15 entity for the conduct of external appeal activities in 16 accordance with section 104 of such Act, the plan 17 shall be treated as meeting the requirement of such 18 section and is not liable for the entity's failure to 19 meet any requirements under such section.

"(5) APPLICATION TO PROHIBITIONS.—Pursuant to rules of the Secretary, if a health insurance issuer offers health insurance coverage in connection
with a group health plan and takes an action in violation of any of the following sections of the Patients' Bill of Rights Act of 2004, the group health

1	plan shall not be liable for such violation unless the
2	plan caused such violation:
3	"(A) Section 131 (relating to prohibition of
4	interference with certain medical communica-
5	tions).
6	"(B) Section 132 (relating to prohibition
7	of discrimination against providers based on li-
8	censure).
9	"(C) Section 133 (relating to prohibition
10	against improper incentive arrangements).
11	"(D) Section 135 (relating to protection
12	for patient advocacy).
13	"(6) CONSTRUCTION.—Nothing in this sub-
14	section shall be construed to affect or modify the re-
15	sponsibilities of the fiduciaries of a group health
16	plan under part 4 of subtitle B.
17	"(7) TREATMENT OF SUBSTANTIALLY COMPLI-
18	ANT STATE LAWS.—For purposes of applying this
19	subsection in connection with health insurance cov-
20	erage, any reference in this subsection to a require-
21	ment in a section or other provision in the Patients'
22	Bill of Rights Act of 2004 with respect to a health
23	insurance issuer is deemed to include a reference to
24	a requirement under a State law that substantially
25	complies (as determined under section $152(c)$ of

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

3 "(8) APPLICATION TO CERTAIN PROHIBITIONS AGAINST RETALIATION.—With respect to compliance 4 5 with the requirements of section 135(b)(1) of the 6 Patients' Bill of Rights Act of 2004, for purposes of 7 this subtitle the term 'group health plan' is deemed 8 to include a reference to an institutional health care 9 provider.

"(c) Enforcement of Certain Requirements.— "(1) COMPLAINTS.—Any protected health care 11 12 professional who believes that the professional has been retaliated or discriminated against in violation 13 14 of section 135(b)(1) of the Patients' Bill of Rights 15 Act of 2004 may file with the Secretary a complaint 16 within 180 days of the date of the alleged retaliation 17 or discrimination.

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

1 "(d) CONFORMING REGULATIONS.—The Secretary 2 shall issue regulations to coordinate the requirements on 3 group health plans and health insurance issuers under this 4 section with the requirements imposed under the other 5 provisions of this title. In order to reduce duplication and clarify the rights of participants and beneficiaries with re-6 7 spect to information that is required to be provided, such 8 regulations shall coordinate the information disclosure re-9 quirements under section 121 of the Patients' Bill of 10 Rights Act of 2004 with the reporting and disclosure requirements imposed under part 1, so long as such coordi-11 12 nation does not result in any reduction in the information 13 that would otherwise be provided to participants and bene-14 ficiaries.".

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

"(b) In the case of a group health plan (as defined
in section 733), compliance with the requirements of subtitle A of title I of the Patients' Bill of Rights Act of 2004,
and compliance with regulations promulgated by the Secretary, in the case of a claims denial, shall be deemed compliance with subsection (a) with respect to such claims denial.".

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

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

"714. Patient protection standards.".

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

10 SEC. 402. AVAILABILITY OF CIVIL REMEDIES.

(a) Availability of Federal Civil Remedies in
Cases not Involving Medically Reviewable Decisions.—

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

18 "(n) CAUSE OF ACTION RELATING TO PROVISION OF19 HEALTH BENEFITS.—

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

21 "(A) a person who is a fiduciary of a
22 group health plan, a health insurance issuer of23 fering health insurance coverage in connection
24 with the plan, or an agent of the plan, issuer,
25 or plan sponsor, upon consideration of a claim

1	for benefits of a participant or beneficiary
2	under section 102 of the Patients' Bill of
3	Rights Act of 2004 (relating to procedures for
4	initial claims for benefits and prior authoriza-
5	tion determinations) or upon review of a denial
6	of such a claim under section 103 of such Act
7	(relating to internal appeal of a denial of a
8	claim for benefits), fails to exercise ordinary
9	care in making a decision—
10	"(i) regarding whether an item or
11	service is covered under the terms and con-
12	ditions of the plan or coverage,
13	"(ii) regarding whether an individual
14	is a participant or beneficiary who is en-
15	rolled under the terms and conditions of
16	the plan or coverage (including the applica-
17	bility of any waiting period under the plan
18	or coverage), or
19	"(iii) as to the application of cost-
20	sharing requirements or the application of
21	a specific exclusion or express limitation on
22	the amount, duration, or scope of coverage
23	of items or services under the terms and
24	conditions of the plan or coverage, and

1	"(B) such failure is a proximate cause of
2	personal injury to, or the death of, the partici-
3	pant or beneficiary,
4	such plan, plan sponsor, or issuer shall be liable to
5	the participant or beneficiary (or the estate of such
6	participant or beneficiary) for economic and non-
7	economic damages (but not exemplary or punitive
8	damages) in connection with such personal injury or
9	death.
10	"(2) CAUSE OF ACTION MUST NOT INVOLVE
11	MEDICALLY REVIEWABLE DECISION.—
12	"(A) IN GENERAL.—A cause of action is
13	established under paragraph (1)(A) only if the
14	decision referred to in paragraph $(1)(A)$ does
15	not include a medically reviewable decision.
16	"(B) MEDICALLY REVIEWABLE DECI-
17	SION.—For purposes of this subsection, the
18	term 'medically reviewable decision' means a de-
19	nial of a claim for benefits under the plan
20	which is described in section $104(d)(2)$ of the
21	Patients' Bill of Rights Act of 2004 (relating to
22	medically reviewable decisions).
23	"(3) Limitation regarding certain types
24	OF ACTIONS SAVED FROM PREEMPTION OF STATE
25	LAW.—A cause of action is not established under

1	paragraph (1)(A) in connection with a failure de-
2	scribed in paragraph (1)(A) to the extent that a
3	cause of action under State law (as defined in sec-
4	tion 514(c)) for such failure would not be preempted
5	under section 514.
6	"(4) Definitions and related rules.—For
7	purposes of this subsection.—
8	"(A) Ordinary care.—The term 'ordi-
9	nary care' means, with respect to a determina-
10	tion on a claim for benefits, that degree of care,
11	skill, and diligence that a reasonable and pru-
12	dent individual would exercise in making a fair
13	determination on a claim for benefits of like
14	kind to the claims involved.
15	"(B) PERSONAL INJURY.—The term 'per-
16	sonal injury' means a physical injury and in-
17	cludes an injury arising out of the treatment
18	(or failure to treat) a mental illness or disease.
19	"(C) CLAIM FOR BENEFITS; DENIAL.—The
20	terms 'claim for benefits' and 'denial of a claim
21	for benefits' have the meanings provided such
22	terms in section 102(e) of the Patients' Bill of
23	Rights Act of 2004.
24	"(D) TERMS AND CONDITIONS.—The term
25	'terms and conditions' includes, with respect to

	102
1	a group health plan or health insurance cov-
2	erage, requirements imposed under title I of the
3	Patients' Bill of Rights Act of 2004.
4	"(E) TREATMENT OF EXCEPTED BENE-
5	FITS.—Under section 154(a) of the Patients'
6	Bill of Rights Act of 2004, the provisions of
7	this subsection and subsection $(a)(1)(C)$ do not
8	apply to certain excepted benefits.
9	"(5) Exclusion of employers and other
10	PLAN SPONSORS.—
11	"(A) CAUSES OF ACTION AGAINST EM-
12	PLOYERS AND PLAN SPONSORS PRECLUDED.—
13	Subject to subparagraph (B), paragraph (1)(A)
14	does not authorize a cause of action against an
15	employer or other plan sponsor maintaining the
16	plan (or against an employee of such an em-
17	ployer or sponsor acting within the scope of em-
18	ployment).
19	"(B) CERTAIN CAUSES OF ACTION PER-
20	MITTED.—Notwithstanding subparagraph (A),
21	a cause of action may arise against an employer
22	or other plan sponsor (or against an employee
23	of such an employer or sponsor acting within
24	the scope of employment) under paragraph
25	(1)(A), to the extent there was direct participa-

1	tion by the employer or other plan sponsor (or
2	employee) in the decision of the plan under sec-
3	tion 102 of the Patients' Bill of Rights Act of
4	2004 upon consideration of a claim for benefits
5	or under section 103 of such Act upon review
6	of a denial of a claim for benefits.
7	"(C) Direct participation.—
8	"(i) IN GENERAL.—For purposes of
9	subparagraph (B), the term 'direct partici-
10	pation' means, in connection with a deci-
11	sion described in paragraph (1)(A), the ac-
12	tual making of such decision or the actual
13	exercise of control in making such decision.
14	"(ii) Rules of construction.—For
15	purposes of clause (i), the employer or plan
16	sponsor (or employee) shall not be con-
17	strued to be engaged in direct participation
18	because of any form of decisionmaking or
19	other conduct that is merely collateral or
20	precedent to the decision described in
21	paragraph (1)(A) on a particular claim for
22	benefits of a participant or beneficiary, in-
23	cluding (but not limited to)—
24	"(I) any participation by the em-
25	ployer or other plan sponsor (or em-

1	ployee) in the selection of the group
2	health plan or health insurance cov-
3	erage involved or the third party ad-
4	ministrator or other agent;
5	"(II) any engagement by the em-
6	ployer or other plan sponsor (or em-
7	ployee) in any cost-benefit analysis
8	undertaken in connection with the se-
9	lection of, or continued maintenance
10	of, the plan or coverage involved;
11	"(III) any participation by the
12	employer or other plan sponsor (or
13	employee) in the process of creating,
14	continuing, modifying, or terminating
15	the plan or any benefit under the
16	plan, if such process was not substan-
17	tially focused solely on the particular
18	situation of the participant or bene-
19	ficiary referred to in paragraph
20	(1)(A); and
21	"(IV) any participation by the
22	employer or other plan sponsor (or
23	employee) in the design of any benefit
24	under the plan, including the amount
22 23	employer or other plan spon employee) in the design of any

- of copayment and limits connected
 with such benefit.
 "(iii) IRRELEVANCE OF CERTAIN COL LATERAL EFFORTS MADE BY EMPLOYER
- 5 OR PLAN SPONSOR.—For purposes of this 6 subparagraph, an employer or plan sponsor 7 shall not be treated as engaged in direct 8 participation in a decision with respect to 9 any claim for benefits or denial thereof in 10 the case of any particular participant or 11 beneficiary solely by reason of—
- 12 "(I) any efforts that may have
 13 been made by the employer or plan
 14 sponsor to advocate for authorization
 15 of coverage for that or any other par16 ticipant or beneficiary (or any group
 17 of participants or beneficiaries), or
- 18 "(II) any provision that may 19 have been made by the employer or 20 plan sponsor for benefits which are 21 not covered under the terms and con-22 ditions of the plan for that or any 23 other participant or beneficiary (or 24 any group of participants or bene-25 ficiaries).

1	"(D) Application to certain plans.—
2	"(i) IN GENERAL.—Notwithstanding
3	any other provision of this subsection, no
4	group health plan described in clause (ii)
5	(or plan sponsor of such a plan) shall be
6	liable under paragraph (1) for the perform-
7	ance of, or the failure to perform, any non-
8	medically reviewable duty under the plan.
9	"(ii) Definition.—A group health
10	plan described in this clause is—
11	"(I) a group health plan that is
12	self-insured and self administered by
13	an employer (including an employee of
14	such an employer acting within the
15	scope of employment); or
16	"(II) a multiemployer plan as de-
17	fined in section $3(37)(A)$ (including
18	an employee of a contributing em-
19	ployer or of the plan, or a fiduciary of
20	the plan, acting within the scope of
21	employment or fiduciary responsi-
22	bility) that is self-insured and self-ad-
23	ministered.
24	"(6) Exclusion of physicians and other
25	HEALTH CARE PROFESSIONALS.—

"(A) IN GENERAL.—No treating physician 1 2 or other treating health care professional of the participant or beneficiary, and no person acting 3 4 under the direction of such a physician or 5 health care professional, shall be liable under 6 paragraph (1) for the performance of, or the 7 failure to perform, any non-medically reviewable 8 duty of the plan, the plan sponsor, or any 9 health insurance issuer offering health insur-10 ance coverage in connection with the plan. 11 "(B) DEFINITIONS.—For purposes of sub-12 paragraph (A)— "(i) Health care professional.— 13 14 The term 'health care professional' means 15 an individual who is licensed, accredited, or 16 certified under State law to provide speci-17 fied health care services and who is oper-18 ating within the scope of such licensure, 19 accreditation, or certification. 20 "(ii) NON-MEDICALLY REVIEWABLE 21 DUTY.—The term 'non-medically review-22 able duty' means a duty the discharge of

which does not include the making of amedically reviewable decision.

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

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

17 "(9) REQUIREMENT OF EXHAUSTION.—

"(A) IN GENERAL.—A cause of action may
not be brought under paragraph (1) in connection with any denial of a claim for benefits of
any individual until all administrative processes
under sections 102 and 103 of the Patients'
Bill of Rights Act of 2004 (if applicable) have
been exhausted.

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1	"(B) EXCEPTION FOR NEEDED CARE.—A
2	participant or beneficiary may seek relief exclu-
3	sively in Federal court under subsection
4	502(a)(1)(B) prior to the exhaustion of admin-
5	istrative remedies under sections 102, 103, or
6	104 of the Patients' Bill of Rights Act of 2004
7	(as required under subparagraph (A)) if it is
8	demonstrated to the court that the exhaustion
9	of such remedies would cause irreparable harm
10	to the health of the participant or beneficiary.
11	Notwithstanding the awarding of relief under
12	subsection $502(a)(1)(B)$ pursuant to this sub-
13	paragraph, no relief shall be available as a re-
14	sult of, or arising under, paragraph (1)(A) or
15	paragraph (10)(B), with respect to a partici-
16	pant or beneficiary, unless the requirements of
17	subparagraph (A) are met.
18	"(C) RECEIPT OF BENEFITS DURING AP-
19	PEALS PROCESS.—Receipt by the participant or
20	beneficiary of the benefits involved in the claim
21	for benefits during the pendency of any admin-
22	istrative processes referred to in subparagraph
23	(A) or of any action commenced under this sub-

24 section—

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1	"(i) shall not preclude continuation of
2	all such administrative processes to their
3	conclusion if so moved by any party, and
4	"(ii) shall not preclude any liability
5	under subsection $(a)(1)(C)$ and this sub-
6	section in connection with such claim.
7	The court in any action commenced under this
8	subsection shall take into account any receipt of
9	benefits during such administrative processes or
10	such action in determining the amount of the
11	damages awarded.
12	"(D) Admissible.—Any determination
13	made by a reviewer in an administrative pro-
14	ceeding under section 103 of the Patients' Bill
15	of Rights Act of 2004 shall be admissible in
16	any Federal court proceeding and shall be pre-
17	sented to the trier of fact.
18	"(10) STATUTORY DAMAGES.—
19	"(A) IN GENERAL.—The remedies set
20	forth in this subsection (n) shall be the exclu-
21	sive remedies for causes of action brought
22	under this subsection.
23	"(B) Assessment of civil penalties.—
24	In addition to the remedies provided for in
25	paragraph (1) (relating to the failure to provide

1	contract benefits in accordance with the plan),
2	a civil assessment, in an amount not to exceed
3	\$5,000,000, payable to the claimant may be
4	awarded in any action under such paragraph if
5	the claimant establishes by clear and convincing
6	evidence that the alleged conduct carried out by
7	the defendant demonstrated bad faith and fla-
8	grant disregard for the rights of the participant
9	or beneficiary under the plan and was a proxi-
10	mate cause of the personal injury or death that
11	is the subject of the claim.
12	"(11) Limitation on attorneys' fees.—
13	"(A) IN GENERAL.—Notwithstanding any
14	other provision of law, or any arrangement,
15	agreement, or contract regarding an attorney's
16	fee, the amount of an attorney's contingency fee
17	allowable for a cause of action brought pursu-
18	ant to this subsection shall not exceed $1\!/\!_3$ of the
19	total amount of the plaintiff's recovery (not in-
20	cluding the reimbursement of actual out-of-
21	pocket expenses of the attorney).
22	"(B) DETERMINATION BY DISTRICT
23	COURT.—The last Federal district court in
24	which the action was pending upon the final
25	disposition, including all appeals, of the action

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1	shall have jurisdiction to review the attorney's
2	fee to ensure that the fee is a reasonable one.
3	"(12) LIMITATION OF ACTION.—Paragraph (1)
4	shall not apply in connection with any action com-
5	menced after 3 years after the later of—
6	"(A) the date on which the plaintiff first
7	knew, or reasonably should have known, of the
8	personal injury or death resulting from the fail-
9	ure described in paragraph (1), or
10	"(B) the date as of which the requirements
11	of paragraph (9) are first met.
12	"(13) TOLLING PROVISION.—The statute of
13	limitations for any cause of action arising under
14	State law relating to a denial of a claim for benefits
15	that is the subject of an action brought in Federal
16	court under this subsection shall be tolled until such
17	time as the Federal court makes a final disposition,
18	including all appeals, of whether such claim should
19	properly be within the jurisdiction of the Federal
20	court. The tolling period shall be determined by the
21	applicable Federal or State law, whichever period is
22	greater.
23	"(14) Purchase of insurance to cover LI-
24	ABILITY.—Nothing in section 410 shall be construed
25	to preclude the purchase by a group health plan of

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1	insurance to cover any liability or losses arising
2	under a cause of action under subsection $(a)(1)(C)$
3	and this subsection.
4	"(15) Exclusion of directed record-
5	KEEPERS.—
6	"(A) IN GENERAL.—Subject to subpara-
7	graph (C), paragraph (1) shall not apply with
8	respect to a directed recordkeeper in connection
9	with a group health plan.
10	"(B) Directed recordkeeper.—For
11	purposes of this paragraph, the term 'directed
12	recordkeeper' means, in connection with a
13	group health plan, a person engaged in directed
14	recordkeeping activities pursuant to the specific
15	instructions of the plan or the employer or
16	other plan sponsor, including the distribution of
17	enrollment information and distribution of dis-
18	closure materials under this Act or title I of the
19	Patients' Bill of Rights Act of 2004 and whose
20	duties do not include making decisions on
21	claims for benefits.
22	"(C) LIMITATION.—Subparagraph (A)
23	does not apply in connection with any directed
24	record keeper to the extent that the directed rec-
25	ordkeeper fails to follow the specific instruction

1 of the plan or the employer or other plan spon-2 sor. 3 ((16))EXCLUSION OF HEALTH INSURANCE 4 AGENTS.—Paragraph (1) does not apply with re-5 spect to a person whose sole involvement with the 6 group health plan is providing advice or administra-7 tive services to the employer or other plan sponsor 8 relating to the selection of health insurance coverage 9 offered in connection with the plan. "(17) NO EFFECT ON STATE LAW.-No provi-10 11 sion of State law (as defined in section 514(c)(1)) 12 shall be treated as superseded or otherwise altered, 13 amended, modified, invalidated, or impaired by rea-14 son of the provisions of subsection (a)(1)(C) and this 15 subsection. "(18) Relief from liability for employer 16 17 OR OTHER PLAN SPONSOR BY MEANS OF DES-18 IGNATED DECISIONMAKER.-19 "(A) IN GENERAL.—Notwithstanding the 20 direct participation (as defined in paragraph 21 (5)(C)(i)) of an employer or plan sponsor, in 22 any case in which there is (or is deemed under 23 subparagraph (B) to be) a designated decision-24 maker under subparagraph (B) that meets the

1	requirements of subsection $(0)(1)$ for an em-
2	ployer or other plan sponsor—
3	"(i) all liability of such employer or
4	plan sponsor involved (and any employee of
5	such employer or sponsor acting within the
6	scope of employment) under this sub-
7	section in connection with any participant
8	or beneficiary shall be transferred to, and
9	assumed by, the designated decisionmaker,
10	and
11	"(ii) with respect to such liability, the
12	designated decisionmaker shall be sub-
13	stituted for the employer or sponsor (or
14	employee) in the action and may not raise
15	any defense that the employer or sponsor
16	(or employee) could not raise if such a de-
17	cisionmaker were not so deemed.
18	"(B) AUTOMATIC DESIGNATION.—A health
19	insurance issuer shall be deemed to be a des-
20	ignated decisionmaker for purposes of subpara-
21	graph (A) with respect to the participants and
22	beneficiaries of an employer or plan sponsor,
23	whether or not the employer or plan sponsor
24	makes such a designation, and shall be deemed
25	to have assumed unconditionally all liability of

1	the employer or plan sponsor under such des-
2	ignation in accordance with subsection (o), un-
3	less the employer or plan sponsor affirmatively
4	enters into a contract to prevent the service of
5	the designated decisionmaker.
6	"(C) TREATMENT OF CERTAIN TRUST
7	FUNDS.—For purposes of this paragraph, the
8	terms 'employer' and 'plan sponsor', in connec-
9	tion with the assumption by a designated deci-
10	sionmaker of the liability of employer or other
11	plan sponsor pursuant to this paragraph, shall
12	be construed to include a trust fund maintained
13	pursuant to section 302 of the Labor Manage-
14	ment Relations Act, 1947 (29 U.S.C. 186) or
15	the Railway Labor Act (45 U.S.C. 151 et seq.).
16	"(19) Previously provided services.—
17	"(A) IN GENERAL.—Except as provided in
18	this paragraph, a cause of action shall not arise
19	under paragraph (1) where the denial involved
20	relates to an item or service that has already
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been fully provided to the participant or bene-

ficiary under the plan or coverage and the claim

relates solely to the subsequent denial of pay-

ment for the provision of such item or service.

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1	"(B) EXCEPTION.—Nothing in subpara-
2	graph (A) shall be construed to—
3	"(i) prohibit a cause of action under
4	paragraph (1) where the nonpayment in-
5	volved results in the participant or bene-
6	ficiary being unable to receive further
7	items or services that are directly related
8	to the item or service involved in the denial
9	referred to in subparagraph (A) or that
10	are part of a continuing treatment or se-
11	ries of procedures; or
12	"(ii) limit liability that otherwise
13	would arise from the provision of the item
14	or services or the performance of a medical
15	procedure.
16	"(20) Exemption from personal liability
17	FOR INDIVIDUAL MEMBERS OF BOARDS OF DIREC-
18	TORS, JOINT BOARDS OF TRUSTEES, ETC.—Any indi-
19	vidual who is—
20	"(A) a member of a board of directors of
21	an employer or plan sponsor; or
22	"(B) a member of an association, com-
23	mittee, employee organization, joint board of
24	trustees, or other similar group of representa-
25	tives of the entities that are the plan sponsor

1	of plan maintained by two or more employers
2	and one or more employee organizations;
3	shall not be personally liable under this subsection
4	for conduct that is within the scope of employment
5	or of plan-related duties of the individuals unless the
6	individual acts in a fraudulent manner for personal
7	enrichment.
8	"(o) Requirements for Designated Decision-
9	makers of Group Health Plans.—
10	"(1) IN GENERAL.—For purposes of subsection
11	(n)(18) and section $514(d)(9)$, a designated decision-
12	maker meets the requirements of this paragraph
13	with respect to any participant or beneficiary if—
14	"(A) such designation is in such form as
15	may be prescribed in regulations of the Sec-
16	retary,
17	"(B) the designated decisionmaker—
18	"(i) meets the requirements of para-
19	graph (2),
20	"(ii) assumes unconditionally all liabil-
21	ity of the employer or plan sponsor in-
22	volved (and any employee of such employer
23	or sponsor acting within the scope of em-
24	ployment) either arising under subsection
25	(n) or arising in a cause of action per-

1	mitted under section 514(d) in connection
2	with actions (and failures to act) of the
3	employer or plan sponsor (or employee) oc-
4	curring during the period in which the des-
5	ignation under subsection $(n)(18)$ or sec-
6	tion $514(d)(9)$ is in effect relating to such
7	participant and beneficiary,
8	"(iii) agrees to be substituted for the
9	employer or plan sponsor (or employee) in
10	the action and not to raise any defense
11	with respect to such liability that the em-
12	ployer or plan sponsor (or employee) may
13	not raise, and
14	"(iv) where paragraph $(2)(B)$ applies,
15	assumes unconditionally the exclusive au-
16	thority under the group health plan to
17	make medically reviewable decisions under
18	the plan with respect to such participant
19	or beneficiary, and
20	"(C) the designated decisionmaker and the
21	participants and beneficiaries for whom the de-
22	cisionmaker has assumed liability are identified
23	in the written instrument required under sec-

1	121(b)(19) of the Patients' Bill of Rights Act
2	of 2004.
3	Any liability assumed by a designated decisionmaker
4	pursuant to this subsection shall be in addition to
5	any liability that it may otherwise have under appli-
6	cable law.
7	"(2) QUALIFICATIONS FOR DESIGNATED DECI-
8	SIONMAKERS.—
9	"(A) IN GENERAL.—Subject to subpara-
10	graph (B), an entity is qualified under this
11	paragraph to serve as a designated decision-
12	maker with respect to a group health plan if the
13	entity has the ability to assume the liability de-
14	scribed in paragraph (1) with respect to partici-
15	pants and beneficiaries under such plan, includ-
16	ing requirements relating to the financial obli-
17	gation for timely satisfying the assumed liabil-
18	ity, and maintains with the plan sponsor and
19	the Secretary certification of such ability. Such
20	certification shall be provided to the plan spon-
21	sor or named fiduciary and to the Secretary
22	upon designation under subsection $(n)(18)(B)$
23	or section $517(d)(9)(B)$ and not less frequently
24	than annually thereafter, or if such designation

1	constitutes a multiyear arrangement, in con-
2	junction with the renewal of the arrangement.
3	"(B) Special qualification in the
4	CASE OF CERTAIN REVIEWABLE DECISIONS.—In
5	the case of a group health plan that provides
6	benefits consisting of medical care to a partici-
7	pant or beneficiary only through health insur-
8	ance coverage offered by a single health insur-
9	ance issue, such issuer is the only entity that
10	may be qualified under this paragraph to serve
11	as a designated decisionmaker with respect to
12	such participant or beneficiary, and shall serve
13	as the designated decision maker unless the em-
14	ployer or other plan sponsor acts affirmatively
15	to prevent such service.
16	"(3) Requirements relating to financial
17	OBLIGATIONS.—For purposes of paragraph (2)(A),
18	the requirements relating to the financial obligation
19	of an entity for liability shall include—
20	"(A) coverage of such entity under an in-
21	surance policy or other arrangement, secured
22	and maintained by such entity, to effectively in-
23	sure such entity against losses arising from pro-

fessional liability claims, including those arising

1	from its service as a designated decisionmaker
2	under this part; or
3	"(B) evidence of minimum capital and sur-
4	plus levels that are maintained by such entity
5	to cover any losses as a result of liability arising
6	from its service as a designated decisionmaker
7	under this part.
8	The appropriate amounts of liability insurance and
9	minimum capital and surplus levels for purposes of
10	subparagraphs (A) and (B) shall be determined by
11	an actuary using sound actuarial principles and ac-
12	counting practices pursuant to established guidelines
13	of the American Academy of Actuaries and in ac-
14	cordance with such regulations as the Secretary may
15	prescribe and shall be maintained throughout the
16	term for which the designation is in effect. The pro-
17	visions of this paragraph shall not apply in the case
18	of a designated decisionmaker that is a group health
19	plan, plan sponsor, or health insurance issuer and
20	that is regulated under Federal law or a State finan-
21	cial solvency law.
22	"(4) Limitation on appointment of treat-

22 "(4) LIMITATION ON APPOINTMENT OF TREAT23 ING PHYSICIANS.—A treating physician who directly
24 delivered the care, treatment, or provided the patient
25 service that is the subject of a cause of action by a

1	participant or beneficiary under subsection (n) or
2	section 514(d) may not be designated as a des-
3	ignated decisionmaker under this subsection with re-
4	spect to such participant or beneficiary.".
5	(2) Conforming Amendment.—Section
6	502(a)(1) of such Act (29 U.S.C. 1132(a)(1)) is
7	amended—
8	(A) by striking "or" at the end of subpara-
9	graph (A);
10	(B) in subparagraph (B), by striking
11	"plan;" and inserting "plan, or"; and
12	(C) by adding at the end the following new
13	subparagraph:
14	"(C) for the relief provided for in sub-
15	section (n) of this section.".
16	(b) Rules Relating to ERISA Preemption.—
17	Section 514 of the Employee Retirement Income Security
18	Act of 1974 (29 U.S.C. 1144) is amended—
19	(1) by redesignating subsection (d) as sub-
20	section (f); and
21	(2) by inserting after subsection (c) the fol-
22	lowing new subsections:
23	"(d) Preemption not to Apply to Causes of Ac-
24	TION UNDER STATE LAW INVOLVING MEDICALLY RE-
25	VIEWABLE DECISION.—

1 "(1) NON-PREEMPTION OF CERTAIN CAUSES OF 2 ACTION.—

3 "(A) IN GENERAL.—Except as provided in 4 this subsection, nothing in this title (including 5 section 502) shall be construed to supersede or 6 otherwise alter, amend, modify, invalidate, or 7 impair any cause of action under State law of a participant or beneficiary under a group 8 9 health plan (or the estate of such a participant 10 or beneficiary) against the plan, the plan spon-11 sor, any health insurance issuer offering health insurance coverage in connection with the plan, 12 13 or any managed care entity in connection with 14 the plan to recover damages resulting from per-15 sonal injury or for wrongful death if such cause of action arises by reason of a medically review-16 17 able decision.

18 "(B) MEDICALLY REVIEWABLE DECI-19 SION.—For purposes of subparagraph (A), the 20 term 'medically reviewable decision' means a de-21 nial of a claim for benefits under the plan 22 which is described in section 104(d)(2) of the 23 Patients' Bill of Rights Act of 2004 (relating to 24 medically reviewable decisions).

"(C) LIMITATION ON PUNITIVE DAM-AGES.—

3	"(i) IN GENERAL.—Except as pro-
4	vided in clauses (ii) and (iii), with respect
5	to a cause of action described in subpara-
6	graph (A) brought with respect to a partic-
7	ipant or beneficiary, State law is super-
8	seded insofar as it provides any punitive,
9	exemplary, or similar damages if, as of the
10	time of the personal injury or death, all
11	the requirements of the following sections
12	of the Patients' Bill of Rights Act of 2004
13	were satisfied with respect to the partici-
14	pant or beneficiary:
15	"(I) Section 102 (relating to pro-
16	cedures for initial claims for benefits
17	and prior authorization determina-
18	tions).
19	"(II) Section 103 of such Act
20	(relating to internal appeals of claims
21	denials).
22	"(III) Section 104 of such Act
23	(relating to independent external ap-
24	peals procedures).

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1	"(ii) EXCEPTION FOR CERTAIN AC-
2	TIONS FOR WRONGFUL DEATH.—Clause (i)
3	shall not apply with respect to an action
4	for wrongful death if the applicable State
5	law provides (or has been construed to pro-
6	vide) for damages in such an action which
7	are only punitive or exemplary in nature.
8	"(iii) EXCEPTION FOR WILLFUL OR
9	WANTON DISREGARD FOR THE RIGHTS OR
10	SAFETY OF OTHERS.—Clause (i) shall not
11	apply with respect to any cause of action
12	described in subparagraph (A) if, in such
13	action, the plaintiff establishes by clear
14	and convincing evidence that conduct car-
15	ried out by the defendant with willful or
16	wanton disregard for the rights or safety
17	of others was a proximate cause of the per-
18	sonal injury or wrongful death that is the
19	subject of the action.
20	"(2) Definitions and related rules.—For
21	purposes of this subsection and subsection (e)—
22	"(A) TREATMENT OF EXCEPTED BENE-
23	FITS.—Under section 154(a) of the Patients'
24	Bill of Rights Act of 2004, the provisions of

1	this subsection do not apply to certain excepted
2	benefits.
3	"(B) PERSONAL INJURY.—The term 'per-
4	sonal injury' means a physical injury and in-
5	cludes an injury arising out of the treatment
6	(or failure to treat) a mental illness or disease.
7	"(C) CLAIM FOR BENEFIT; DENIAL.—The
8	terms 'claim for benefits' and 'denial of a claim
9	for benefits' shall have the meaning provided
10	such terms under section 102(e) of the Pa-
11	tients' Bill of Rights Act of 2004.
12	"(D) MANAGED CARE ENTITY.—
13	"(i) IN GENERAL.—The term 'man-
14	aged care entity' means, in connection with
15	a group health plan and subject to clause
16	(ii), any entity that is involved in deter-
17	mining the manner in which or the extent
18	to which items or services (or reimburse-
19	ment therefor) are to be provided as bene-
20	fits under the plan.
21	"(ii) TREATMENT OF TREATING PHY-
22	SICIANS, OTHER TREATING HEALTH CARE
23	PROFESSIONALS, AND TREATING HOS-
24	PITALS.—Such term does not include a
25	treating physician or other treating health

1	care professional (as defined in section
2	502(n)(6)(B)(i)) of the participant or ben-
3	eficiary and also does not include a treat-
4	ing hospital insofar as it is acting solely in
5	the capacity of providing treatment or care
6	to the participant or beneficiary. Nothing
7	in the preceding sentence shall be con-
8	strued to preempt vicarious liability of any
9	plan, plan sponsor, health insurance issuer,
10	or managed care entity.
11	"(3) Exclusion of employers and other
12	PLAN SPONSORS.—
13	"(A) CAUSES OF ACTION AGAINST EM-
14	PLOYERS AND PLAN SPONSORS PRECLUDED
15	Subject to subparagraph (B), paragraph (1)
16	does not apply with respect to—
17	"(i) any cause of action against an
18	employer or other plan sponsor maintain-
19	ing the plan (or against an employee of
20	such an employer or sponsor acting within
21	the scope of employment), or
22	"(ii) a right of recovery, indemnity, or
23	contribution by a person against an em-
24	ployer or other plan sponsor (or such an
25	employee) for damages assessed against

- 1 the person pursuant to a cause of action to 2 which paragraph (1) applies. "(B) CERTAIN CAUSES OF ACTION PER-3 4 MITTED.—Notwithstanding subparagraph (A), 5 paragraph (1) applies with respect to any cause 6 of action that is brought by a participant or 7 beneficiary under a group health plan (or the 8 estate of such a participant or beneficiary) to 9 recover damages resulting from personal injury 10 or for wrongful death against any employer or 11 other plan sponsor maintaining the plan (or 12 against an employee of such an employer or 13 sponsor acting within the scope of employment) 14 if such cause of action arises by reason of a 15 medically reviewable decision, to the extent that 16 there was direct participation by the employer 17 or other plan sponsor (or employee) in the deci-18 sion. 19 "(C) DIRECT PARTICIPATION.— 20 "(i) DIRECT PARTICIPATION IN DECI-21 SIONS.—For purposes of subparagraph 22 (B), the term 'direct participation' means, 23 in connection with a decision described in
- 24 subparagraph (B), the actual making of25 such decision or the actual exercise of con-

1	trol in making such decision or in the con-
2	duct constituting the failure.
3	"(ii) Rules of construction.—For
4	purposes of clause (i), the employer or plan
5	sponsor (or employee) shall not be con-
6	strued to be engaged in direct participation
7	because of any form of decisionmaking or
8	other conduct that is merely collateral or
9	precedent to the decision described in sub-
10	paragraph (B) on a particular claim for
11	benefits of a particular participant or bene-
12	ficiary, including (but not limited to)—
13	"(I) any participation by the em-
14	ployer or other plan sponsor (or em-
15	ployee) in the selection of the group
16	health plan or health insurance cov-
17	erage involved or the third party ad-
18	ministrator or other agent;
19	"(II) any engagement by the em-
20	ployer or other plan sponsor (or em-
21	ployee) in any cost-benefit analysis
22	undertaken in connection with the se-
23	lection of, or continued maintenance
24	of, the plan or coverage involved;

1	"(III) any participation by the
2	employer or other plan sponsor (or
3	employee) in the process of creating,
4	continuing, modifying, or terminating
5	the plan or any benefit under the
6	plan, if such process was not substan-
7	tially focused solely on the particular
8	situation of the participant or bene-
9	ficiary referred to in paragraph
10	(1)(A); and
11	"(IV) any participation by the
12	employer or other plan sponsor (or
13	employee) in the design of any benefit
14	under the plan, including the amount
15	of copayment and limits connected
16	with such benefit.
17	"(iv) IRRELEVANCE OF CERTAIN COL-
18	LATERAL EFFORTS MADE BY EMPLOYER
19	OR PLAN SPONSOR.—For purposes of this
20	subparagraph, an employer or plan sponsor
21	shall not be treated as engaged in direct
22	participation in a decision with respect to
23	any claim for benefits or denial thereof in
24	the case of any particular participant or
25	beneficiary solely by reason of—

1	"(I) any efforts that may have
2	been made by the employer or plan
3	sponsor to advocate for authorization
4	of coverage for that or any other par-
5	ticipant or beneficiary (or any group
6	of participants or beneficiaries), or
7	"(II) any provision that may
8	have been made by the employer or
9	plan sponsor for benefits which are
10	not covered under the terms and con-
11	ditions of the plan for that or any
12	other participant or beneficiary (or
13	any group of participants or bene-
14	ficiaries).
15	"(4) Requirement of exhaustion.—
16	"(A) IN GENERAL.—Except as provided in
17	subparagraph (D), a cause of action may not be
18	brought under paragraph (1) in connection with
19	any denial of a claim for benefits of any indi-
20	vidual until all administrative processes under
21	sections 102, 103, and 104 of the Patients' Bill
22	of Rights Act of 2004 (if applicable) have been
23	exhausted.
24	"(B) LATE MANIFESTATION OF INJURY.—

1	
1	"(i) IN GENERAL.—A participant or
2	beneficiary shall not be precluded from
3	pursuing a review under section 104 of the
4	Patients' Bill of Rights Act of 2004 re-
5	garding an injury that such participant or
6	beneficiary has experienced if the external
7	review entity first determines that the in-
8	jury of such participant or beneficiary is a
9	late manifestation of an earlier injury.
10	"(ii) Definition.—In this subpara-
11	graph, the term 'late manifestation of an
12	earlier injury' means an injury sustained
13	by the participant or beneficiary which was
14	not known, and should not have been
15	known, by such participant or beneficiary
16	by the latest date that the requirements of
17	subparagraph (A) should have been met
18	regarding the claim for benefits which was
19	denied.
20	"(C) EXCEPTION FOR NEEDED CARE.—A
21	participant or beneficiary may seek relief exclu-
22	sively in Federal court under subsection
23	502(a)(1)(B) prior to the exhaustion of admin-
24	istrative remedies under sections 102, 103, or
25	104 of the Patients' Bill of Rights Act of 2004

1	(as required under subparagraph (A)) if it is
2	demonstrated to the court that the exhaustion
3	of such remedies would cause irreparable harm
4	to the health of the participant or beneficiary.
5	Notwithstanding the awarding of relief under
6	subsection $502(a)(1)(B)$ pursuant to this sub-
7	paragraph, no relief shall be available as a re-
8	sult of, or arising under, paragraph (1)(A) un-
9	less the requirements of subparagraph (A) are
10	met.
11	"(D) FAILURE TO REVIEW.—
12	"(i) IN GENERAL.—If the external re-
13	view entity fails to make a determination
14	within the time required under section
15	104(e)(1)(A)(i), a participant or bene-
16	ficiary may bring an action under section
17	514(d) after 10 additional days after the
18	date on which such time period has expired
19	and the filing of such action shall not af-
20	fect the duty of the independent medical
21	reviewer (or reviewers) to make a deter-
22	mination pursuant to section
23	104(e)(1)(A)(i).
24	"(ii) Expedited determination.—
25	If the external review entity fails to make

1	a determination within the time required
2	under section 104(e)(1)(A)(ii), a partici-
3	pant or beneficiary may bring an action
4	under this subsection and the filing of such
5	an action shall not affect the duty of the
6	independent medical reviewer (or review-
7	ers) to make a determination pursuant to
8	section 104(e)(1)(A)(ii).
9	"(E) RECEIPT OF BENEFITS DURING AP-
10	PEALS PROCESS.—Receipt by the participant or
11	beneficiary of the benefits involved in the claim
12	for benefits during the pendency of any admin-
13	istrative processes referred to in subparagraph
14	(A) or of any action commenced under this sub-
15	section—
16	"(i) shall not preclude continuation of
17	all such administrative processes to their
18	conclusion if so moved by any party, and
19	"(ii) shall not preclude any liability
20	under subsection $(a)(1)(C)$ and this sub-
21	section in connection with such claim.
22	"(F) Admissible.—Any determination
23	made by a reviewer in an administrative pro-
24	ceeding under section 104 of the Patients' Bill
25	of Rights Act of 2004 shall be admissible in

1	any Federal or State court proceeding and shall
2	be presented to the trier of fact.
3	"(5) TOLLING PROVISION.—The statute of limi-
4	tations for any cause of action arising under section
5	502(n) relating to a denial of a claim for benefits
6	that is the subject of an action brought in State
7	court shall be tolled until such time as the State
8	court makes a final disposition, including all ap-
9	peals, of whether such claim should properly be
10	within the jurisdiction of the State court. The tolling
11	period shall be determined by the applicable Federal
12	or State law, whichever period is greater.
13	"(6) Exclusion of directed record-
14	KEEPERS.—
15	"(A) IN GENERAL.—Subject to subpara-
16	graph (C), paragraph (1) shall not apply with
17	respect to a directed recordkeeper in connection
18	with a group health plan.
19	"(B) DIRECTED RECORDKEEPER.—For
20	purposes of this paragraph, the term 'directed
21	recordkeeper' means, in connection with a
22	group health plan, a person engaged in directed
23	record keeping activities pursuant to the specific
24	instructions of the plan or the employer or
25	other plan sponsor, including the distribution of

1	enrollment information and distribution of dis-
2	closure materials under this Act or title I of the
3	Patients' Bill of Rights Act of 2004 and whose
4	duties do not include making decisions on
5	claims for benefits.
6	"(C) LIMITATION.—Subparagraph (A)
7	does not apply in connection with any directed
8	recordkeeper to the extent that the directed rec-
9	ordkeeper fails to follow the specific instruction
10	of the plan or the employer or other plan spon-
11	sor.
12	"(7) CONSTRUCTION.—Nothing in this sub-
13	section shall be construed as—
13 14	section shall be construed as— "(A) saving from preemption a cause of
14	"(A) saving from preemption a cause of
14 15	"(A) saving from preemption a cause of action under State law for the failure to provide
14 15 16	"(A) saving from preemption a cause of action under State law for the failure to provide a benefit for an item or service which is specifi-
14 15 16 17 18	"(A) saving from preemption a cause of action under State law for the failure to provide a benefit for an item or service which is specifi- cally excluded under the group health plan in-
14 15 16 17	"(A) saving from preemption a cause of action under State law for the failure to provide a benefit for an item or service which is specifi- cally excluded under the group health plan in- volved, except to the extent that—
14 15 16 17 18 19	"(A) saving from preemption a cause of action under State law for the failure to provide a benefit for an item or service which is specifi- cally excluded under the group health plan in- volved, except to the extent that— "(i) the application or interpretation
 14 15 16 17 18 19 20 	"(A) saving from preemption a cause of action under State law for the failure to provide a benefit for an item or service which is specifi- cally excluded under the group health plan in- volved, except to the extent that— "(i) the application or interpretation of the exclusion involves a determination
 14 15 16 17 18 19 20 21 	 "(A) saving from preemption a cause of action under State law for the failure to provide a benefit for an item or service which is specifically excluded under the group health plan involved, except to the extent that— "(i) the application or interpretation of the exclusion involves a determination described in section 104(d)(2) of the Pa-

1	eral law or under applicable State law con-
2	sistent with subsection $(b)(2)(B)$;
3	"(B) preempting a State law which re-
4	quires an affidavit or certificate of merit in a
5	civil action;
6	"(C) affecting a cause of action or remedy
7	under State law in connection with the provi-
8	sion or arrangement of excepted benefits (as de-
9	fined in section 733(c)), other than those de-
10	scribed in section $733(c)(2)(A)$; or
11	"(D) affecting a cause of action under
12	State law other than a cause of action described
13	in paragraph $(1)(A)$.
14	"(8) Purchase of insurance to cover LI-
15	ABILITY.—Nothing in section 410 shall be construed
16	to preclude the purchase by a group health plan of
17	insurance to cover any liability or losses arising
18	under a cause of action described in paragraph
19	(1)(A).
20	"(9) Relief from liability for employer
21	OR OTHER PLAN SPONSOR BY MEANS OF DES-
22	IGNATED DECISIONMAKER.—
23	"(A) IN GENERAL.—Paragraph (1) shall
24	not apply with respect to any cause of action
25	described in paragraph (1)(A) under State law

1	insofar as such cause of action provides for li-
2	ability with respect to a participant or bene-
3	ficiary of an employer or plan sponsor (or an
4	employee of such employer or sponsor acting
5	within the scope of employment), if with respect
6	to the employer or plan sponsor there is (or is
7	deemed under subparagraph (B) to be) a des-
8	ignated decisionmaker that meets the require-
9	ments of section $502(0)(1)$ with respect to such
10	participant or beneficiary. Such paragraph (1)
11	shall apply with respect to any cause of action
12	described in paragraph (1)(A) under State law
13	against the designated decisionmaker of such
14	employer or other plan sponsor with respect to
15	the participant or beneficiary.
16	"(B) AUTOMATIC DESIGNATION.—A health

17 insurance issuer shall be deemed to be a des-18 ignated decisionmaker for purposes of subpara-19 graph (A) with respect to the participants and beneficiaries of an employer or plan sponsor, 20 21 whether or not the employer or plan sponsor 22 makes such a designation, and shall be deemed 23 to have assumed unconditionally all liability of the employer or plan sponsor under such des-24 25 ignation in accordance with subsection (o), unless the employer or plan sponsor affirmatively enters into a contract to prevent the service of the designated decisionmaker.

4 "(C) TREATMENT OF CERTAIN TRUST 5 FUNDS.—For purposes of this paragraph, the terms 'employer' and 'plan sponsor', in connec-6 7 tion with the assumption by a designated deci-8 sionmaker of the liability of employer or other 9 plan sponsor pursuant to this paragraph, shall 10 be construed to include a trust fund maintained 11 pursuant to section 302 of the Labor Manage-12 ment Relations Act, 1947 (29 U.S.C. 186) or 13 the Railway Labor Act (45 U.S.C. 151 et seq.). 14 "(10) Previously provided services.—

15 "(A) IN GENERAL.—Except as provided in 16 this paragraph, a cause of action shall not arise 17 under paragraph (1) where the denial involved 18 relates to an item or service that has already 19 been fully provided to the participant or bene-20 ficiary under the plan or coverage and the claim 21 relates solely to the subsequent denial of pay-22 ment for the provision of such item or service. 23 "(B) EXCEPTION.—Nothing in subpara-

graph (A) shall be construed to—

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1	"(i) prohibit a cause of action under
2	paragraph (1) where the nonpayment in-
3	volved results in the participant or bene-
4	ficiary being unable to receive further
5	items or services that are directly related
6	to the item or service involved in the denial
7	referred to in subparagraph (A) or that
8	are part of a continuing treatment or se-
9	ries of procedures;
10	"(ii) prohibit a cause of action under
11	paragraph (1) relating to quality of care;
12	OF
13	"(iii) limit liability that otherwise
14	would arise from the provision of the item
15	or services or the performance of a medical
16	procedure.
17	"(11) Exemption from personal liability
18	FOR INDIVIDUAL MEMBERS OF BOARDS OF DIREC-
19	TORS, JOINT BOARDS OF TRUSTEES, ETC.—Any indi-
20	vidual who is—
21	"(A) a member of a board of directors of
22	an employer or plan sponsor; or
23	"(B) a member of an association, com-
24	mittee, employee organization, joint board of
25	trustees, or other similar group of representa-

1	tives of the entities that are the plan sponsor
2	of plan maintained by two or more employers
3	and one or more employee organizations;
4	shall not be personally liable under this subsection
5	for conduct that is within the scope of employment
6	or of plan-related duties of the individuals unless the
7	individual acts in a fraudulent manner for personal
8	enrichment.
9	"(12) CHOICE OF LAW.—A cause of action
10	brought under paragraph (1) shall be governed by
11	the law (including choice of law rules) of the State
12	in which the plaintiff resides.
13	"(13) Limitation on attorneys' fees.—
14	"(A) IN GENERAL.—Notwithstanding any
15	other provision of law, or any arrangement,
16	agreement, or contract regarding an attorney's
17	fee, the amount of an attorney's contingency fee
18	allowable for a cause of action brought under
19	paragraph (1) shall not exceed $\frac{1}{3}$ of the total
20	amount of the plaintiff's recovery (not including
21	the reimbursement of actual out-of-pocket ex-
22	penses of the attorney).
23	"(B) DETERMINATION BY COURT.—The
24	last court in which the action was pending upon
25	the final disposition, including all appeals, of

1	the action may review the attorney's fee to en-
2	sure that the fee is a reasonable one.
3	"(C) NO PREEMPTION OF STATE LAW
4	Subparagraph (A) shall not apply with respect
5	to a cause of action under paragraph (1) that
6	is brought in a State that has a law or frame-
7	work of laws with respect to the amount of an
8	attorney's contingency fee that may be incurred
9	for the representation of a participant or bene-
10	ficiary (or the estate of such participant or ben-
11	eficiary) who brings such a cause of action.
12	"(e) Rules of Construction Relating to
13	HEALTH CARE.—Nothing in this title shall be construed
14	as—
15	"(1) affecting any State law relating to the
16	practice of medicine or the provision of, or the fail-
17	ure to provide, medical care, or affecting any action
18	(whether the liability is direct or vicarious) based
19	upon such a State law,
20	"(2) superseding any State law permitted under
21	section $152(b)(1)(A)$ of the Patients' Bill of Rights
22	Act of 2004, or
23	"(3) affecting any applicable State law with re-
24	spect to limitations on monetary damages.

1 "(f) NO RIGHT OF ACTION FOR RECOVERY, INDEM-2 NITY, OR CONTRIBUTION BY ISSUERS AGAINST TREATING 3 HEALTH CARE PROFESSIONALS AND TREATING HOS-4 PITALS.—In the case of any care provided, or any treat-5 ment decision made, by the treating health care professional or the treating hospital of a participant or bene-6 7 ficiary under a group health plan which consists of medical 8 care provided under such plan, any cause of action under 9 State law against the treating health care professional or 10 the treating hospital by the plan or a health insurance issuer providing health insurance coverage in connection 11 12 with the plan for recovery, indemnity, or contribution in 13 connection with such care (or any medically reviewable de-14 cision made in connection with such care) or such treat-15 ment decision is superseded.".

(c) EFFECTIVE DATE.—The amendments made by
this section shall apply to acts and omissions (from which
a cause of action arises) occurring on or after the applicable effective date under section 601.

20SEC. 403. COOPERATION BETWEEN FEDERAL AND STATE21AUTHORITIES.

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

1 "SEC. 735. COOPERATION BETWEEN FEDERAL AND STATE2AUTHORITIES.

3 "(a) AGREEMENT WITH STATES.—A State may enter into an agreement with the Secretary for the delega-4 5 tion to the State of some or all of the Secretary's authority under this title to enforce the requirements applicable 6 7 under title I of the Patients' Bill of Rights Act of 2004 8 with respect to health insurance coverage offered by a health insurance issuer and with respect to a group health 9 plan that is a non-Federal governmental plan. 10

11 "(b) DELEGATIONS.—Any department, agency, or instrumentality of a State to which authority is delegated 12 13 pursuant to an agreement entered into under this section 14 may, if authorized under State law and to the extent consistent with such agreement, exercise the powers of the 15 Secretary under this title which relate to such authority.". 16 TITLE V—AMENDMENTS TO THE 17 INTERNAL REVENUE CODE 18 **OF 1986** 19 **Subtitle A—Application of Patient** 20**Protection Provisions** 21 22 SEC. 501. APPLICATION TO GROUP HEALTH PLANS UNDER 23 THE INTERNAL REVENUE CODE OF 1986. 24 Subchapter B of chapter 100 of the Internal Revenue Code of 1986 is amended— 25

1 (1) in the table of sections, by inserting after 2 the item relating to section 9812 the following new 3 item: "9813. Standard relating to patients' bill of rights."; 4 and (2) by inserting after section 9812 the fol-5 6 lowing: 7 "SEC. 9813. STANDARD RELATING TO PATIENTS' BILL OF 8 **RIGHTS.** 9 "A group health plan shall comply with the requirements of title I of the Patients' Bill of Rights Act of 2004 10 (as in effect as of the date of the enactment of such Act), 11 12 and such requirements shall be deemed to be incorporated into this section.". 13 14 SEC. 502. CONFORMING ENFORCEMENT FOR WOMEN'S 15 HEALTH AND CANCER RIGHTS. 16 Subchapter B of chapter 100 of the Internal Revenue Code of 1986, as amended by section 501, is further 17 18 amended-19 (1) in the table of sections, by inserting after 20 the item relating to section 9813 the following new 21 item: "9814. Standard relating to women's health and cancer rights."; 22 and 23 (2) by inserting after section 9813 the fol-24 lowing:

1 "SEC. 9814. STANDARD RELATING TO WOMEN'S HEALTH2AND CANCER RIGHTS.

3 "The provisions of section 713 of the Employee Re4 tirement Income Security Act of 1974 (as in effect as of
5 the date of the enactment of this section) shall apply to
6 group health plans as if included in this subchapter.".

7 Subtitle B—Health Care Coverage 8 Access Tax Incentives

9 SEC. 511. CREDIT FOR HEALTH INSURANCE EXPENSES OF

10 SMALL BUSINESSES.

(a) IN GENERAL.—Subpart D of part IV of subchapter A of chapter 1 of the Internal Revenue Code of
1986 (relating to business-related credits) is amended by
adding at the end the following:

15 "SEC. 45E. SMALL BUSINESS HEALTH INSURANCE EX-16 PENSES.

17 "(a) GENERAL RULE.—For purposes of section 38, 18 in the case of a small employer, the health insurance credit 19 determined under this section for the taxable year is an 20 amount equal to the applicable percentage of the expenses 21 paid by the taxpayer during the taxable year for health 22 insurance coverage for such year provided under a new 23 health plan for employees of such employer.

24 "(b) APPLICABLE PERCENTAGE.—For purposes of
25 subsection (a), the applicable percentage is—

1	((1) in the case of insurance purchased as a
2	member of a qualified health benefit purchasing coa-
3	lition (as defined in section 9841), 30 percent, and
4	((2) in the case of insurance not described in
5	paragraph (1), 20 percent.
6	"(c) Limitations.—
7	"(1) PER EMPLOYEE DOLLAR LIMITATION.—
8	The amount of expenses taken into account under
9	subsection (a) with respect to any employee for any
10	taxable year shall not exceed—
11	"(A) \$2,000 in the case of self-only cov-
12	erage, and
13	"(B) \$5,000 in the case of family coverage.
14	In the case of an employee who is covered by a new
15	health plan of the employer for only a portion of
16	such taxable year, the limitation under the preceding
17	sentence shall be an amount which bears the same
18	ratio to such limitation (determined without regard
19	to this sentence) as such portion bears to the entire
20	taxable year.
21	"(2) PERIOD OF COVERAGE.—Expenses may be
22	taken into account under subsection (a) only with
23	respect to coverage for the 4-year period beginning
24	on the date the employer establishes a new health
25	plan.

1	"(d) Definitions.—For purposes of this section—
2	"(1) HEALTH INSURANCE COVERAGE.—The
3	term 'health insurance coverage' has the meaning
4	given such term by section $9832(b)(1)$.
5	"(2) New Health plan.—
6	"(A) IN GENERAL.—The term 'new health
7	plan' means any arrangement of the employer
8	which provides health insurance coverage to em-
9	ployees if—
10	"(i) such employer (and any prede-
11	cessor employer) did not establish or main-
12	tain such arrangement (or any similar ar-
13	rangement) at any time during the 2 tax-
14	able years ending prior to the taxable year
15	in which the credit under this section is
16	first allowed, and
17	"(ii) such arrangement provides
18	health insurance coverage to at least 70
19	percent of the qualified employees of such
20	employer.
21	"(B) QUALIFIED EMPLOYEE.—
22	"(i) IN GENERAL.—The term 'quali-
23	fied employee' means any employee of an
24	employer if the annual rate of such em-

1	ployee's compensation (as defined in sec-
2	tion 414(s)) exceeds \$10,000.
3	"(ii) TREATMENT OF CERTAIN EM-
4	PLOYEES.—The term 'employee' shall in-
5	clude a leased employee within the mean-
6	ing of section 414(n).
7	"(3) SMALL EMPLOYER.—The term 'small em-
8	ployer' has the meaning given to such term by sec-
9	tion $4980D(d)(2)$; except that only qualified employ-
10	ees shall be taken into account.
11	"(e) Special Rules.—
12	"(1) Certain rules made applicable.—For
13	purposes of this section, rules similar to the rules of
14	section 52 shall apply.
15	"(2) Amounts paid under salary reduc-
16	TION ARRANGEMENTS.—No amount paid or incurred
17	pursuant to a salary reduction arrangement shall be
18	taken into account under subsection (a).
19	"(f) TERMINATION.—This section shall not apply to
20	expenses paid or incurred by an employer with respect to
21	any arrangement established on or after January 1,
22	2013.".
23	(b) Credit to Be Part of General Business
24	CREDIT.—Section 38(b) of such Code (relating to current
25	year business credit) is amended by striking "plus" at the

end of paragraph (12), by striking the period at the end
 of paragraph (13) and inserting ", plus", and by adding
 at the end the following:

4 "(14) in the case of a small employer (as de5 fined in section 45E(d)(3)), the health insurance
6 credit determined under section 45E(a).".

7 (c) NO CARRYBACKS.—Subsection (d) of section 39
8 of such Code (relating to carryback and carryforward of
9 unused credits) is amended by adding at the end the fol10 lowing:

11 "(10) NO CARRYBACK OF SECTION 45E CREDIT
12 BEFORE EFFECTIVE DATE.—No portion of the un13 used business credit for any taxable year which is
14 attributable to the employee health insurance ex15 penses credit determined under section 45E may be
16 carried back to a taxable year ending before the date
17 of the enactment of section 45E.".

(d) DENIAL OF DOUBLE BENEFIT.—Section 280C of
such Code is amended by adding at the end the following
new subsection:

21 "(d) CREDIT FOR SMALL BUSINESS HEALTH INSUR22 ANCE EXPENSES.—

23 "(1) IN GENERAL.—No deduction shall be al24 lowed for that portion of the expenses (otherwise al25 lowable as a deduction) taken into account in deter-

mining the credit under section 45E for the taxable
 year which is equal to the amount of the credit de termined for such taxable year under section
 45E(a).

5 "(2) CONTROLLED GROUPS.—Persons treated 6 as a single employer under subsection (a) or (b) of 7 section 52 shall be treated as 1 person for purposes 8 of this section.".

9 (e) CLERICAL AMENDMENT.—The table of sections 10 for subpart D of part IV of subchapter A of chapter 1 11 of such Code is amended by adding at the end the fol-12 lowing:

"45E. Small business health insurance expenses.".

(f) EFFECTIVE DATE.—The amendments made by
this section shall apply to amounts paid or incurred in taxable years beginning after December 31, 2004, for arrangements established after the date of the enactment
of this Act.

18 SEC. 512. CERTAIN GRANTS BY PRIVATE FOUNDATIONS TO
19 QUALIFIED HEALTH BENEFIT PURCHASING
20 COALITIONS.

(a) IN GENERAL.—Section 4942 of the Internal Revenue Code of 1986 (relating to taxes on failure to distribute income) is amended by adding at the end the following:

1 "(k) CERTAIN QUALIFIED HEALTH BENEFIT PUR-2 CHASING COALITION DISTRIBUTIONS.— 3 "(1) IN GENERAL.—For purposes of subsection 4 (g), sections 170, 501, 507, 509, and 2522, and this 5 chapter, a qualified health benefit purchasing coalition distribution by a private foundation shall be 6 7 considered to be a distribution for a charitable pur-8 pose. (2)9 QUALIFIED HEALTH BENEFIT PUR-10 CHASING COALITION DISTRIBUTION.—For purposes 11 of paragraph (1)— "(A) IN GENERAL.—The term 'qualified 12 13 health benefit purchasing coalition distribution' 14 means any amount paid or incurred by a pri-15 vate foundation to or on behalf of a qualified 16 health benefit purchasing coalition (as defined 17 in section 9841) for purposes of payment or re-18 imbursement of amounts paid or incurred in 19 connection with the establishment and mainte-20 nance of such coalition.

21 "(B) EXCLUSIONS.—Such term shall not
22 include any amount used by a qualified health
23 benefit purchasing coalition (as so defined)—

"(i) for the purchase of real property,

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1	"(ii) as payment to, or for the benefit
2	of, members (or employees or affiliates of
3	such members) of such coalition, or
4	"(iii) for any expense paid or incurred
5	more than 48 months after the date of es-
6	tablishment of such coalition.
7	"(3) TERMINATION.—This subsection shall not
8	apply—
9	"(A) to qualified health benefit purchasing
10	coalition distributions paid or incurred after
11	December 31, 2012, and
12	"(B) with respect to start-up costs of a co-
13	alition which are paid or incurred after Decem-
14	ber 31, 2013.".
15	(b) Qualified Health Benefit Purchasing Co-
16	ALITION.—
17	(1) IN GENERAL.—Chapter 100 of such Code
18	(relating to group health plan requirements) is
19	amended by adding at the end the following new
20	subchapter:
21	"Subchapter D—Qualified Health Benefit
22	Purchasing Coalition

"Sec. 9841. Qualified health benefit purchasing coalition.

1	"SEC. 9841. QUALIFIED HEALTH BENEFIT PURCHASING CO-
2	ALITION.
3	"(a) IN GENERAL.—A qualified health benefit pur-
4	chasing coalition is a private not-for-profit corporation
5	which—
6	"(1) sells health insurance through State li-
7	censed health insurance issuers in the State in which
8	the employers to which such coalition is providing
9	insurance are located, and
10	"(2) establishes to the Secretary, under State
11	certification procedures or other procedures as the
12	Secretary may provide by regulation, that such coali-
13	tion meets the requirements of this section.
14	"(b) BOARD OF DIRECTORS.—
15	"(1) IN GENERAL.—Each purchasing coalition
16	under this section shall be governed by a Board of
17	Directors.
18	"(2) ELECTION.—The Secretary shall establish
19	procedures governing election of such Board.
20	"(3) Membership.—The Board of Directors
21	shall—
22	"(A) be composed of representatives of the
23	members of the coalition, in equal number, in-
24	cluding small employers and employee rep-
25	resentatives of such employers, but

1	"(B) not include other interested parties,
2	such as service providers, health insurers, or in-
3	surance agents or brokers which may have a
4	conflict of interest with the purposes of the coa-
5	lition.
6	"(c) Membership of Coalition.—
7	"(1) IN GENERAL.—A purchasing coalition
8	shall accept all small employers residing within the
9	area served by the coalition as members if such em-
10	ployers request such membership.
11	"(2) OTHER MEMBERS.—The coalition, at the
12	discretion of its Board of Directors, may be open to
13	individuals and large employers.
14	"(3) VOTING.—Members of a purchasing coali-
15	tion shall have voting rights consistent with the rules
16	established by the State.
17	"(d) DUTIES OF PURCHASING COALITIONS.—Each
18	purchasing coalition shall—
19	"(1) enter into agreements with small employ-
20	ers (and, at the discretion of its Board, with individ-
21	uals and other employers) to provide health insur-
22	ance benefits to employees and retirees of such em-
23	ployers,

1	"(2) where feasible, enter into agreements with
2	3 or more unaffiliated, qualified licensed health
3	plans, to offer benefits to members,
4	"(3) offer to members at least 1 open enroll-
5	ment period of at least 30 days per calendar year,
6	"(4) serve a significant geographical area and
7	market to all eligible members in that area, and
8	"(5) carry out other functions provided for
9	under this section.
10	"(e) LIMITATION ON ACTIVITIES.—A purchasing coa-
11	lition shall not—
12	"(1) perform any activity (including certifi-
13	cation or enforcement) relating to compliance or li-
14	censing of health plans,
15	"(2) assume insurance or financial risk in rela-
16	tion to any health plan, or
17	"(3) perform other activities identified by the
18	State as being inconsistent with the performance of
19	its duties under this section.
20	"(f) Additional Requirements for Purchasing
21	COALITIONS.—As provided by the Secretary in regula-
22	tions, a purchasing coalition shall be subject to require-
23	ments similar to the requirements of a group health plan
24	under this chapter.
25	"(g) Relation to Other Laws.—

"(1) 1 PREEMPTION OF STATE FICTITIOUS 2 GROUP LAWS.—Requirements (commonly referred to 3 as fictitious group laws) relating to grouping and 4 similar requirements for health insurance coverage 5 are preempted to the extent such requirements im-6 pede the establishment and operation of qualified 7 health benefit purchasing coalitions.

8 (2)ALLOWING SAVINGS TO BE PASSED 9 THROUGH.—Any State law that prohibits health in-10 surance issuers from reducing premiums on health 11 insurance coverage sold through a qualified health 12 benefit purchasing coalition to reflect administrative 13 savings is preempted. This paragraph shall not be 14 construed to preempt State laws that impose restric-15 tions on premiums based on health status, claims 16 history, industry, age, gender, or other underwriting 17 factors.

18 "(3) NO WAIVER OF HIPAA REQUIREMENTS.— 19 Nothing in this section shall be construed to change 20 the obligation of health insurance issuers to comply 21 with the requirements of title XXVII of the Public 22 Health Service Act with respect to health insurance 23 coverage offered to small employers in the small 24 group market through a qualified health benefit pur-25 chasing coalition.

"(h) DEFINITION OF SMALL EMPLOYER.—For pur poses of this section—

3 "(1) IN GENERAL.—The term 'small employer' 4 means, with respect to any calendar year, any em-5 ployer if such employer employed an average of at 6 least 2 and not more than 50 qualified employees on 7 business days during either of the 2 preceding cal-8 endar years. For purposes of the preceding sentence, 9 a preceding calendar year may be taken into account 10 only if the employer was in existence throughout 11 such year.

12 "(2) Employers not in existence in pre-13 CEDING YEAR.—In the case of an employer which 14 was not in existence throughout the 1st preceding 15 calendar year, the determination under paragraph 16 (1) shall be based on the average number of quali-17 fied employees that it is reasonably expected such 18 employer will employ on business days in the current 19 calendar year.".

20 (2) CONFORMING AMENDMENT.—The table of
21 subchapters for chapter 100 of such Code is amend22 ed by adding at the end the following item:
"SUBCHAPTER D. QUALIFIED HEALTH BENEFIT PURCHASING COALITION".

23 (c) EFFECTIVE DATE.—The amendment made by
24 subsection (a) shall apply to taxable years beginning after
25 December 31, 2001.

3 (a) IN GENERAL.—The Secretary of Health and Human Services (in this section referred to as the "Sec-4 5 retary") shall establish a program (in this section referred to as the "program") to award demonstration grants 6 7 under this section to States to allow States to demonstrate 8 the effectiveness of innovative ways to increase access to 9 health insurance through market reforms and other inno-10 vative means. Such innovative means may include (and are 11 not limited to) any of the following:

(1) Alternative group purchasing or pooling arrangements, such as purchasing cooperatives for
small businesses, reinsurance pools, or high risk
pools.

- 16 (2) Individual or small group market reforms.
 - (3) Consumer education and outreach.

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18 (4) Subsidies to individuals, employers, or both,19 in obtaining health insurance.

(b) SCOPE; DURATION.—The program shall be limited to not more than 10 States and to a total period of
5 years, beginning on the date the first demonstration
grant is made.

24 (c) Conditions for Demonstration Grants.—

25 (1) IN GENERAL.—The Secretary may not pro26 vide for a demonstration grant to a State under the
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program unless the Secretary finds that under the
proposed demonstration grant—
(A) the State will provide for demonstrated
increase of access for some portion of the exist-
ing uninsured population through a market in-
novation (other than merely through a financial
expansion of a program initiated before the
date of the enactment of this Act);
(B) the State will comply with applicable
Federal laws;
(C) the State will not discriminate among
participants on the basis of any health status-
related factor (as defined in section $2791(d)(9)$
of the Public Health Service Act), except to the
extent a State wishes to focus on populations
that otherwise would not obtain health insur-
ance because of such factors; and
(D) the State will provide for such evalua-
tion, in coordination with the evaluation re-
quired under subsection (d), as the Secretary
may specify.
(2) APPLICATION.—The Secretary shall not
provide a demonstration grant under the program to
a State unless—

1	(A) the State submits to the Secretary
2	such an application, in such a form and man-
3	ner, as the Secretary specifies;
4	(B) the application includes information
5	regarding how the demonstration grant will ad-
6	dress issues such as governance, targeted popu-
7	lation, expected cost, and the continuation after
8	the completion of the demonstration grant pe-
9	riod; and
10	(C) the Secretary determines that the dem-
11	onstration grant will be used consistent with
12	this section.
13	(3) Focus.—A demonstration grant proposal
14	under section need not cover all uninsured individ-
15	uals in a State or all health care benefits with re-
16	spect to such individuals.
17	(d) EVALUATION.—The Secretary shall enter into a
18	contract with an appropriate entity outside the Depart-
19	ment of Health and Human Services to conduct an overall
20	evaluation of the program at the end of the program pe-
21	riod. Such evaluation shall include an analysis of improve-
22	ments in access, costs, quality of care, or choice of cov-
23	erage, under different demonstration grants.
24	(e) Option to Provide for Initial Planning
25	GRANTS.—Notwithstanding the previous provisions of this

section, under the program the Secretary may provide for
 a portion of the amounts appropriated under subsection
 (f) (not to exceed \$5,000,000) to be made available to any
 State for initial planning grants to permit States to de velop demonstration grant proposals under the previous
 provisions of this section.

7 (f) AUTHORIZATION OF APPROPRIATIONS.—There 8 are authorized to be appropriated \$100,000,000 for each 9 fiscal year to carry out this section. Amounts appropriated 10 under this subsection shall remain available until ex-11 pended.

(g) STATE DEFINED.—For purposes of this section,
the term "State" has the meaning given such term for
purposes of title XIX of the Social Security Act.

15 SEC. 514. GRANT PROGRAM TO FACILITATE HEALTH BENE-

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FITS INFORMATION FOR SMALL EMPLOYERS.

(a) IN GENERAL.—The Small Business Administration shall award grants to 1 or more States, local governments, and non-profit organizations for the purposes of—

(1) demonstrating new and effective ways to
provide information about the benefits of health insurance to small employers, including tax benefits,
increased productivity of employees, and decreased
turnover of employees,

(2) making employers aware of their current
 rights in the marketplace under State and Federal
 health insurance reforms, and

4 (3) making employers aware of the tax treat-5 ment of insurance premiums.

6 (b) AUTHORIZATION.—There is authorized to be appropriated \$10,000,000 for each of the first 5 fiscal years
8 beginning after the date of the enactment of this Act for
9 grants under subsection (a).

10sec. 515. State grant program for market innova-11tion.

12 (a) IN GENERAL.—The Secretary of Health and Human Services (in this section referred to as the "Sec-13 retary") shall establish a program (in this section referred 14 15 to as the "program") to award demonstration grants under this section to States to allow States to demonstrate 16 the effectiveness of innovative ways to increase access to 17 health insurance through market reforms and other inno-18 vative means. Such innovative means may include (and are 19 20 not limited to) any of the following:

(1) Alternative group purchasing or pooling arrangements, such as purchasing cooperatives for
small businesses, reinsurance pools, or high risk
pools.

25 (2) Individual or small group market reforms.

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1	(3) Consumer education and outreach.
2	(4) Subsidies to individuals, employers, or both,
3	in obtaining health insurance.
4	(b) SCOPE; DURATION.—The program shall be lim-
5	ited to not more than 10 States and to a total period of
6	5 years, beginning on the date the first demonstration
7	grant is made.
8	(c) Conditions for Demonstration Grants.—
9	(1) IN GENERAL.—The Secretary may not pro-
10	vide for a demonstration grant to a State under the
11	program unless the Secretary finds that under the
12	proposed demonstration grant—
13	(A) the State will provide for demonstrated
14	increase of access for some portion of the exist-
15	ing uninsured population through a market in-
16	novation (other than merely through a financial
17	expansion of a program initiated before the
18	date of the enactment of this Act);
19	(B) the State will comply with applicable
20	Federal laws;
21	(C) the State will not discriminate among
22	participants on the basis of any health status-
23	related factor (as defined in section $2791(d)(9)$
24	of the Public Health Service Act), except to the
25	extent a State wishes to focus on populations

1	that otherwise would not obtain health insur-
2	ance because of such factors; and
3	(D) the State will provide for such evalua-
4	tion, in coordination with the evaluation re-
5	quired under subsection (d), as the Secretary
6	may specify.
7	(2) APPLICATION.—The Secretary shall not
8	provide a demonstration grant under the program to
9	a State unless—
10	(A) the State submits to the Secretary
11	such an application, in such a form and man-
12	ner, as the Secretary specifies;
13	(B) the application includes information
14	regarding how the demonstration grant will ad-
15	dress issues such as governance, targeted popu-
16	lation, expected cost, and the continuation after
17	the completion of the demonstration grant pe-
18	riod; and
19	(C) the Secretary determines that the dem-
20	onstration grant will be used consistent with
21	this section.
22	(3) Focus.—A demonstration grant proposal
23	under section need not cover all uninsured individ-
24	uals in a State or all health care benefits with re-
25	spect to such individuals.

1 (d) EVALUATION.—The Secretary shall enter into a 2 contract with an appropriate entity outside the Depart-3 ment of Health and Human Services to conduct an overall 4 evaluation of the program at the end of the program pe-5 riod. Such evaluation shall include an analysis of improve-6 ments in access, costs, quality of care, or choice of cov-7 erage, under different demonstration grants.

8 (e) Option to Provide for Initial Planning 9 GRANTS.—Notwithstanding the previous provisions of this 10 section, under the program the Secretary may provide for a portion of the amounts appropriated under subsection 11 12 (f) (not to exceed \$5,000,000) to be made available to any 13 State for initial planning grants to permit States to develop demonstration grant proposals under the previous 14 15 provisions of this section.

16 (f) AUTHORIZATION OF APPROPRIATIONS.—There 17 are authorized to be appropriated \$100,000,000 for each 18 fiscal year to carry out this section. Amounts appropriated 19 under this subsection shall remain available until ex-20 pended.

(g) STATE DEFINED.—For purposes of this section,
the term "State" has the meaning given such term for
purposes of title XIX of the Social Security Act.

1 TITLE VI—EFFECTIVE DATES;2 COORDINATION IN IMPLE-3 MENTATION

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4 SEC. 601. EFFECTIVE DATES.

5 (a) GROUP HEALTH COVERAGE.—

6 (1) IN GENERAL.—Subject to paragraph (2) 7 and subsection (d), the amendments made by sec-8 tions 201(a), 401, 501, and 502 (and title I insofar 9 as it relates to such sections) shall apply with re-10 spect to group health plans, and health insurance 11 coverage offered in connection with group health 12 plans, for plan years beginning on or after October 13 1, 2005 (in this section referred to as the "general 14 effective date").

15 (2) TREATMENT OF COLLECTIVE BARGAINING 16 AGREEMENTS.—In the case of a group health plan 17 maintained pursuant to one or more collective bar-18 gaining agreements between employee representa-19 tives and one or more employers ratified before the 20 date of the enactment of this Act, the amendments 21 made by sections 201(a), 401, 501, and 502 (and 22 title I insofar as it relates to such sections) shall not 23 apply to plan years beginning before the later of— 24 (A) the date on which the last collective

24 (A) the date on which the last collective 25 bargaining agreements relating to the plan ter-

1	minates (excluding any extension thereof agreed
2	to after the date of the enactment of this Act);
3	or
4	(B) the general effective date;
5	but shall apply not later than 1 year after the gen-
6	eral effective date. For purposes of subparagraph
7	(A), any plan amendment made pursuant to a collec-
8	tive bargaining agreement relating to the plan which
9	amends the plan solely to conform to any require-
10	ment added by this Act shall not be treated as a ter-
11	mination of such collective bargaining agreement.
12	(b) Individual Health Insurance Coverage.—
13	Subject to subsection (d), the amendments made by sec-
14	tion 202 shall apply with respect to individual health in-
15	surance coverage offered, sold, issued, renewed, in effect,
16	or operated in the individual market on or after the gen-
17	eral effective date.
18	(c) TREATMENT OF RELIGIOUS NONMEDICAL PRO-
19	VIDERS.—
20	(1) IN GENERAL.—Nothing in this Act (or the
21	amendments made thereby) shall be construed to—
22	(A) restrict or limit the right of group
23	health plans, and of health insurance issuers of-
24	fering health insurance coverage, to include as

providers religious nonmedical providers;

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1 (B) require such plans or issuers to— 2 (i) utilize medically based eligibility 3 standards or criteria in deciding provider 4 status of religious nonmedical providers; (ii) use medical professionals or cri-5 6 teria to decide patient access to religious nonmedical providers; 7 8 (iii) utilize medical professionals or 9 criteria in making decisions in internal or external appeals regarding coverage for 10 11 care by religious nonmedical providers; or 12 (iv) compel a participant or bene-13 ficiary to undergo a medical examination 14 or test as a condition of receiving health 15 insurance coverage for treatment by a reli-16 gious nonmedical provider; or 17 (C) require such plans or issuers to ex-18 clude religious nonmedical providers because 19 they do not provide medical or other required 20 data, if such data is inconsistent with the reli-21 gious nonmedical treatment or nursing care 22 provided by the provider. 23 (2) Religious nonmedical provider.—For 24 purposes of this subsection, the term "religious non-25 medical provider" means a provider who provides no

medical care but who provides only religious non medical treatment or religious nonmedical nursing
 care.

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

7 (1) subsection (a) with respect to a group
8 health plan that is maintained as of the general ef9 fective date, not later than 30 days before the begin10 ning of the first plan year to which title I applies
11 in connection with the plan under such subsection;
12 or

(2) subsection (b) with respect to an individual
health insurance coverage that is in effect as of the
general effective date, not later than 30 days before
the first date as of which title I applies to the coverage under such subsection.

18 SEC. 602. COORDINATION IN IMPLEMENTATION.

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

(1) regulations, rulings, and interpretations
issued by such Secretaries relating to the same matter over which such Secretaries have responsibility

under the provisions of this Act (and the amend ments made thereby) are administered so as to have
 the same effect at all times; and

4 (2) coordination of policies relating to enforcing
5 the same requirements through such Secretaries in
6 order to have a coordinated enforcement strategy
7 that avoids duplication of enforcement efforts and
8 assigns priorities in enforcement.

9 SEC. 603. SEVERABILITY.

10 If any provision of this Act, an amendment made by 11 this Act, or the application of such provision or amend-12 ment to any person or circumstance is held to be unconsti-13 tutional, the remainder of this Act, the amendments made 14 by this Act, and the application of the provisions of such 15 to any person or circumstance shall not be affected there-16 by.

17 TITLE VII—MISCELLANEOUS 18 PROVISIONS

19 SEC. 701. NO IMPACT ON SOCIAL SECURITY TRUST FUND.

(a) IN GENERAL.—Nothing in this Act (or an amendment made by this Act) shall be construed to alter or
amend the Social Security Act (or any regulation promulgated under that Act).

24 (b) TRANSFERS.—

1 (1) ESTIMATE OF SECRETARY.—The Secretary 2 of the Treasury shall annually estimate the impact 3 that the enactment of this Act has on the income 4 and balances of the trust funds established under 5 section 201 of the Social Security Act (42 U.S.C. 6 401). (2) TRANSFER OF FUNDS.—If, under para-7 8 graph (1), the Secretary of the Treasury estimates 9 that the enactment of this Act has a negative impact 10 on the income and balances of the trust funds estab-11 lished under section 201 of the Social Security Act 12 (42 U.S.C. 401), the Secretary shall transfer, not 13 less frequently than quarterly, from the general reve-14 nues of the Federal Government an amount suffi-15 cient so as to ensure that the income and balances

of such trust funds are not reduced as a result of
the enactment of such Act.

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