# Calendar No. 164

106TH CONGRESS S. 1256

# A BILL

Entitled the "Patients' Bill of Rights".

 $J_{\text{UNE}}$  22, 1999

Read the second time and placed on the calendar

#### Calendar No. 164

106TH CONGRESS 1ST SESSION

### S. 1256

Entitled the "Patients' Bill of Rights".

#### IN THE SENATE OF THE UNITED STATES

June 21, 1999

Mr. Daschle introduced the following bill; which was read the first time

June 22, 1999

Read the second time and placed on the calendar

#### A BILL

Entitled the "Patients' Bill of Rights".

- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,
- 3 SEC. \_\_\_01. SHORT TITLE.
- 4 This title may be cited as the "Patients' Bill of
- 5 Rights Act of 1999".

#### Subtitle A—Health Insurance Bill 1 of Rights 2 CHAPTER 1—ACCESS TO CARE 3 SEC. \_\_\_101. ACCESS TO EMERGENCY CARE. 4 5 (a) Coverage of Emergency Services.— 6 (1) IN GENERAL.—If a group health plan, or 7 health insurance coverage offered by a health insur-8 ance issuer, provides any benefits with respect to 9 emergency services (as defined in paragraph (2)(B)), 10 the plan or issuer shall cover emergency services fur-11 nished under the plan or coverage— 12 (A) without the need for any prior author-13 ization determination; 14 (B) whether or not the health care pro-15 vider furnishing such services is a participating 16 provider with respect to such services; 17 (C) in a manner so that, if such services 18 are provided to a participant, beneficiary, or en-19 rollee by a nonparticipating health care provider 20 without prior authorization by the plan or 21 issuer, the participant, beneficiary, or enrollee 22 is not liable for amounts that exceed the 23 amounts of liability that would be incurred if 24 the services were provided by a participating

health care provider with prior authorization by the plan or issuer; 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).

#### (2) Definitions.—In this section:

(A) EMERGENCY MEDICAL CONDITION
BASED ON PRUDENT LAYPERSON STANDARD.—
The term "emergency medical condition" means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act.

1	(B) Emergency services.—The term
2	"emergency services" means—
3	(i) a medical screening examination
4	(as required under section 1867 of the So-
5	cial Security Act) that is within the capa-
6	bility of the emergency department of a
7	hospital, including ancillary services rou-
8	tinely available to the emergency depart-
9	ment to evaluate an emergency medical
10	condition (as defined in subparagraph
11	(A)), and
12	(ii) within the capabilities of the staff
13	and facilities available at the hospital, such
14	further medical examination and treatment
15	as are required under section 1867 of such
16	Act to stabilize the patient.
17	(b) Reimbursement for Maintenance Care and
18	Post-Stabilization Care.—In the case of services
19	(other than emergency services) for which benefits are
20	available under a group health plan, or under health insur-
21	ance coverage offered by a health insurance issuer, the
22	plan or issuer shall provide for reimbursement with re-
23	spect to such services provided to a participant, bene-
24	ficiary, or enrollee other than through a participating
25	health care provider in a manner consistent with sub-

- 1 section (a)(1)(C) (and shall otherwise comply with the
- 2 guidelines established under section 1852(d)(2) of the So-
- 3 cial Security Act (relating to promoting efficient and time-
- 4 ly coordination of appropriate maintenance and post-sta-
- 5 bilization care of an enrollee after an enrollee has been
- 6 determined to be stable), or, in the absence of guidelines
- 7 under such section, such guidelines as the Secretary shall
- 8 establish to carry out this subsection), if the services are
- 9 maintenance care or post-stabilization care covered under
- 10 such guidelines.
- 11 SEC. \_\_\_102. OFFERING OF CHOICE OF COVERAGE OP-
- 12 TIONS UNDER GROUP HEALTH PLANS.
- 13 (a) Requirement.—
- 14 (1) Offering of Point-of-Service Cov-
- 15 ERAGE OPTION.—Except as provided in paragraph
- 16 (2), if a group health plan (or health insurance cov-
- erage offered by a health insurance issuer in connec-
- tion with a group health plan) provides benefits only
- through participating health care providers, the plan
- or issuer shall offer the participant the option to
- 21 purchase point-of-service coverage (as defined in
- subsection (b)) for all such benefits for which cov-
- erage is otherwise so limited. Such option shall be
- made available to the participant at the time of en-
- 25 rollment under the plan or coverage and at such

1	other times as the plan or issuer offers the partici-
2	pant a choice of coverage options.
3	(2) Exception.—Paragraph (1) shall not
4	apply with respect to a participant in a group health
5	plan if the plan offers the participant—
6	(A) a choice of health insurance coverage;
7	and
8	(B) one or more coverage options that do
9	not provide benefits only through participating
10	health care providers.
11	(b) Point-of-Service Coverage Defined.—In
12	this section, the term "point-of-service coverage" means,
13	with respect to benefits covered under a group health plan
14	or health insurance issuer, coverage of such benefits when
15	provided by a nonparticipating health care provider. Such
16	coverage need not include coverage of providers that the
17	plan or issuer excludes because of fraud, quality, or similar
18	reasons.
19	(c) Construction.—Nothing in this section shall be
20	construed—
21	(1) as requiring coverage for benefits for a par-
22	ticular type of health care provider;
23	(2) as requiring an employer to pay any costs
24	as a result of this section or to make equal contribu-

- tions with respect to different health coverage options; or
- 3 (3) as preventing a group health plan or health 4 insurance issuer from imposing higher premiums or 5 cost-sharing on a participant for the exercise of a 6 point-of-service coverage option.
- 7 (d) No Requirement for Guaranteed Avail-
- 8 ABILITY.—If a health insurance issuer offers health insur-
- 9 ance coverage that includes point-of-service coverage with
- 10 respect to an employer solely in order to meet the require-
- 11 ment of subsection (a), nothing in section 2711(a)(1)(A)
- 12 of the Public Health Service Act shall be construed as re-
- 13 quiring the offering of such coverage with respect to an-
- 14 other employer.

#### 15 SEC. \_\_\_103. CHOICE OF PROVIDERS.

- 16 (a) Primary Care.—A group health plan, and a
- 17 health insurance issuer that offers health insurance cov-
- 18 erage, shall permit each participant, beneficiary, and en-
- 19 rollee to receive primary care from any participating pri-
- 20 mary care provider who is available to accept such indi-
- 21 vidual.
- 22 (b) Specialists.—
- 23 (1) In General.—Subject to paragraph (2), a
- group health plan and a health insurance issuer that
- offers health insurance coverage shall permit each

- participant, beneficiary, or enrollee to receive medically necessary or appropriate specialty care, pursuant to appropriate referral procedures, from any qualified participating health care provider who 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 providers with respect to such care.

#### 11 SEC. \_\_\_104. ACCESS TO SPECIALTY CARE.

- (a) Obstetrical and Gynecological Care.—
  - (1) IN GENERAL.—If a group health plan, or a health insurance issuer in connection with the provision of health insurance coverage, requires or provides for a participant, beneficiary, or enrollee to designate a participating primary care provider—
    - (A) the plan or issuer shall permit such an individual who is a female to designate a participating physician who specializes in obstetrics and gynecology as the individual's primary care provider; and
    - (B) if such an individual has not designated such a provider as a primary care provider, the plan or issuer—

1	(i) may not require authorization or a
2	referral by the individual's primary care
3	provider or otherwise for coverage of rou-
4	tine gynecological care (such as preventive
5	women's health examinations) and preg-
6	nancy-related services provided by a par-
7	ticipating health care professional who spe-
8	cializes in obstetrics and gynecology to the
9	extent such care is otherwise covered, and
10	(ii) may treat the ordering of other
11	gynecological care by such a participating
12	health professional as the authorization of
13	the primary care provider with respect to
14	such care under the plan or coverage.
15	(2) Construction.—Nothing in paragraph
16	(1)(B)(ii) shall waive any requirements of coverage
17	relating to medical necessity or appropriateness with
18	respect to coverage of gynecological care so ordered.
19	(b) Specialty Care.—
20	(1) Specialty care for covered serv-
21	ICES.—
22	(A) In general.—If—
23	(i) an individual is a participant or
24	beneficiary under a group health plan or
25	an enrollee who is covered under health in-

1	surance coverage offered by a health insur-
2	ance issuer,
3	(ii) the individual has a condition or
4	disease of sufficient seriousness and com-
5	plexity to require treatment by a specialist,
6	and
7	(iii) benefits for such treatment are
8	provided under the plan or coverage,
9	the plan or issuer shall make or provide for a
10	referral to a specialist who is available and ac-
11	cessible to provide the treatment for such condi-
12	tion or disease.
13	(B) Specialist defined.—For purposes
14	of this subsection, the term "specialist" means,
15	with respect to a condition, a health care practi-
16	tioner, facility, or center (such as a center of
17	excellence) that has adequate expertise through
18	appropriate training and experience (including,
19	in the case of a child, appropriate pediatric ex-
20	pertise) to provide high quality care in treating
21	the condition.
22	(C) CARE UNDER REFERRAL.—A group
23	health plan or health insurance issuer may re-
24	quire that the care provided to an individual

1	pursuant to such referral under subparagraph
2	(A) be—
3	(i) pursuant to a treatment plan, only
4	if the treatment plan is developed by the
5	specialist and approved by the plan or
6	issuer, in consultation with the designated
7	primary care provider or specialist and the
8	individual (or the individual's designee),
9	and
10	(ii) in accordance with applicable
11	quality assurance and utilization review
12	standards of the plan or issuer.
13	Nothing in this subsection shall be construed as
14	preventing such a treatment plan for an indi-
15	vidual from requiring a specialist to provide the
16	primary care provider with regular updates on
17	the specialty care provided, as well as all nec-
18	essary medical information.
19	(D) Referrals to participating pro-
20	VIDERS.—A group health plan or health insur-
21	ance issuer is not required under subparagraph
22	(A) to provide for a referral to a specialist that
23	is not a participating provider, unless the plan
24	or issuer does not have an appropriate specialist
25	that is available and accessible to treat the indi-

vidual's condition and that is a participating provider with respect to such treatment.

- (E) TREATMENT OF NONPARTICIPATING PROVIDERS.—If a plan or issuer refers an individual to a nonparticipating specialist pursuant to subparagraph (A), services provided pursuant to the approved treatment plan (if any) shall be provided at no additional cost to the individual beyond what the individual would otherwise pay for services received by such a specialist that is a participating provider.
- (2) Specialists as primary care providers.—
  - (A) In General.—A group health plan, or a health insurance issuer, in connection with the provision of health insurance coverage, shall have a procedure by which an individual who is a participant, beneficiary, or enrollee and who has an ongoing special condition (as defined in subparagraph (C)) may receive a referral to a specialist for such condition who shall be responsible for and capable of providing and coordinating the individual's primary and specialty care. If such an individual's care would most appropriately be coordinated by such a

	10
1	specialist, such plan or issuer shall refer the in-
2	dividual to such specialist.
3	(B) Treatment as primary care pro-
4	VIDER.—Such specialist shall be permitted to

VIDER.—Such specialist shall be permitted to treat the individual without a referral from the individual's primary care provider and may authorize such referrals, procedures, tests, and other medical services as the individual's primary care provider would otherwise be permitted to provide or authorize, subject to the terms of the treatment plan (referred to in

paragraph (1)(C)(i).

- (C) Ongoing special condition defined.—In this paragraph, the term "special condition" means a condition or disease that—
  - (i) is life-threatening, degenerative, or disabling, and
  - (ii) requires specialized medical care over a prolonged period of time.
- (D) TERMS OF REFERRAL.—The provisions of subparagraphs (C) through (E) of paragraph (1) apply with respect to referrals under subparagraph (A) of this paragraph in the same manner as they apply to referrals under paragraph (1)(A).

#### (3) Standing referrals.—

(A) IN GENERAL.—A group health plan, and a health insurance issuer in connection with the provision of health insurance coverage, shall have a procedure by which an individual who is a participant, beneficiary, or enrollee and who has a condition that requires ongoing care from a specialist may receive a standing referral to such specialist for treatment of such condition. If the plan or issuer, or if the primary care provider in consultation with the medical director of the plan or issuer and the specialist (if any), determines that such a standing referral is appropriate, the plan or issuer shall make such a referral to such a specialist.

(B) TERMS OF REFERRAL.—The provisions of subparagraphs (C) through (E) of paragraph (1) apply with respect to referrals under subparagraph (A) of this paragraph in the same manner as they apply to referrals under paragraph (1)(A).

#### 23 SEC. \_\_\_105. CONTINUITY OF CARE.

24 (a) IN GENERAL.—

- (1) TERMINATION OF PROVIDER.—If a contract between a group health plan, or a health insurance issuer in connection with the provision of health insurance coverage, and a health care provider is terminated (as defined in paragraph (3)), or benefits or coverage provided by a health care provider are terminated because of a change in the terms of provider participation in a group health plan, and an individual who is a participant, beneficiary, or enrollee in the plan or coverage is undergoing a course of treatment from the provider at the time of such termination, the plan or issuer shall—
  - (A) notify the individual on a timely basis of such termination, and
  - (B) subject to subsection (c), permit the individual to continue or be covered with respect to the course of treatment with the provider during a transitional period (provided under subsection (b)).
  - (2) Treatment of termination of contract with health insurance issuer.—If a contract for the provision of health insurance coverage between a group health plan and a health insurance issuer is terminated and, as a result of such termination, coverage of services of a health care

- provider is terminated with respect to an individual, the provisions of paragraph (1) (and the succeeding provisions of this section) shall apply under the plan in the same manner as if there had been a contract between the plan and the provider that had been terminated, but only with respect to benefits that are covered under the plan after the contract termination.
  - (3) TERMINATION.—In this section, the term "terminated" includes, with respect to a contract, the expiration or nonrenewal of the contract, but does not include a termination of the contract by the plan or issuer for failure to meet applicable quality standards or for fraud.

#### (b) Transitional Period.—

- (1) IN GENERAL.—Except as provided in paragraphs (2) through (4), the transitional period under this subsection shall extend for at least 90 days from the date of the notice described in subsection (a)(1)(A) of the provider's termination.
- (2) Institutional care.—The transitional period under this subsection for institutional or inpatient care from a provider shall extend until the discharge or termination of the period of institutionalization and also shall include institutional care pro-

vided within a reasonable time of the date of termination of the provider status if the care was scheduled before the date of the announcement of the termination of the provider status under subsection (a)(1)(A) or if the individual on such date was on an established waiting list or otherwise scheduled to have such care.

#### (3) Pregnancy.—If—

- (A) a participant, beneficiary, or enrollee has entered the second trimester of pregnancy at the time of a provider's termination of participation, and
- (B) the provider was treating the pregnancy before date of the termination, the transitional period under this subsection with respect to provider's treatment of the pregnancy shall extend through the provision of post-partum care directly related to the delivery.

#### (4) Terminal Illness.—If—

(A) a participant, beneficiary, or enrollee was determined to be terminally ill (as determined under section 1861(dd)(3)(A) of the Social Security Act) at the time of a provider's termination of participation, and

1 (B) the provider was treating the terminal 2 illness before the date of termination,

the transitional period under this subsection shall extend for the remainder of the individual's life for care directly related to the treatment of the terminal

6 illness.

- 7 (c) PERMISSIBLE TERMS AND CONDITIONS.—A
  8 group health plan or health insurance issuer may condi9 tion coverage of continued treatment by a provider under
  10 subsection (a)(1)(B) upon the provider agreeing to the fol11 lowing terms and conditions:
- 12 (1) The provider agrees to accept reimburse-13 ment from the plan or issuer and individual involved 14 (with respect to cost-sharing) at the rates applicable 15 prior to the start of the transitional period as pay-16 ment in full (or, in the case described in subsection 17 (a)(2), at the rates applicable under the replacement 18 plan or issuer after the date of the termination of 19 the contract with the health insurance issuer) and 20 not to impose cost-sharing with respect to the indi-21 vidual in an amount that would exceed the cost-shar-22 ing that could have been imposed if the contract re-23 ferred to in subsection (a)(1) had not been termi-24 nated.

- 1 (2) The provider agrees to adhere to the quality 2 assurance standards of the plan or issuer responsible 3 for payment under paragraph (1) and to provide to 4 such plan or issuer necessary medical information 5 related to the care provided.
- 6 (3) The provider agrees otherwise to adhere to
  7 such plan's or issuer's policies and procedures, in8 cluding procedures regarding referrals and obtaining
  9 prior authorization and providing services pursuant
  10 to a treatment plan (if any) approved by the plan or
  11 issuer.
- 12 (d) Construction.—Nothing in this section shall be 13 construed to require the coverage of benefits which would 14 not have been covered if the provider involved remained 15 a participating provider.
- 16 SEC. \_\_\_106. COVERAGE FOR INDIVIDUALS PARTICIPATING
  17 IN APPROVED CLINICAL TRIALS.
- 18 (a) Coverage.—
- 19 (1) IN GENERAL.—If a group health plan, or 20 health insurance issuer that is providing health in-21 surance coverage, provides coverage to a qualified in-22 dividual (as defined in subsection (b)), the plan or 23 issuer—

- 1 (A) may not deny the individual participa-2 tion in the clinical trial referred to in subsection 3 (b)(2);
  - (B) subject to subsection (c), may not deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and services furnished in connection with participation in the trial; and
  - (C) may not discriminate against the individual on the basis of the enrollee's participation in such trial.
  - (2) EXCLUSION OF CERTAIN COSTS.—For purposes of paragraph (1)(B), routine patient costs do not include the cost of the tests or measurements conducted primarily for the purpose of the clinical trial involved.
  - (3) USE OF IN-NETWORK PROVIDERS.—If one or more participating providers is participating in a clinical trial, nothing in paragraph (1) shall be construed 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.

1	(b) Qualified Individual Defined.—For pur-
2	poses of subsection (a), the term "qualified individual"
3	means an individual who is a participant or beneficiary
4	in a group health plan, or who is an enrollee under health
5	insurance coverage, and who meets the following condi-
6	tions:
7	(1)(A) The individual has a life-threatening or
8	serious illness for which no standard treatment is ef-
9	fective.
10	(B) The individual is eligible to participate in
11	an approved clinical trial according to the trial pro-
12	tocol with respect to treatment of such illness.
13	(C) The individual's participation in the trial
14	offers meaningful potential for significant clinical
15	benefit for the individual.
16	(2) Either—
17	(A) the referring physician is a partici-
18	pating health care professional and has con-
19	cluded that the individual's participation in
20	such trial would be appropriate based upon the
21	individual meeting the conditions described in
22	paragraph (1); or
23	(B) the participant, beneficiary, or enrollee
24	provides medical and scientific information es-
25	tablishing that the individual's participation in

1 such trial would be appropriate based upon the 2 individual meeting the conditions described in 3 paragraph (1). 4 (c) Payment.— (1) In General.—Under this section a group 5 6 health plan or health insurance issuer shall provide 7 for payment for routine patient costs described in 8 subsection (a)(2) but is not required to pay for costs 9 of items and services that are reasonably expected 10 (as determined by the Secretary) to be paid for by 11 the sponsors of an approved clinical trial. 12 (2) Payment rate.—In the case of covered 13 items and services provided by— 14 (A) a participating provider, the payment 15 rate shall be at the agreed upon rate, or 16 (B) a nonparticipating provider, the pay-17 ment rate shall be at the rate the plan or issuer 18 would normally pay for comparable services 19 under subparagraph (A). 20 (d) APPROVED CLINICAL TRIAL DEFINED.— 21 (1) IN GENERAL.—In this section, the term "approved clinical trial" means a clinical research 22 23 study or clinical investigation approved and funded

(which may include funding through in-kind con-

tributions) by one or more of the following:

24

1	(A) The National Institutes of Health.
2	(B) A cooperative group or center of the
3	National Institutes of Health.
4	(C) Either of the following if the condi-
5	tions described in paragraph (2) are met:
6	(i) The Department of Veterans Af-
7	fairs.
8	(ii) The Department of Defense.
9	(2) Conditions for Departments.—The
10	conditions described in this paragraph, for a study
11	or investigation conducted by a Department, are
12	that the study or investigation has been reviewed
13	and approved through a system of peer review that
14	the Secretary determines—
15	(A) to be comparable to the system of peer
16	review of studies and investigations used by the
17	National Institutes of Health, and
18	(B) assures unbiased review of the highest
19	scientific standards by qualified individuals who
20	have no interest in the outcome of the review.
21	(e) Construction.—Nothing in this section shall be
22	construed to limit a plan's or issuer's coverage with re-
23	spect to clinical trials.

1	SEC107. ACCESS TO NEEDED PRESCRIPTION DRUGS.
2	(a) In General.—If a group health plan, or health
3	insurance issuer that offers health insurance coverage,
4	provides benefits with respect to prescription drugs but
5	the coverage limits such benefits to drugs included in a
6	formulary, the plan or issuer shall—
7	(1) ensure participation of participating physi-
8	cians and pharmacists in the development of the for-
9	mulary;
10	(2) disclose to providers and, disclose upon re-
11	quest under section121(e)(6) to participants,
12	beneficiaries, and enrollees, the nature of the for-
13	mulary restrictions; and
14	(3) consistent with the standards for a utiliza-
15	tion review program under section115, provide
16	for exceptions from the formulary limitation when a
17	non-formulary alternative is medically indicated.
18	(b) Coverage of Approved Drugs and Medical
19	Devices.—
20	(1) In general.—A group health plan (or
21	health insurance coverage offered in connection with
22	such a plan) that provides any coverage of prescrip-
23	tion drugs or medical devices shall not deny coverage
24	of such a drug or device on the basis that the use
25	is investigational, if the use—
26	(A) in the case of a prescription drug—

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

health plan (or health insurance coverage offered in

- 1 connection with such a plan) to provide any coverage
- 2 of prescription drugs or medical devices.

#### 3 SEC. \_\_\_108. ADEQUACY OF PROVIDER NETWORK.

- 4 (a) In General.—Each group health plan, and each
- 5 health insurance issuer offering health insurance coverage,
- 6 that provides benefits, in whole or in part, through partici-
- 7 pating health care providers shall have (in relation to the
- 8 coverage) a sufficient number, distribution, and variety of
- 9 qualified participating health care providers to ensure that
- 10 all covered health care services, including specialty serv-
- 11 ices, will be available and accessible in a timely manner
- 12 to all participants, beneficiaries, and enrollees under the
- 13 plan or coverage. This subsection shall only apply to a
- 14 plan's or issuer's application of restrictions on the partici-
- 15 pation of health care providers in a network and shall not
- 16 be construed as requiring a plan or issuer to create or
- 17 establish new health care providers in an area.
- 18 (b) Treatment of Certain Providers.—The
- 19 qualified health care providers under subsection (a) may
- 20 include Federally qualified health centers, rural health
- 21 clinics, migrant health centers, and other essential com-
- 22 munity providers located in the service area of the plan
- 23 or issuer and shall include such providers if necessary to
- 24 meet the standards established to carry out such sub-
- 25 section.

1	SEC109. NONDISCRIMINATION IN DELIVERY OF SERV-
2	ICES.
3	(a) Application to Delivery of Services.—Sub-
4	ject to subsection (b), a group health plan, and health in-
5	surance issuer in relation to health insurance coverage,
6	may not discriminate against a participant, beneficiary, or
7	enrollee in the delivery of health care services consistent
8	with the benefits covered under the plan or coverage or
9	as required by law based on race, color, ethnicity, national
10	origin, religion, sex, age, mental or physical disability, sex-
11	ual orientation, genetic information, or source of payment.
12	(b) Construction.—Nothing in subsection (a) shall
13	be construed as relating to the eligibility to be covered,
14	or the offering (or guaranteeing the offer) of coverage,
15	under a plan or health insurance coverage, the application
16	of any pre-existing condition exclusion consistent with ap-
17	plicable law, or premiums charged under such plan or cov-
18	erage. Pursuant to section192(b), except as provided
19	in section152, nothing in this subtitle shall be con-
20	strued as requiring a group health plan or health insur-
21	ance issuer to provide specific benefits under the terms
22	of such plan or coverage.
23	CHAPTER 2—QUALITY ASSURANCE
24	SEC111. INTERNAL QUALITY ASSURANCE PROGRAM.
25	(a) Requirement.—A group health plan, and a
26	health insurance issuer that offers health insurance cov-

1	erage, shall establish and maintain an ongoing, internal
2	quality assurance and continuous quality improvement
3	program that meets the requirements of subsection (b).
4	(b) Program Requirements.—The requirements of
5	this subsection for a quality improvement program of a
6	plan or issuer are as follows:
7	(1) Administration.—The plan or issuer has
8	a separate identifiable unit with responsibility for
9	administration of the program.
10	(2) Written plan.—The plan or issuer has a
11	written plan for the program that is updated annu-
12	ally and that specifies at least the following:
13	(A) The activities to be conducted.
14	(B) The organizational structure.
15	(C) The duties of the medical director.
16	(D) Criteria and procedures for the assess-
17	ment of quality.
18	(3) Systematic review.—The program pro-
19	vides for systematic review of the type of health
20	services provided, consistency of services provided
21	with good medical practice, and patient outcomes.
22	(4) QUALITY CRITERIA.—The program—
23	(A) uses criteria that are based on per-
24	formance and patient outcomes where feasible
25	and appropriate;

- 1 (B) includes criteria that are directed spe-2 cifically at meeting the needs of at-risk populations and covered individuals with chronic 3 4 conditions or severe illnesses, including genderspecific criteria and pediatric-specific criteria 5 6 where available and appropriate; 7 (C) includes methods for informing covered 8 individuals of the benefit of preventive care and 9 what specific benefits with respect to preventive 10 care are covered under the plan or coverage; 11 and 12 (D) makes available to the public a de-13 scription of the criteria used under subpara-14 graph (A). (5) System for reporting.—The program 15 16 has procedures for reporting of possible quality con-17 cerns by providers and enrollees and for remedial ac-18 tions to correct quality problems, including written 19 procedures for responding to concerns and taking 20 appropriate corrective action. 21 (6) Data analysis.—The program provides, 22 using data that include the data collected under sec-
- issuer's performance on quality measures.

tion \_\_\_\_112, for an analysis of the plan's or

1	(7) Drug utilization review.—The program
2	provides for a drug utilization review program in ac-
3	cordance with section114.
4	(c) Deeming.—For purposes of subsection (a), the
5	requirements of—
6	(1) subsection (b) (other than paragraph (5))
7	are deemed to be met with respect to a health insur-
8	ance issuer that is a qualified health maintenance
9	organization (as defined in section 1310(c) of the
10	Public Health Service Act); or
11	(2) subsection (b) are deemed to be met with
12	respect to a health insurance issuer that is accred-
13	ited by a national accreditation organization that the
14	Secretary certifies as applying, as a condition of cer-
15	tification, standards at least as stringent as those
16	required for a quality improvement program under
17	subsection (b).
18	(d) Variation Permitted.—The Secretary may
19	provide for variations in the application of the require-
20	ments of this section to group health plans and health in-
21	surance issuers based upon differences in the delivery sys-
22	tem among such plans and issuers as the Secretary deems
23	appropriate.

1	SEC112. COLLECTION OF STANDARDIZED DATA.
2	(a) In General.—A group health plan and a health
3	insurance issuer that offers health insurance coverage
4	shall collect uniform quality data that include a minimum
5	uniform data set described in subsection (b).
6	(b) Minimum Uniform Data Set.—The Secretary
7	shall specify (and may from time to time update) the data
8	required to be included in the minimum uniform data set
9	under subsection (a) and the standard format for such
10	data. Such data shall include at least—
11	(1) aggregate utilization data;
12	(2) data on the demographic characteristics of
13	participants, beneficiaries, and enrollees;
14	(3) data on disease-specific and age-specific
15	mortality rates and (to the extent feasible) morbidity
16	rates of such individuals;
17	(4) data on satisfaction (including satisfaction
18	with respect to services to children) of such individ-
19	uals, including data on voluntary disenrollment and
20	grievances; and
21	(5) data on quality indicators and health out-
22	comes, including, to the extent feasible and appro-
23	priate, data on pediatric cases and on a gender-spe-
24	cific basis.
25	(c) AVAILABILITY.—A summary of the data collected
26	under subsection (a) shall be disclosed under section

- 1 \_\_\_\_121(b)(9). The Secretary shall be provided access to
- 2 all the data so collected.
- 3 (d) Variation Permitted.—The Secretary may
- 4 provide for variations in the application of the require-
- 5 ments of this section to group health plans and health in-
- 6 surance issuers based upon differences in the delivery sys-
- 7 tem among such plans and issuers as the Secretary deems
- 8 appropriate.
- 9 (e) Exception for Non-Medical, Religious
- 10 Care Providers.—The requirements of subsection (a),
- 11 insofar as they may apply to a provider of health care,
- 12 do not apply to a provider that provides no medical care
- 13 and that provides only a religious method of healing or
- 14 religious nonmedical nursing care.
- 15 SEC. \_\_\_113. PROCESS FOR SELECTION OF PROVIDERS.
- 16 (a) IN GENERAL.—A group health plan and a health
- 17 insurance issuer that offers health insurance coverage
- 18 shall, if it provides benefits through participating health
- 19 care professionals, have a written process for the selection
- 20 of participating health care professionals, including min-
- 21 imum professional requirements.
- 22 (b) Verification of Background.—Such process
- 23 shall include verification of a health care provider's license
- 24 and a history of suspension or revocation.

1	(c) Restriction.—Such process shall not use a
2	high-risk patient base or location of a provider in an area
3	with residents with poorer health status as a basis for ex-
4	cluding providers from participation.
5	(d) Nondiscrimination Based on Licensure.—
6	(1) In general.—Such process shall not dis-
7	criminate with respect to participation or indem-
8	nification as to any provider who is acting within the
9	scope of the provider's license or certification under
10	applicable State law, solely on the basis of such li-
11	cense or certification.
12	(2) Construction.—Paragraph (1) shall not
13	be construed—
14	(A) as requiring the coverage under a plan
15	or coverage of particular benefits or services or
16	to prohibit a plan or issuer from including pro-
17	viders only to the extent necessary to meet the
18	needs of the plan's or issuer's participants,
19	beneficiaries, or enrollees or from establishing
20	any measure designed to maintain quality and
21	control costs consistent with the responsibilities
22	of the plan or issuer; or
23	(B) to override any State licensure or
24	scope-of-practice law.
25	(e) General Nondiscrimination.—

- (1) In General.—Subject to paragraph (2), 1 2 such process shall not discriminate with respect to 3 selection of a health care professional to be a participating health care provider, or with respect to the 5 terms and conditions of such participation, based on 6 the professional's race, color, religion, sex, national 7 origin, age, sexual orientation, or disability (con-8 sistent with the Americans with Disabilities Act of 9 1990).
- 10 (2) Rules.—The appropriate Secretary may 11 establish such definitions, rules, and exceptions as 12 may be appropriate to carry out paragraph (1), tak-13 ing into account comparable definitions, rules, and 14 exceptions in effect under employment-based non-15 discrimination laws and regulations that relate to 16 each of the particular bases for discrimination de-17 scribed in such paragraph.

#### 18 SEC. \_\_\_114. DRUG UTILIZATION PROGRAM.

drug utilization program which—

A group health plan, and a health insurance issuer
that provides health insurance coverage, that includes benefits for prescription drugs shall establish and maintain,
as part of its internal quality assurance and continuous
quality improvement program under section \_\_\_\_111, a

1	(1) encourages appropriate use of prescription
2	drugs by participants, beneficiaries, and enrollees
3	and providers, and

(2) takes appropriate action to reduce the incidence of improper drug use and adverse drug reactions and interactions.

## 7 SEC. \_\_\_115. STANDARDS FOR UTILIZATION REVIEW AC-

#### (a) Compliance with Requirements.—

- (1) In General.—A group health plan, and a health insurance issuer that provides health insurance coverage, shall conduct utilization review activities in connection with the provision of benefits under such plan or coverage only in accordance with a utilization review program that meets the requirements of this section.
- (2) Use of outside agents.—Nothing in this section shall be construed as preventing a group health plan or health insurance issuer from arranging through a contract or otherwise for persons or entities to conduct utilization review activities on behalf of the plan or issuer, so long as such activities are conducted in accordance with a utilization review program that meets the requirements of this section.

(3) Utilization review defined.—For purposes of this section, the terms "utilization review" and "utilization review activities" mean procedures used to monitor or evaluate the clinical necessity, appropriateness, efficacy, or efficiency of health care services, procedures or settings, and includes prospective review, concurrent review, second opinions, case management, discharge planning, or retrospective review.

## (b) Written Policies and Criteria.—

(1) Written Policies.—A utilization review program shall be conducted consistent with written policies and procedures that govern all aspects of the program.

#### (2) Use of written criteria.—

- (A) IN GENERAL.—Such a program shall utilize written clinical review criteria developed pursuant to the program with the input of appropriate physicians. Such criteria shall include written clinical review criteria described in section \_\_\_\_111(b)(4)(B).
- (B) CONTINUING USE OF STANDARDS IN RETROSPECTIVE REVIEW.—If a health care service has been specifically pre-authorized or approved for an enrollee under such a program,

the program shall not, pursuant to retrospective review, revise or modify the specific standards, criteria, or procedures used for the utilization review for procedures, treatment, and services delivered to the enrollee during the same course of treatment.

## (c) CONDUCT OF PROGRAM ACTIVITIES.—

- (1) Administration by Health care professionals.—A utilization review program shall be administered by qualified health care professionals who shall oversee review decisions. In this subsection, the term "health care professional" means a physician or other health care practitioner licensed, accredited, or certified to perform specified health services consistent with State law.
- (2) Use of qualified, independent personnel.—
  - (A) IN GENERAL.—A utilization review program shall provide for the conduct of utilization review activities only through personnel who are qualified and, to the extent required, who have received appropriate training in the conduct of such activities under the program.
- (B) PEER REVIEW OF SAMPLE OF AD-VERSE CLINICAL DETERMINATIONS.—Such a

1	program shall provide that clinical peers (as de-
2	fined in section191(c)(2)) shall evaluate
3	the clinical appropriateness of at least a sample
4	of adverse clinical determinations.
5	(C) Prohibition of contingent com-
6	PENSATION ARRANGEMENTS.—Such a program
7	shall not, with respect to utilization review ac-
8	tivities, permit or provide compensation or any-
9	thing of value to its employees, agents, or con-
10	tractors in a manner that—
11	(i) provides incentives, direct or indi-
12	rect, for such persons to make inappro-
13	priate review decisions, or
14	(ii) is based, directly or indirectly, on
15	the quantity or type of adverse determina-
16	tions rendered.
17	(D) Prohibition of conflicts.—Such a
18	program shall not permit a health care profes-
19	sional who provides health care services to an
20	individual to perform utilization review activi-
21	ties in connection with the health care services
22	being provided to the individual.
23	(3) Accessibility of Review.—Such a pro-
24	gram shall provide that appropriate personnel per-
25	forming utilization review activities under the pro-

- gram are reasonably accessible by toll-free telephone during normal business hours to discuss patient care and allow response to telephone requests, and that appropriate provision is made to receive and respond promptly to calls received during other hours.
  - (4) LIMITS ON FREQUENCY.—Such a program shall not provide for the performance of utilization review activities with respect to a class of services furnished to an individual more frequently than is reasonably required to assess whether the services under review are medically necessary or appropriate.
  - (5) Limitation on information requests.— Under such a program, information shall be required to be provided by health care providers only to the extent it is necessary to perform the utilization review activity involved.

## (d) Deadline for Determinations.—

(1) Prior authorization services.—Except as provided in paragraph (2), in the case of a utilization review activity involving the prior authorization of health care items and services for an individual, the utilization review program shall make a determination concerning such authorization, and provide notice of the determination to the individual or the individual's designee and the individual's

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health care provider by telephone and in printed form, as soon as possible in accordance with the medical exigencies of the cases, and in no event later than 3 business days after the date of receipt of information that is reasonably necessary to make such determination.

(2) Continued care.—In the case of a utilization review activity involving authorization for continued or extended health care services for an individual, or additional services for an individual undergoing a course of continued treatment prescribed by a health care provider, the utilization review program shall make a determination concerning such authorization, and provide notice of the determination to the individual or the individual's designee and the individual's health care provider by telephone and in printed form, as soon as possible in accordance with the medical exigencies of the cases, and in no event later than 1 business day after the date of receipt of information that is reasonably necessary to make such determination. Such notice shall include, with respect to continued or extended health care services, the number of extended services approved, the new total of approved services, the date of onset of services, and the next review date, if any.

- (3) Previously provided services.—In the case of a utilization review activity involving retrospective review of health care services previously provided for an individual, the utilization review program shall make a determination concerning such services, and provide notice of the determination to the individual or the individual's designee and the individual's health care provider by telephone and in printed form, within 30 days of the date of receipt of information that is reasonably necessary to make such determination.
  - (4) Reference to special rules for emergency services, maintenance care, and post-stabilization care, see subsections (a)(1) and (b) of section \_\_\_\_101, respectively.

# (e) Notice of Adverse Determinations.—

- (1) In General.—Notice of an adverse determination under a utilization review program shall be provided in printed form and shall include—
- 23 (A) the reasons for the determination (in-24 cluding the clinical rationale);

1	(B) instructions on how to initiate an ap-
2	peal under section132; and
3	(C) notice of the availability, upon request
4	of the individual (or the individual's designee)
5	of the clinical review criteria relied upon to
6	make such determination.
7	(2) Specification of any additional infor-
8	MATION.—Such a notice shall also specify what (if
9	any) additional necessary information must be pro-
10	vided to, or obtained by, the person making the de-
11	termination in order to make a decision on such an
12	appeal.
13	SEC116. HEALTH CARE QUALITY ADVISORY BOARD.
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14	(a) Establishment.—The President shall establish
14	(a) Establishment.—The President shall establish
<ul><li>14</li><li>15</li><li>16</li></ul>	(a) ESTABLISHMENT.—The President shall establish an advisory board to provide information to Congress and
<ul><li>14</li><li>15</li><li>16</li><li>17</li></ul>	(a) Establishment.—The President shall establish an advisory board to provide information to Congress and the administration on issues relating to quality monitoring
<ul><li>14</li><li>15</li><li>16</li><li>17</li></ul>	(a) ESTABLISHMENT.—The President shall establish an advisory board to provide information to Congress and the administration on issues relating to quality monitoring and improvement in the health care provided under group
14 15 16 17 18	(a) ESTABLISHMENT.—The President shall establish an advisory board to provide information to Congress and the administration on issues relating to quality monitoring and improvement in the health care provided under group health plans and health insurance coverage.
14 15 16 17 18	<ul> <li>(a) ESTABLISHMENT.—The President shall establish an advisory board to provide information to Congress and the administration on issues relating to quality monitoring and improvement in the health care provided under group health plans and health insurance coverage.</li> <li>(b) NUMBER AND APPOINTMENT.—The advisory</li> </ul>
14 15 16 17 18 19 20	<ul> <li>(a) ESTABLISHMENT.—The President shall establish an advisory board to provide information to Congress and the administration on issues relating to quality monitoring and improvement in the health care provided under group health plans and health insurance coverage.</li> <li>(b) NUMBER AND APPOINTMENT.—The advisory board shall be composed of the Secretary of Health and</li> </ul>
14 15 16 17 18 19 20 21	<ul> <li>(a) Establishment.—The President shall establish an advisory board to provide information to Congress and the administration on issues relating to quality monitoring and improvement in the health care provided under group health plans and health insurance coverage.</li> <li>(b) Number and Appointment.—The advisory board shall be composed of the Secretary of Health and Human Services (or the Secretary's designee), the Secretary's designee)</li> </ul>

1	and House of Representatives. The members so appointed
2	shall include individuals with expertise in—
3	(1) consumer needs;
4	(2) education and training of health profes-
5	sionals;
6	(3) health care services;
7	(4) health plan management;
8	(5) health care accreditation, quality assurance,
9	improvement, measurement, and oversight;
10	(6) medical practice, including practicing physi-
11	cians;
12	(7) prevention and public health; and
13	(8) public and private group purchasing for
14	small and large employers or groups.
15	(c) Duties.—The advisory board shall—
16	(1) identify, update, and disseminate measures
17	of health care quality for group health plans and
18	health insurance issuers, including network and non-
19	network plans;
20	(2) advise the Secretary on the development
21	and maintenance of the minimum data set in section
22	112(b); and
23	(3) advise the Secretary on standardized for-
24	mats for information on group health plans and
25	health insurance coverage.

- 1 The measures identified under paragraph (1) may be used
- 2 on a voluntary basis by such plans and issuers. In carrying
- 3 out paragraph (1), the advisory board shall consult and
- 4 cooperate with national health care standard setting bod-
- 5 ies which define quality indicators, the Agency for Health
- 6 Care Policy and Research, the Institute of Medicine, and
- 7 other public and private entities that have expertise in
- 8 health care quality.
- 9 (d) Report.—The advisory board shall provide an
- 10 annual report to Congress and the President on the qual-
- 11 ity of the health care in the United States and national
- 12 and regional trends in health care quality. Such report
- 13 shall include a description of determinants of health care
- 14 quality and measurements of practice and quality varia-
- 15 bility within the United States.
- 16 (e) Secretarial Consultation.—In serving on
- 17 the advisory board, the Secretaries of Health and Human
- 18 Services and Labor (or their designees) shall consult with
- 19 the Secretaries responsible for other Federal health insur-
- 20 ance and health care programs.
- 21 (f) VACANCIES.—Any vacancy on the board shall be
- 22 filled in such manner as the original appointment. Mem-
- 23 bers of the board shall serve without compensation but
- 24 shall be reimbursed for travel, subsistence, and other nec-
- 25 essary expenses incurred by them in the performance of

1	their duties. Administrative support, scientific support,
2	and technical assistance for the advisory board shall be
3	provided by the Secretary of Health and Human Services.
4	(g) Continuation.—Section 14(a)(2)(B) of the
5	Federal Advisory Committee Act (5 U.S.C. App.; relating
6	to the termination of advisory committees) shall not apply
7	to the advisory board.
8	CHAPTER 3—PATIENT INFORMATION
9	SEC121. PATIENT INFORMATION.
10	(a) Disclosure Requirement.—
11	(1) Group Health Plans.—A group health
12	plan shall—
13	(A) provide to participants and bene-
14	ficiaries at the time of initial coverage under
15	the plan (or the effective date of this section, in
16	the case of individuals who are participants or
17	beneficiaries as of such date), and at least an-
18	nually thereafter, the information described in
19	subsection (b) in printed form;
20	(B) provide to participants and bene-
21	ficiaries, within a reasonable period (as speci-
22	fied by the appropriate Secretary) before or
23	after the date of significant changes in the in-
24	formation described in subsection (b), informa-

1	tion in printed form on such significant
2	changes; and
3	(C) upon request, make available to par-
4	ticipants and beneficiaries, the applicable au-
5	thority, and prospective participants and bene-
6	ficiaries, the information described in sub-
7	section (b) or (c) in printed form.
8	(2) Health insurance issuers.—A health
9	insurance issuer in connection with the provision of
10	health insurance coverage shall—
11	(A) provide to individuals enrolled under
12	such coverage at the time of enrollment, and at
13	least annually thereafter, the information de-
14	scribed in subsection (b) in printed form;
15	(B) provide to enrollees, within a reason-
16	able period (as specified by the appropriate Sec-
17	retary) before or after the date of significant
18	changes in the information described in sub-
19	section (b), information in printed form on such
20	significant changes; and
21	(C) upon request, make available to the
22	applicable authority, to individuals who are pro-
23	spective enrollees, and to the public the infor-
24	mation described in subsection (b) or (c) in
25	printed form.

1	(b) Information Provided.—The information de-
2	scribed in this subsection with respect to a group health
3	plan or health insurance coverage offered by a health in-
4	surance issuer includes the following:
5	(1) Service area.—The service area of the
6	plan or issuer.
7	(2) Benefits.—Benefits offered under the
8	plan or coverage, including—
9	(A) covered benefits, including benefit lim-
10	its and coverage exclusions;
11	(B) cost sharing, such as deductibles, coin-
12	surance, and copayment amounts, including any
13	liability for balance billing, any maximum limi-
14	tations on out of pocket expenses, and the max-
15	imum out of pocket costs for services that are
16	provided by nonparticipating providers or that
17	are furnished without meeting the applicable
18	utilization review requirements;
19	(C) the extent to which benefits may be ob-
20	tained from nonparticipating providers;
21	(D) the extent to which a participant, ben-
22	eficiary, or enrollee may select from among par-
23	ticipating providers and the types of providers
24	participating in the plan or issuer network;

1	(E) process for determining experimental
2	coverage; and
3	(F) use of a prescription drug formulary.
4	(3) Access.—A description of the following:
5	(A) The number, mix, and distribution of
6	providers under the plan or coverage.
7	(B) Out-of-network coverage (if any) pro-
8	vided by the plan or coverage.
9	(C) Any point-of-service option (including
10	any supplemental premium or cost-sharing for
11	such option).
12	(D) The procedures for participants, bene-
13	ficiaries, and enrollees to select, access, and
14	change participating primary and specialty pro-
15	viders.
16	(E) The rights and procedures for obtain-
17	ing referrals (including standing referrals) to
18	participating and nonparticipating providers.
19	(F) The name, address, and telephone
20	number of participating health care providers
21	and an indication of whether each such provider
22	is available to accept new patients.
23	(G) Any limitations imposed on the selec-
24	tion of qualifying participating health care pro-

1	viders, including any limitations imposed under
2	section103(b)(2).
3	(H) How the plan or issuer addresses the
4	needs of participants, beneficiaries, and enroll-
5	ees and others who do not speak English or
6	who have other special communications needs in
7	accessing providers under the plan or coverage,
8	including the provision of information described
9	in this subsection and subsection (c) to such in-
10	dividuals and including the provision of infor-
11	mation in a language other than English if 5
12	percent of the number of participants, bene-
13	ficiaries, and enrollees communicate in that lan-
14	guage instead of English.
15	(4) Out-of-area coverage.—Out-of-area cov-
16	erage provided by the plan or issuer.
17	(5) Emergency coverage.—Coverage of
18	emergency services, including—
19	(A) the appropriate use of emergency serv-
20	ices, including use of the 911 telephone system
21	or its local equivalent in emergency situations
22	and an explanation of what constitutes an
23	emergency situation;
24	(B) the process and procedures of the plan
25	or issuer for obtaining emergency services; and

- 1 (C) the locations of (i) emergency depart-2 ments, and (ii) other settings, in which plan 3 physicians and hospitals provide emergency 4 services and post-stabilization care.
  - (6) Percentage of Premiums used for Benefits (Loss-Ratios).—In the case of health insurance coverage only (and not with respect to group health plans that do not provide coverage through health insurance coverage), a description of the overall loss-ratio for the coverage (as defined in accordance with rules established or recognized by the Secretary of Health and Human Services).
  - (7) Prior authorization rules.—Rules regarding prior authorization or other review requirements that could result in noncoverage or non-payment.
  - (8) Grievance and appeals procedures.—All appeal or grievance rights and procedures under the plan or coverage, including the method for filing grievances and the time frames and circumstances for acting on grievances and appeals, who is the applicable authority with respect to the plan or issuer, and the availability of assistance through an ombudsman to individuals in relation to group health plans and health insurance coverage.

- 1 (9) QUALITY ASSURANCE.—A summary descrip2 tion of the data on quality collected under section
  3 \_\_\_\_112(a), including a summary description of the
  4 data on satisfaction of participants, beneficiaries,
  5 and enrollees (including data on individual voluntary
  6 disenrollment and grievances and appeals) described
  7 in section \_\_\_\_112(b)(4).
  - (10) Summary of Provider financial incentives.—A summary description of the information on the types of financial payment incentives (described in section 1852(j)(4) of the Social Security Act) provided by the plan or issuer under the coverage.
  - (11) Information on issuer.—Notice of appropriate mailing addresses and telephone numbers to be used by participants, beneficiaries, and enrollees in seeking information or authorization for treatment.
- 19 (12) AVAILABILITY OF INFORMATION ON RE-20 QUEST.—Notice that the information described in 21 subsection (c) is available upon request.
- 22 (c) Information Made Available Upon Re-23 Quest.—The information described in this subsection is 24 the following:

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1 (1) Utilization review activities.—A de-2 scription of procedures used and requirements (in-3 cluding circumstances, time frames, and appeal rights) under any utilization review program under section \_\_\_\_115, including under any drug for-5 6 mulary program under section \_\_\_\_\_107. 7 (2) Grievance and appeals information.— 8 Information on the number of grievances and ap-9 peals and on the disposition in the aggregate of such 10 matters. 11 (3) METHOD OF PHYSICIAN COMPENSATION.— An overall summary description as to the method of 12 13 compensation of participating physicians, including 14 information on the types of financial payment incen-15 tives (described in section 1852(j)(4) of the Social 16 Security Act) provided by the plan or issuer under 17 the coverage. 18 (4) Specific information on credentials 19 OF PARTICIPATING PROVIDERS.—In the case of each 20 participating provider, a description of the creden-21 tials of the provider. 22 (5) Confidentiality policies and proce-23 DURES.—A description of the policies and proce-

dures established to carry out section 122.

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- 1 (6) FORMULARY RESTRICTIONS.—A description 2 of the nature of any drug formula restrictions.
  - (7) Participating provider list.—A list of current participating health care providers.

## (d) Form of Disclosure.—

- (1) Uniformity.—Information required to be disclosed under this section shall be provided in accordance with uniform, national reporting standards specified by the Secretary, after consultation with applicable State authorities, so that prospective enrollees may compare the attributes of different issuers and coverage offered within an area.
- (2) Information into handbook.—Nothing in this section shall be construed as preventing a group health plan or health insurance issuer from making the information under subsections (b) and (c) available to participants, beneficiaries, and enrollees through an enrollee handbook or similar publication.
- (3) UPDATING PARTICIPATING PROVIDER IN-FORMATION.—The information on participating health care providers described in subsection (b)(3)(C) shall be updated within such reasonable period as determined appropriate by the Secretary. Nothing in this section shall prevent an issuer from

1	changing or updating other information made avail-
2	able under this section.
3	(e) Construction.—Nothing in this section shall be
4	construed as requiring public disclosure of individual con-
5	tracts or financial arrangements between a group health
6	plan or health insurance issuer and any provider.
7	SEC122. PROTECTION OF PATIENT CONFIDENTIALITY.
8	Insofar as a group health plan, or a health insurance
9	issuer that offers health insurance coverage, maintains
10	medical records or other health information regarding par-
11	ticipants, beneficiaries, and enrollees, the plan or issuer
12	shall establish procedures—
13	(1) to safeguard the privacy of any individually
14	identifiable enrollee information;
15	(2) to maintain such records and information in
16	a manner that is accurate and timely, and
17	(3) to assure timely access of such individuals
18	to such records and information.
19	SEC123. HEALTH INSURANCE OMBUDSMEN.
20	(a) In General.—Each State that obtains a grant
21	under subsection (c) shall provide for creation and oper-

ation of a Health Insurance Ombudsman through a con-

tract with a not-for-profit organization that operates inde-

24 pendent of group health plans and health insurance

- 1 issuers. Such Ombudsman shall be responsible for at least
- 2 the following:
- 3 (1) To assist consumers in the State in choos-
- 4 ing among health insurance coverage or among cov-
- 5 erage options offered within group health plans.
- 6 (2) To provide counseling and assistance to en-
- 7 rollees dissatisfied with their treatment by health in-
- 8 surance issuers and group health plans in regard to
- 9 such coverage or plans and with respect to griev-
- ances and appeals regarding determinations under
- such coverage or plans.
- 12 (b) FEDERAL ROLE.—In the case of any State that
- 13 does not provide for such an Ombudsman under sub-
- 14 section (a), the Secretary shall provide for the creation
- 15 and operation of a Health Insurance Ombudsman through
- 16 a contract with a not-for-profit organization that operates
- 17 independent of group health plans and health insurance
- 18 issuers and that is responsible for carrying out with re-
- 19 spect to that State the functions otherwise provided under
- 20 subsection (a) by a Health Insurance Ombudsman.
- (c) Authorization of Appropriations.—There
- 22 are authorized to be appropriated to the Secretary of
- 23 Health and Human Services such amounts as may be nec-
- 24 essary to provide for grants to States for contracts for

1	Health Insurance Ombudsmen under subsection (a) or
2	contracts for such Ombudsmen under subsection (b).
3	(d) Construction.—Nothing in this section shall be
4	construed to prevent the use of other forms of enrollee
5	assistance.
6	CHAPTER 4—GRIEVANCE AND APPEALS
7	PROCEDURES
8	SEC131. ESTABLISHMENT OF GRIEVANCE PROCESS.
9	(a) Establishment of Grievance System.—
10	(1) In general.—A group health plan, and a
11	health insurance issuer in connection with the provi-
12	sion of health insurance coverage, shall establish and
13	maintain a system to provide for the presentation
14	and resolution of oral and written grievances
15	brought by individuals who are participants, bene-
16	ficiaries, or enrollees, or health care providers or
17	other individuals acting on behalf of an individual
18	and with the individual's consent, regarding any as-
19	pect of the plan's or issuer's services.
20	(2) Scope.—The system shall include griev-
21	ances regarding access to and availability of services,
22	quality of care, choice and accessibility of providers,
23	network adequacy, and compliance with the require-

ments of this subtitle.

1	(b) Grievance System.—Such system shall include
2	the following components with respect to individuals who
3	are participants, beneficiaries, or enrollees:
4	(1) Written notification to all such individuals
5	and providers of the telephone numbers and business
6	addresses of the plan or issuer personnel responsible
7	for resolution of grievances and appeals.
8	(2) A system to record and document, over a
9	period of at least 3 previous years, all grievances
10	and appeals made and their status.
11	(3) A process providing for timely processing
12	and resolution of grievances.
13	(4) Procedures for follow-up action, including
14	the methods to inform the person making the griev-
15	ance of the resolution of the grievance.
16	(5) Notification to the continuous quality im-
17	provement program under section111(a) of all
18	grievances and appeals relating to quality of care.
19	SEC132. INTERNAL APPEALS OF ADVERSE DETER-
20	MINATIONS.
21	(a) Right of Appeal.—
22	(1) In general.—A participant or beneficiary
23	in a group health plan, and an enrollee in health in-
24	surance coverage offered by a health insurance
25	issuer, and any provider or other person acting on

1 behalf of such an individual with the individual's 2 consent, may appeal any appealable decision (as de-3 fined in paragraph (2)) under the procedures described in this section and (to the extent applicable) 5 section \_\_\_\_133. Such individuals and providers 6 shall be provided with a written explanation of the 7 appeal process and the determination upon the con-8 clusion of the appeals process and as provided in section 121(b)(8). 9 (2) APPEALABLE DECISION DEFINED.—In this 10 11 section, the term "appealable decision" means any of 12 the following: 13 (A) Denial, reduction, or termination of, or 14 failure to provide or make payment (in whole or 15 in part) for a benefit, including a failure to 16 cover an item or service for which benefits are 17 otherwise provided because it is determined to 18 be experimental or investigational or not medi-19 cally necessary or appropriate. 20 (B) Failure to provide coverage of emer-21 gency services or reimbursement of mainte-22 nance care or post-stabilization care under section \_\_\_\_101. 23 24 (C) Failure to provide a choice of provider under section \_\_\_\_103. 25

1	(D) Failure to provide qualified health care
2	providers under section103.
3	(E) Failure to provide access to specialty
4	and other care under section104.
5	(F) Failure to provide continuation of care
6	under section105.
7	(G) Failure to provide coverage of routine
8	patient costs in connection with an approval
9	clinical trial under section106.
10	(H) Failure to provide access to needed
11	drugs under section $_{}107(a)(3)$ or $107(b)$ .
12	(I) Discrimination in delivery of services in
13	violation of section109.
14	(J) An adverse determination under a utili-
15	zation review program under section115.
16	(K) The imposition of a limitation that is
17	prohibited under section151.
18	(b) Internal Appeal Process.—
19	(1) In general.—Each group health plan and
20	health insurance issuer shall establish and maintain
21	an internal appeal process under which any partici-
22	pant, beneficiary, or enrollee, or any provider or
23	other person acting on behalf of such an individual
24	with the individual's consent, who is dissatisfied with
25	any appealable decision has the opportunity to ap-

1	peal the decision through an internal appeal process.
2	The appeal may be communicated orally.
3	(2) Conduct of Review.—
4	(A) In general.—The process shall in-
5	clude a review of the decision by a physician or
6	other health care professional (or professionals)
7	who has been selected by the plan or issuer and
8	who has not been involved in the appealable de-
9	cision at issue in the appeal.
10	(B) AVAILABILITY AND PARTICIPATION OF
11	CLINICAL PEERS.—The individuals conducting
12	such review shall include one or more clinical
13	peers (as defined in section191(c)(2)) who
14	have not been involved in the appealable deci-
15	sion at issue in the appeal.
16	(3) Deadline.—
17	(A) In general.—Subject to subsection
18	(c), the plan or issuer shall conclude each ap-
19	peal as soon as possible after the time of the re-
20	ceipt of the appeal in accordance with medical
21	exigencies of the case involved, but in no event
22	later than—
23	(i) 72 hours after the time of receipt
24	of an expedited appeal, and

(ii) except as provided in subparagraph (B), 30 business days after such time (or, if the participant, beneficiary, or enrollee supplies additional information that was not available to the plan or issuer at the time of the receipt of the appeal, after the date of supplying such additional information) in the case of all other appeals.

(B) EXTENSION.—In the case of an appeal that does not relate to a decision regarding an expedited appeal and that does not involve medical exigencies, if a group health plan or health insurance issuer is unable to conclude the appeal within the time period provided under subparagraph (A)(ii) due to circumstances beyond the control of the plan or issuer, the deadline shall be extended for up to an additional 10 business days if the plan or issuer provides, on or before 10 days before the deadline otherwise applicable, written notice to the participant, beneficiary, or enrollee and the provider involved of the extension and the reasons for the extension.

(4) Notice.—If a plan or issuer denies an appeal, the plan or issuer shall provide the participant, beneficiary, or enrollee and provider involved with notice in printed form of the denial and the reasons therefore, together with a notice in printed form of rights to any further appeal.

## (c) Expedited Review Process.—

(1) In General.—A group health plan, and a health insurance issuer, shall establish procedures in writing for the expedited consideration of appeals under subsection (b) in situations in which the application of the normal timeframe for making a determination could seriously jeopardize the life or health of the participant, beneficiary, or enrollee (including in the case of a child, development) or such an individual's ability to regain maximum function.

## (2) Process.—Under such procedures—

- (A) the request for expedited appeal may be submitted orally or in writing by an individual or provider who is otherwise entitled to request the appeal; and
- (B) all necessary information, including the plan's or issuer's decision, shall be transmitted between the plan or issuer and the re-

- quester by telephone, facsimile, or other similarly expeditious available method.
- 3 (d) DIRECT USE OF FURTHER APPEALS.—In the
- 4 event that the plan or issuer fails to comply with any of
- 5 the deadlines for completion of appeals under this section
- 6 or in the event that the plan or issuer for any reason ex-
- 7 pressly waives its rights to an internal review of an appeal
- 8 under subsection (b), the participant, beneficiary, or en-
- 9 rollee involved and the provider involved shall be relieved
- 10 of any obligation to complete the appeal involved and may,
- 11 at such an individual's or provider's option, proceed di-
- 12 rectly to seek further appeal through any applicable exter-
- 13 nal appeals process.
- 14 SEC. \_\_\_133. EXTERNAL APPEALS OF ADVERSE DETER-
- 15 MINATIONS.
- 16 (a) RIGHT TO EXTERNAL APPEAL.—
- 17 (1) IN GENERAL.—A group health plan, and a
- health insurance issuer offering group health insur-
- ance coverage, shall provide for an external appeals
- 20 process that meets the requirements of this section
- in the case of an externally appealable decision de-
- scribed in paragraph (2). The appropriate Secretary
- shall establish standards to carry out such require-
- 24 ments.

1	(2) Externally appealable decision de-
2	FINED.—For purposes of this section, the term "ex-
3	ternally appealable decision" means an appealable
4	decision (as defined in section132(a)(2)) if—
5	(A) the amount involved exceeds a signifi-
6	cant threshold; or
7	(B) the patient's life or health is jeopard-
8	ized (including, in the case of a child, develop-
9	ment) as a consequence of the decision.
10	Such term does not include a denial of coverage for
11	services that are specifically listed in plan or cov-
12	erage documents as excluded from coverage.
13	(3) Exhaustion of internal appeals proc-
14	ESS.—A plan or issuer may condition the use of an
15	external appeal process in the case of an externally
16	appealable decision upon completion of the internal
17	review process provided under section132, but
18	only if the decision is made in a timely basis con-
19	sistent with the deadlines provided under this chap-
20	ter.
21	(b) General Elements of External Appeals
22	Process.—
23	(1) Contract with qualified external ap-
24	PEAL ENTITY.—

1 (A) CONTRACT REQUIREMENT.—Subject to
2 subparagraph (B), the external appeal process
3 under this section of a plan or issuer shall be
4 conducted under a contract between the plan or
5 issuer and one or more qualified external appeal
6 entities (as defined in subsection (c)).
7 (B) RESTRICTIONS ON QUALIFIED EXTER-

# (B) RESTRICTIONS ON QUALIFIED EXTERNAL APPEAL ENTITY.—

- (i) By STATE FOR HEALTH INSUR-ANCE ISSUERS.—With respect to health insurance issuers in a State, the State may provide for external review activities to be conducted by a qualified external appeal entity that is designated by the State or that is selected by the State in such a manner as to assure an unbiased determination.
- (ii) BY FEDERAL GOVERNMENT FOR GROUP HEALTH PLANS.—With respect to group health plans, the appropriate Secretary may exercise the same authority as a State may exercise with respect to health insurance issuers under clause (i). Such authority may include requiring the use of

1	the qualified external appeal entity des-
2	ignated or selected under such clause.
3	(iii) Limitation on plan or issuer
4	SELECTION.—If an applicable authority
5	permits more than one entity to qualify as
6	a qualified external appeal entity with re-
7	spect to a group health plan or health in-
8	surance issuer and the plan or issuer may
9	select among such qualified entities, the
10	applicable authority—
11	(I) shall assure that the selection
12	process will not create any incentives
13	for external appeal entities to make a
14	decision in a biased manner, and
15	(II) shall implement procedures
16	for auditing a sample of decisions by
17	such entities to assure that no such
18	decisions are made in a biased man-
19	ner.
20	(C) OTHER TERMS AND CONDITIONS.—
21	The terms and conditions of a contract under
22	this paragraph shall be consistent with the
23	standards the appropriate Secretary shall estab-
24	lish to assure there is no real or apparent con-
25	flict of interest in the conduct of external ap-

1	peal activities. Such contract shall provide that
2	the direct costs of the process (not including
3	costs of representation of a participant, bene-
4	ficiary, or enrollee) shall be paid by the plan
5	or issuer, and not by the participant, bene-
6	ficiary, or enrollee.
7	(2) Elements of process.—An external ap-
8	peal process shall be conducted consistent with
9	standards established by the appropriate Secretary
10	that include at least the following:
11	(A) Fair process; de novo determina-
12	TION.—The process shall provide for a fair, de
13	novo determination.
14	(B) Determination concerning exter-
15	NALLY APPEALABLE DECISIONS.—A qualified
16	external appeal entity shall determine whether a
17	decision is an externally appealable decision and
18	related decisions, including—
19	(i) whether such a decision involves ar
20	expedited appeal;
21	(ii) the appropriate deadlines for in-
22	ternal review process required due to med-
23	ical exigencies in a case; and
24	(iii) whether such a process has been
25	completed.

1	(C) Opportunity to submit evidence,
2	HAVE REPRESENTATION, AND MAKE ORAL
3	PRESENTATION.—Each party to an externally
4	appealable decision—
5	(i) may submit and review evidence
6	related to the issues in dispute,
7	(ii) may use the assistance or rep-
8	resentation of one or more individuals (any
9	of whom may be an attorney), and
10	(iii) may make an oral presentation.
11	(D) Provision of Information.—The
12	plan or issuer involved shall provide timely ac-
13	cess to all its records relating to the matter of
14	the externally appealable decision and to all
15	provisions of the plan or health insurance cov-
16	erage (including any coverage manual) relating
17	to the matter.
18	(E) Timely decisions.—A determination
19	by the external appeal entity on the decision
20	shall—
21	(i) be made orally or in writing and
22	if it is made orally, shall be supplied to the
23	parties in writing as soon as possible;
24	(ii) be binding on the plan or issuer:

1	(iii) be made in accordance with the
2	medical exigencies of the case involved, but
3	in no event later than 60 days (or 72
4	hours in the case of an expedited appeal)
5	from the date of completion of the filing of
6	notice of external appeal of the decision;
7	(iv) state, in layperson's language, the
8	basis for the determination, including, if
9	relevant, any basis in the terms or condi-
10	tions of the plan or coverage; and
11	(v) inform the participant, beneficiary,
12	or enrollee of the individual's rights to seek
13	further review by the courts (or other proc-
14	ess) of the external appeal determination.
15	(c) Qualifications of External Appeal Enti-
16	TIES.—
17	(1) In general.—For purposes of this section,
18	the term "qualified external appeal entity" means,
19	in relation to a plan or issuer, an entity (which may
20	be a governmental entity) that is certified under
21	paragraph (2) as meeting the following require-
22	ments:
23	(A) There is no real or apparent conflict of
24	interest that would impede the entity con-

1	ducting external appeal activities independent
2	of the plan or issuer.
3	(B) The entity conducts external appeal
4	activities through clinical peers.
5	(C) The entity has sufficient medical, legal,
6	and other expertise and sufficient staffing to
7	conduct external appeal activities for the plan
8	or issuer on a timely basis consistent with sub-
9	section $(b)(3)(E)$ .
10	(D) The entity meets such other require-
11	ments as the appropriate Secretary may im-
12	pose.
13	(2) Certification of external appeal en-
14	TITIES.—
15	(A) IN GENERAL.—In order to be treated
16	as a qualified external appeal entity with re-
17	spect to—
18	(i) a group health plan, the entity
19	must be certified (and, in accordance with
20	subparagraph (B), periodically recertified)
21	as meeting the requirements of paragraph
22	(1) by the Secretary of Labor (or under a
23	process recognized or approved by the Sec-
24	retary of Labor); or

1	(ii) a health insurance issuer oper-
2	ating in a State, the entity must be cer-
3	tified (and, in accordance with subpara-
4	graph (B), periodically recertified) as
5	meeting such requirements by the applica-
6	ble State authority (or, if the State has not
7	established an adequate certification and
8	recertification process, by the Secretary of
9	Health and Human Services, or under a
10	process recognized or approved by such
11	Secretary).

- (B) RECERTIFICATION PROCESS.—The appropriate Secretary shall develop standards for the recertification of external appeal entities. Such standards shall include a specification of—
  - (i) the information required to be submitted as a condition of recertification on the entity's performance of external appeal activities, which information shall include the number of cases reviewed, a summary of the disposition of those cases, the length of time in making determinations on those cases, and such information as may be necessary to assure the independence of the

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1	entity from the plans or issuers for which
2	external appeal activities are being con-
3	ducted; and
4	(ii) the periodicity which recertifi-
5	cation will be required.
6	(d) Continuing Legal Rights of Enrollees.—
7	Nothing in this subtitle shall be construed as removing
8	any legal rights of participants, beneficiaries, enrollees,
9	and others under State or Federal law, including the right
10	to file judicial actions to enforce rights.
11	CHAPTER 5—PROTECTING THE DOCTOR-
12	PATIENT RELATIONSHIP
13	SEC141. PROHIBITION OF INTERFERENCE WITH CER-
13 14	SEC141. PROHIBITION OF INTERFERENCE WITH CERTAIN MEDICAL COMMUNICATIONS.
14	TAIN MEDICAL COMMUNICATIONS.
14 15	TAIN MEDICAL COMMUNICATIONS.  (a) PROHIBITION.—
14 15 16	tain medical communications.  (a) Prohibition.—  (1) General rule.—The provisions of any
14 15 16 17	tain medical communications.  (a) Prohibition.—  (1) General rule.—The provisions of any contract or agreement, or the operation of any con-
14 15 16 17	TAIN MEDICAL COMMUNICATIONS.  (a) PROHIBITION.—  (1) General rule.—The provisions of any contract or agreement, or the operation of any contract or agreement, between a group health plan or
114 115 116 117 118	TAIN MEDICAL COMMUNICATIONS.  (a) PROHIBITION.—  (1) GENERAL RULE.—The provisions of any contract or agreement, or the operation of any contract or agreement, between a group health plan or health insurance issuer in relation to health insur-
14 15 16 17 18 19 20	tain medical communications.  (a) Prohibition.—  (1) General rule.—The provisions of any contract or agreement, or the operation of any contract or agreement, between a group health plan or health insurance issuer in relation to health insurance coverage (including any partnership, association).
14 15 16 17 18 19 20 21	tain Medical Communications.  (a) Prohibition.—  (1) General rule.—The provisions of any contract or agreement, or the operation of any contract or agreement, between a group health plan or health insurance issuer in relation to health insurance coverage (including any partnership, association, or other organization that enters into or ad-

- from engaging in medical communications with the provider's patient.
- 3 (2) NULLIFICATION.—Any contract provision or 4 agreement that restricts or prohibits medical com-5 munications in violation of paragraph (1) shall be 6 null and void.
- 7 (b) Rules of Construction.—Nothing in this sec-8 tion shall be construed—
  - (1) to prohibit the enforcement, as part of a contract or agreement to which a health care provider is a party, of any mutually agreed upon terms and conditions, including terms and conditions requiring a health care provider to participate in, and cooperate with, all programs, policies, and procedures developed or operated by a group health plan or health insurance issuer to assure, review, or improve the quality and effective utilization of health care services (if such utilization is according to guidelines or protocols that are based on clinical or scientific evidence and the professional judgment of the provider) but only if the guidelines or protocols under such utilization do not prohibit or restrict medical communications between providers and their patients; or

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1	(2) to permit a health care provider to mis-
2	represent the scope of benefits covered under the
3	group health plan or health insurance coverage or to
4	otherwise require a group health plan health insur-
5	ance issuer to reimburse providers for benefits not
6	covered under the plan or coverage.
7	(c) Medical Communication Defined.—In this
8	section:
9	(1) In general.—The term "medical commu-
10	nication" means any communication made by a
11	health care provider with a patient of the health care
12	provider (or the guardian or legal representative of
13	such patient) with respect to—
14	(A) the patient's health status, medical
15	care, or treatment options;
16	(B) any utilization review requirements
17	that may affect treatment options for the pa-
18	tient; or
19	(C) any financial incentives that may af-
20	fect the treatment of the patient.
21	(2) Misrepresentation.—The term "medical
22	communication" does not include a communication
23	by a health care provider with a patient of the
24	health care provider (or the guardian or legal rep-

resentative of such patient) if the communication in-

1	volves a knowing or willful misrepresentation by
2	such provider.
3	SEC142. PROHIBITION AGAINST TRANSFER OF INDEM-
4	NIFICATION OR IMPROPER INCENTIVE AR-
5	RANGEMENTS.
6	(a) Prohibition of Transfer of Indemnifica-
7	TION.—
8	(1) In general.—No contract or agreement
9	between a group health plan or health insurance
10	issuer (or any agent acting on behalf of such a plan
11	or issuer) and a health care provider shall contain
12	any provision purporting to transfer to the health
13	care provider by indemnification or otherwise any li-
14	ability relating to activities, actions, or omissions of
15	the plan, issuer, or agent (as opposed to the pro-
16	vider).
17	(2) Nullification.—Any contract or agree-
18	ment provision described in paragraph (1) shall be
19	null and void.
20	(b) Prohibition of Improper Physician Incen-
21	TIVE PLANS.—
22	(1) In general.—A group health plan and a
23	health insurance issuer offering health insurance
24	coverage may not operate any physician incentive
25	plan (as defined in subparagraph (B) of section

- 1 1876(i)(8) of the Social Security Act) unless the re-2 quirements described in subparagraph (A) of such 3 section are met with respect to such a plan.
- (2) Application.—For purposes of carrying 5 paragraph (1), any reference in section 6 1876(i)(8) of the Social Security Act to the Sec-7 retary, an eligible organization, or an individual en-8 rolled with the organization shall be treated as a ref-9 erence to the applicable authority, a group health 10 plan or health insurance issuer, respectively, and a 11 participant, beneficiary, or enrollee with the plan or 12 organization, respectively.

# 13 SEC. \_\_\_143. ADDITIONAL RULES REGARDING PARTICIPA-

#### 14 TION OF HEALTH CARE PROFESSIONALS.

- 15 (a) PROCEDURES.—Insofar as a group health plan, 16 or health insurance issuer that offers health insurance cov-17 erage, provides benefits through participating health care 18 professionals, the plan or issuer shall establish reasonable 19 procedures relating to the participation (under an agree-
- 20 ment between a professional and the plan or issuer) of
- 21 such professionals under the plan or coverage. Such proce-
- 22 dures shall include—
- 23 (1) providing notice of the rules regarding participation;

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

- 3 (3) providing a process within the plan or issuer 4 for appealing such adverse decisions, including the 5 presentation of information and views of the profes-6 sional regarding such decision.
- 7 (b) Consultation in Medical Policies.—A group
- 8 health plan, and health insurance issuer that offers health
- 9 insurance coverage, shall consult with participating physi-
- 10 cians (if any) regarding the plan's or issuer's medical pol-
- 11 icy, quality, and medical management procedures.
- 12 SEC. \_\_\_144. PROTECTION FOR PATIENT ADVOCACY.
- 13 (a) Protection for Use of Utilization Review
- 14 AND GRIEVANCE PROCESS.—A group health plan, and a
- 15 health insurance issuer with respect to the provision of
- 16 health insurance coverage, may not retaliate against a par-
- 17 ticipant, beneficiary, enrollee, or health care provider
- 18 based on the participant's, beneficiary's, enrollee's or pro-
- 19 vider's use of, or participation in, a utilization review proc-
- 20 ess or a grievance process of the plan or issuer (including
- 21 an internal or external review or appeal process) under
- 22 this subtitle.
- 23 (b) Protection for Quality Advocacy by
- 24 Health Care Professionals.—

- (1) IN GENERAL.—A group health plan or health insurance issuer may not retaliate or discriminate against a protected health care professional 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 accreditation body, or appropriate management personnel of the plan or issuer; or
  - (B) initiates, cooperates, or otherwise participates in an investigation or proceeding by such an agency with respect to such care, services, or conditions.

If an institutional health care provider is a participating provider with such a plan or issuer or otherwise receives payments for benefits provided by such a plan or issuer, the provisions of the previous sentence shall apply to the provider in relation to care, services, or conditions affecting one or more patients within an institutional health care provider in the same manner as they apply to the plan or issuer in relation to care, services, or conditions provided to one or more participants, beneficiaries, or enrollees;

- and for purposes of applying this sentence, any reference to a plan or issuer is deemed a reference to the institutional health care provider.
  - (2) Good faith action.—For purposes of paragraph (1), a protected health care professional is considered to be acting in good faith with respect to disclosure of information or participation if, with respect to the information disclosed as part of the action—
    - (A) the disclosure is made on the basis of personal knowledge and is consistent with that degree of learning and skill ordinarily possessed by health care professionals with the same licensure or certification and the same experience;
    - (B) the professional reasonably believes the information to be true;
    - (C) the information evidences either a violation of a law, rule, or regulation, of an applicable accreditation standard, or of a generally recognized professional or clinical standard or that a patient is in imminent hazard of loss of life or serious injury; and
    - (D) subject to subparagraphs (B) and (C) of paragraph (3), the professional has followed

reasonable internal procedures of the plan, issuer, or institutional health care provider established for the purpose of addressing quality concerns before making the disclosure.

### (3) Exception and special rule.—

- (A) GENERAL EXCEPTION.—Paragraph (1) does not protect disclosures that would violate Federal or State law or diminish or impair the rights of any person to the continued protection of confidentiality of communications provided by such law.
- (B) Notice of internal procedures.—Subparagraph (D) of paragraph (2) shall not apply unless the internal procedures involved are reasonably expected to be known to the health care professional involved. For purposes of this subparagraph, a health care professional is reasonably expected to know of internal procedures if those procedures have been made available to the professional through distribution or posting.
- (C) Internal procedure exception.—
  Subparagraph (D) of paragraph (2) also shall not apply if—

1	(i) the disclosure relates to an immi-
2	nent hazard of loss of life or serious injury
3	to a patient;
4	(ii) the disclosure is made to an ap-
5	propriate private accreditation body pursu-
6	ant to disclosure procedures established by
7	the body; or
8	(iii) the disclosure is in response to an
9	inquiry made in an investigation or pro-
10	ceeding of an appropriate public regulatory
11	agency and the information disclosed is
12	limited to the scope of the investigation or
13	proceeding.
14	(4) Additional considerations.—It shall
15	not be a violation of paragraph (1) to take an ad-
16	verse action against a protected health care profes-
17	sional if the plan, issuer, or provider taking the ad-
18	verse action involved demonstrates that it would
19	have taken the same adverse action even in the ab-
20	sence of the activities protected under such para-
21	graph.
22	(5) Notice.—A group health plan, health in-
23	surance issuer, and institutional health care provider
24	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.

#### (6) Constructions.—

- (A) DETERMINATIONS OF COVERAGE.—
  Nothing in this subsection shall be construed to prohibit a plan or issuer from making a determination not to pay for a particular medical treatment or service or the services of a type of health care professional.
- (B) Enforcement of Peer Review Protocols and internal procedures.—Nothing in this subsection shall be construed to prohibit a plan, issuer, or provider from establishing and enforcing reasonable peer review or utilization review protocols or determining whether a protected health care professional has complied with those protocols or from establishing and enforcing internal procedures for 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.

1	(7) Protected health care professional
2	DEFINED.—For purposes of this subsection, the
3	term "protected health care professional" means an
4	individual who is a licensed or certified health care
5	professional and who—
6	(A) with respect to a group health plan or
7	health insurance issuer, is an employee of the
8	plan or issuer or has a contract with the plan
9	or issuer for provision of services for which ben-
10	efits are available under the plan or issuer; or
11	(B) with respect to an institutional health
12	care provider, is an employee of the provider or
13	has a contract or other arrangement with the
14	provider respecting the provision of health care
15	services.
16	CHAPTER 6—PROMOTING GOOD MEDICAL
17	PRACTICE
18	SEC151. PROMOTING GOOD MEDICAL PRACTICE.
19	(a) Prohibiting Arbitrary Limitations or Con-
20	DITIONS FOR THE PROVISION OF SERVICES.—
21	(1) In general.—A group health plan, and a
22	health insurance issuer in connection with the provi-
23	sion of health insurance coverage, may not arbi-
24	trarily interfere with or alter the decision of the
25	treating physician regarding the manner or setting

- 1 in which particular services are delivered if the serv-
- 2 ices are medically necessary or appropriate for treat-
- 3 ment or diagnosis to the extent that such treatment
- 4 or diagnosis is otherwise a covered benefit.
- 5 (2) Construction.—Paragraph (1) shall not
- 6 be construed as prohibiting a plan or issuer from
- 7 limiting the delivery of services to one or more
- 8 health care providers within a network of such pro-
- 9 viders.
- 10 (3) Manner or setting defined.—In para-
- graph (1), the term "manner or setting" means the
- location of treatment, such as whether treatment is
- provided on an inpatient or outpatient basis, and the
- duration of treatment, such as the number of days
- in a hospital. Such term does not include the cov-
- erage of a particular service or treatment.
- 17 (b) No Change in Coverage.—Subsection (a) shall
- 18 not be construed as requiring coverage of particular serv-
- 19 ices the coverage of which is otherwise not covered under
- 20 the terms of the plan or coverage or from conducting utili-
- 21 zation review activities consistent with this subsection.
- (c) Medical Necessity or Appropriateness De-
- 23 FINED.—In subsection (a), the term "medically necessary
- 24 or appropriate" means, with respect to a service or benefit,

1	a service or benefit which is consistent with generally ac-
2	cepted principles of professional medical practice.
3	SEC152. STANDARDS RELATING TO BENEFITS FOR
4	CERTAIN BREAST CANCER TREATMENT.
5	(a) Inpatient Care.—
6	(1) In general.—A group health plan, and a
7	health insurance issuer offering group health insur-
8	ance coverage, that provides medical and surgical
9	benefits shall ensure that inpatient coverage with re-
10	spect to the treatment of breast cancer is provided
11	for a period of time as is determined by the attend-
12	ing physician, in his or her professional judgment
13	consistent with generally accepted medical stand-
14	ards, in consultation with the patient, to be medi-
15	cally appropriate following—
16	(A) a mastectomy;
17	(B) a lumpectomy; or
18	(C) a lymph node dissection for the treat-
19	ment of breast cancer.
20	(2) Exception.—Nothing in this section shall
21	be construed as requiring the provision of inpatient
22	coverage if the attending physician and patient de-
23	termine that a shorter period of hospital stay is
24	medically appropriate.

- 1 (b) Prohibitions.—A group health plan, and a
- 2 health insurance issuer offering group health insurance
- 3 coverage in connection with a group health plan, may
- 4 not—
- 5 (1) deny to a woman eligibility, or continued
- 6 eligibility, to enroll or to renew coverage under the
- 7 terms of the plan, solely for the purpose of avoiding
- 8 the requirements of this section;
- 9 (2) provide monetary payments or rebates to
- women to encourage such women to accept less than
- the minimum protections available under this sec-
- tion;
- 13 (3) penalize or otherwise reduce or limit the re-
- imbursement of an attending provider because such
- provider provided care to an individual participant
- or beneficiary in accordance with this section;
- 17 (4) provide incentives (monetary or otherwise)
- to an attending provider to induce such provider to
- provide care to an individual participant or bene-
- ficiary in a manner inconsistent with this section; or
- 21 (5) subject to subsection (c)(3), restrict benefits
- for any portion of a period within a hospital length
- of stay required under subsection (a) in a manner
- 24 which is less favorable than the benefits provided for
- any preceding portion of such stay.

### (c) Rules of Construction.—

- (1) Nothing in this section shall be construed to require a woman who is a participant or beneficiary—
  - (A) to undergo a mastectomy or lymph node dissection in a hospital; or
  - (B) to stay in the hospital for a fixed period of time following a mastectomy or lymph node dissection.
- (2) This section shall not apply with respect to any group health plan, or any group health insurance coverage offered by a health insurance issuer, which does not provide benefits for hospital lengths of stay in connection with a mastectomy or lymph node dissection for the treatment of breast cancer.
- (3) Nothing in this section shall be construed as preventing a group health plan or issuer from imposing deductibles, coinsurance, or other cost-sharing in relation to benefits for hospital lengths of stay in connection with a mastectomy or lymph node dissection for the treatment of breast cancer under the plan (or under health insurance coverage offered in connection with a group health plan), except that such coinsurance or other cost-sharing for any portion of a period within a hospital length of stay re-

1	quired under subsection (a) may not be greater than
2	such coinsurance or cost-sharing for any preceding
3	portion of such stay.
4	(d) LEVEL AND TYPE OF REIMBURSEMENTS.—Noth-
5	ing in this section shall be construed to prevent a group
6	health plan or a health insurance issuer offering group
7	health insurance coverage from negotiating the level and
8	type of reimbursement with a provider for care provided
9	in accordance with this section.
10	(e) Exception for Health Insurance Coverage
11	IN CERTAIN STATES.—
12	(1) In general.—The requirements of this
13	section shall not apply with respect to health insur-
14	ance coverage if there is a State law (as defined in
15	section 2723(d)(1) of the Public Health Service Act
16	for a State that regulates such coverage that is de-
17	scribed in any of the following subparagraphs:
18	(A) Such State law requires such coverage
19	to provide for at least a 48-hour hospital length
20	of stay following a mastectomy performed for
21	treatment of breast cancer and at least a 24-
22	hour hospital length of stay following a lymph
23	node dissection for treatment of breast cancer.
24	(B) Such State law requires, in connection
25	with such coverage for surgical treatment of

- 1 breast cancer, that the hospital length of stay
- 2 for such care is left to the decision of (or re-
- quired to be made by) the attending provider in
- 4 consultation with the woman involved.
- 5 (2) Construction.—Section 2723(a)(1) of the
- 6 Public Health Service Act and section 731(a)(1) of
- 7 the Employee Retirement Income Security Act of
- 8 1974 shall not be construed as superseding a State
- 9 law described in paragraph (1).
- 10 CHAPTER 7—DEFINITIONS
- 11 SEC. \_\_\_191. DEFINITIONS.
- 12 (a) Incorporation of General Definitions.—
- 13 The provisions of section 2971 of the Public Health Serv-
- 14 ice Act shall apply for purposes of this subtitle in the same
- 15 manner as they apply for purposes of title XXVII of such
- 16 Act.
- 17 (b) Secretary.—Except as otherwise provided, the
- 18 term "Secretary" means the Secretary of Health and
- 19 Human Services, in consultation with the Secretary of
- 20 Labor and the Secretary of the Treasury and the term
- 21 "appropriate Secretary" means the Secretary of Health
- 22 and Human Services in relation to carrying out this sub-
- 23 title under sections 2707 and 2753 of the Public Health
- 24 Service Act, the Secretary of Labor in relation to carrying
- 25 out this subtitle under section 714 of the Employee Retire-

1	ment Income Security Act of 1974, and the Secretary of
2	the Treasury in relation to carrying out this subtitle under
3	chapter 100 and section 4980D of the Internal Revenue
4	Code of 1986.
5	(c) Additional Definitions.—For purposes of this
6	subtitle:
7	(1) APPLICABLE AUTHORITY.—The term "ap-
8	plicable authority" means—
9	(A) in the case of a group health plan, the
10	Secretary of Health and Human Services and
11	the Secretary of Labor; and
12	(B) in the case of a health insurance issuer
13	with respect to a specific provision of this sub-
14	title, the applicable State authority (as defined
15	in section 2791(d) of the Public Health Service
16	Act), or the Secretary of Health and Human
17	Services, if such Secretary is enforcing such
18	provision under section 2722(a)(2) or
19	2761(a)(2) of the Public Health Service Act.
20	(2) CLINICAL PEER.—The term "clinical peer"
21	means, with respect to a review or appeal, a physi-
22	cian (allopathic or osteopathic) or other health care
23	professional who holds a non-restricted license in a
24	State and who is appropriately credentialed in the

same or similar specialty as typically manages the

- medical condition, procedure, or treatment under review or appeal and includes a pediatric specialist where appropriate; except that only a physician may be a clinical peer with respect to the review or appeal of treatment rendered by a physician.
  - (3) HEALTH CARE PROVIDER.—The term "health care provider" includes a physician or other health care professional, as well as an institutional provider of health care services.
  - (4) Nonparticipating.—The term "non-participating" means, with respect to a health care provider that provides health care items and services to a participant, beneficiary, or enrollee under group health plan or health insurance coverage, a health care provider that is not a participating health care provider with respect to such items and services.
  - (5) Participating.—The term "participating" means, with respect to a health care provider that provides health care items and services to a participant, beneficiary, or enrollee under group health plan or health insurance coverage offered by a health insurance issuer, a health care provider that furnishes such items and services under a contract or other arrangement with the plan or issuer.

1	SEC192. PREEMPTION; STATE FLEXIBILITY; CON-
2	STRUCTION.
3	(a) Continued Applicability of State Law
4	WITH RESPECT TO HEALTH INSURANCE ISSUERS.—
5	(1) In general.—Subject to paragraph (2),
6	this subtitle shall not be construed to supersede any
7	provision of State law which establishes, implements,
8	or continues in effect any standard or requirement
9	solely relating to health insurance issuers in connec-
10	tion with group health insurance coverage except to
11	the extent that such standard or requirement pre-
12	vents the application of a requirement of this sub-
13	title.
14	(2) Continued preemption with respect
15	TO GROUP HEALTH PLANS.—Nothing in this subtitle
16	shall be construed to affect or modify the provisions
17	of section 514 of the Employee Retirement Income
18	Security Act of 1974 with respect to group health
19	plans.
20	(b) Rules of Construction.—Except as provided
21	in section152, nothing in this subtitle shall be con-
22	strued as requiring a group health plan or health insur-
23	ance coverage to provide specific benefits under the terms
24	of such plan or coverage.
25	(c) Definitions.—For purposes of this section:

- 1 (1) STATE LAW.—The term "State law" in-
- 2 cludes all laws, decisions, rules, regulations, or other
- 3 State action having the effect of law, of any State.
- 4 A law of the United States applicable only to the
- 5 District of Columbia shall be treated as a State law
- 6 rather than a law of the United States.
- 7 (2) STATE.—The term "State" includes a
- 8 State, the Northern Mariana Islands, any political
- 9 subdivisions of a State or such Islands, or any agen-
- 10 cy or instrumentality of either.
- 11 SEC. \_\_\_193. REGULATIONS.
- 12 The Secretaries of Health and Human Services,
- 13 Labor, and the Treasury shall issue such regulations as
- 14 may be necessary or appropriate to carry out this subtitle.
- 15 Such regulations shall be issued consistent with section
- 16 104 of the Health Insurance Portability and Account-
- 17 ability Act of 1996. Such Secretaries may promulgate any
- 18 interim final rules as the Secretaries determine are appro-
- 19 priate to carry out this subtitle.

# Subtitle B—Application of Patient

- 2 Protection Standards to Group
- 3 Health Plans and Health Insur-
- 4 ance Coverage Under Public
- 5 Health Service Act
- 6 SEC. 201. APPLICATION TO GROUP HEALTH PLANS AND
- 7 GROUP HEALTH INSURANCE COVERAGE.
- 8 (a) In General.—Subpart 2 of part A of title
- 9 XXVII of the Public Health Service Act, as amended by
- 10 the Omnibus Consolidated and Emergency Supplemental
- 11 Appropriations Act, 1999 (Public Law 105–277), is
- 12 amended by adding at the end the following new section:
- 13 "SEC. 2707. PATIENT PROTECTION STANDARDS.
- 14 "(a) IN GENERAL.—Each group health plan shall
- 15 comply with patient protection requirements under sub-
- 16 title A of the Patients' Bill of Rights Act of 1999, and
- 17 each health insurance issuer shall comply with patient pro-
- 18 tection requirements under such subtitle with respect to
- 19 group health insurance coverage it offers, and such re-
- 20 quirements shall be deemed to be incorporated into this
- 21 subsection.
- 22 "(b) Notice.—A group health plan shall comply with
- 23 the notice requirement under section 711(d) of the Em-
- 24 ployee Retirement Income Security Act of 1974 with re-
- 25 spect to the requirements referred to in subsection (a) and

- 1 a health insurance issuer shall comply with such notice
- 2 requirement as if such section applied to such issuer and
- 3 such issuer were a group health plan.".
- 4 (b) Conforming Amendment.—Section
- 5 2721(b)(2)(A) of the Public Health Service Act (42
- 6 U.S.C. 300gg-21(b)(2)(A)) is amended by inserting
- 7 "(other than section 2707)" after "requirements of such
- 8 subparts".
- 9 SEC. \_\_202. APPLICATION TO INDIVIDUAL HEALTH INSUR-
- 10 ANCE COVERAGE.
- 11 Subpart 3 of part B of title XXVII of the Public
- 12 Health Service Act, as amended by the Omnibus Consoli-
- 13 dated and Emergency Supplemental Appropriations Act,
- 14 1999 (Public Law 105–277), is amended by adding at the
- 15 end the following new section:
- 16 "SEC. 2753. PATIENT PROTECTION STANDARDS.
- 17 "(a) In General.—Each health insurance issuer
- 18 shall comply with patient protection requirements under
- 19 subtitle A of the Patients' Bill of Rights Act of 1999 with
- 20 respect to individual health insurance coverage it offers,
- 21 and such requirements shall be deemed to be incorporated
- 22 into this subsection.
- 23 "(b) Notice.—A health insurance issuer under this
- 24 part shall comply with the notice requirement under sec-
- 25 tion 711(d) of the Employee Retirement Income Security

- 1 Act of 1974 with respect to the requirements of such sub-
- 2 title as if such section applied to such issuer and such
- 3 issuer were a group health plan.".
- 4 Subtitle C—Amendments to the
- 5 Employee Retirement Income
- 6 Security Act of 1974
- 7 SEC. \_\_\_301. APPLICATION OF PATIENT PROTECTION
- 8 STANDARDS TO GROUP HEALTH PLANS AND
- 9 GROUP HEALTH INSURANCE COVERAGE
- 10 UNDER THE EMPLOYEE RETIREMENT IN-
- 11 COME SECURITY ACT OF 1974.
- 12 (a) IN GENERAL.—Subpart B of part 7 of subtitle
- 13 B of title I of the Employee Retirement Income Security
- 14 Act of 1974, as amended by the Omnibus Consolidated
- 15 and Emergency Supplemental Appropriations Act, 1999
- 16 (Public Law 105–277), is amended by adding at the end
- 17 the following:
- 18 "SEC. 714. PATIENT PROTECTION STANDARDS.
- 19 "(a) IN GENERAL.—Subject to subsection (b), a
- 20 group health plan (and a health insurance issuer offering
- 21 group health insurance coverage in connection with such
- 22 a plan) shall comply with the requirements of subtitle A
- 23 of the Patients' Bill of Rights Act of 1999 (as in effect
- 24 as of the date of the enactment of such Act), and such

1	requirements shall be deemed to be incorporated into this
2	subsection.
3	"(b) Plan Satisfaction of Certain Require-
4	MENTS.—
5	"(1) Satisfaction of Certain require-
6	MENTS THROUGH INSURANCE.—For purposes of
7	subsection (a), insofar as a group health plan pro-
8	vides benefits in the form of health insurance cov-
9	erage through a health insurance issuer, the plan
10	shall be treated as meeting the following require-
11	ments of subtitle A of the Patients' Bill of Rights
12	Act of 1999 with respect to such benefits and not
13	be considered as failing to meet such requirements
14	because of a failure of the issuer to meet such re-
15	quirements so long as the plan sponsor or its rep-
16	resentatives did not cause such failure by the issuer:
17	"(A) Section101 (relating to access
18	to emergency care).
19	"(B) Section102(a)(1) (relating to of-
20	fering option to purchase point-of-service cov-
21	erage), but only insofar as the plan is meeting
22	such requirement through an agreement with
23	the issuer to offer the option to purchase point-
24	of-service coverage under such section.

1	"(C) Section103 (relating to choice of
2	providers).
3	"(D) Section104 (relating to access
4	to specialty care).
5	"(E) Section105(a)(1) (relating to
6	continuity in case of termination of provider
7	contract) and section105(a)(2) (relating
8	to continuity in case of termination of issuer
9	contract), but only insofar as a replacement
10	issuer assumes the obligation for continuity of
11	care.
12	"(F) Section106 (relating to coverage
13	for individuals participating in approved clinical
14	trials.)
15	"(G) Section107 (relating to access
16	to needed prescription drugs).
17	"(H) Section108 (relating to ade-
18	quacy of provider network).
19	"(I) Chapter 2 of subtitle A (relating to
20	quality assurance).
21	"(J) Section143 (relating to addi-
22	tional rules regarding participation of health
23	care professionals).

1 "(K) Section \_\_\_\_152 (relating to stand-2 ards relating to benefits for certain breast can-3 cer treatment).

"(2) Information.—With respect to information required to be provided or made available under section \_\_\_\_\_121, in the case of a group health plan that provides benefits in the form of health insurance coverage through a health insurance issuer, the Secretary shall determine the circumstances under which the plan is not required to provide or make available the information (and is not liable for the issuer's failure to provide or make available the information), if the issuer is obligated to provide and make available (or provides and makes available) such information.

"(3) GRIEVANCE AND INTERNAL APPEALS.—
With respect to the grievance system and internal appeals process required to be established under sections 131 and 132, in the case of a group health plan that provides benefits in the form of health insurance coverage through a health insurance issuer, the Secretary shall determine the circumstances under which the plan is not required to provide for such system and process (and is not liable for the issuer's failure to provide for such system and process.)

1	ess), if the issuer is obligated to provide for (and
2	provides for) such system and process.
3	"(4) External appeals.—Pursuant to rules
4	of the Secretary, insofar as a group health plan en-
5	ters into a contract with a qualified external appeal
6	entity for the conduct of external appeal activities in
7	accordance with section133, the plan shall be
8	treated as meeting the requirement of such section
9	and is not liable for the entity's failure to meet any
10	requirements under such section.
11	"(5) Application to prohibitions.—Pursu-
12	ant to rules of the Secretary, if a health insurance
13	issuer offers health insurance coverage in connection
14	with a group health plan and takes an action in vio-
15	lation of any of the following sections, the group
16	health plan shall not be liable for such violation un-
17	less the plan caused such violation:
18	"(A) Section109 (relating to non-
19	discrimination in delivery of services).
20	"(B) Section141 (relating to prohibi-
21	tion of interference with certain medical com-
22	munications).
23	"(C) Section142 (relating to prohibi-
24	tion against transfer of indemnification or im-
25	proper incentive arrangements).

1	"(D) Section144 (relating to prohibi-
2	tion on retaliation).
3	"(E) Section151 (relating to pro-
4	moting good medical practice).
5	"(6) Construction.—Nothing in this sub-
6	section shall be construed to affect or modify the re-
7	sponsibilities of the fiduciaries of a group health
8	plan under part 4 of subtitle B.
9	"(7) Application to certain prohibitions
10	AGAINST RETALIATION.—With respect to compliance
11	with the requirements of section144(b)(1) of
12	the Patients' Bill of Rights Act of 1999, for pur-
13	poses of this subtitle the term 'group health plan' is
14	deemed to include a reference to an institutional
15	health care provider.
16	"(c) Enforcement of Certain Requirements.—
17	"(1) Complaints.—Any protected health care
18	professional who believes that the professional has
19	been retaliated or discriminated against in violation
20	of section144(b)(1) of the Patients' Bill of
21	Rights Act of 1999 may file with the Secretary a
22	complaint within 180 days of the date of the alleged
23	retaliation or discrimination.
24	"(2) Investigation.—The Secretary shall in-
25	vestigate such complaints and shall determine if a

- 1 violation of such section has occurred and, if so,
- 2 shall issue an order to ensure that the protected
- 3 health care professional does not suffer any loss of
- 4 position, pay, or benefits in relation to the plan,
- 5 issuer, or provider involved, as a result of the viola-
- 6 tion found by the Secretary.
- 7 "(d) Conforming Regulations.—The Secretary
- 8 may issue regulations to coordinate the requirements on
- 9 group health plans under this section with the require-
- 10 ments imposed under the other provisions of this title.".
- 11 (b) Satisfaction of ERISA Claims Procedure
- 12 REQUIREMENT.—Section 503 of the Employee Retirement
- 13 Income Security Act of 1974 (29 U.S.C. 1133) is amended
- 14 by inserting "(a)" after "Sec. 503." and by adding at
- 15 the end the following new subsection:
- 16 "(b) In the case of a group health plan (as defined
- 17 in section 733) compliance with the requirements of chap-
- 18 ter 4 (and section \_\_\_\_115) of subtitle A of the Patients'
- 19 Bill of Rights Act of 1999 in the case of a claims denial
- 20 shall be deemed compliance with subsection (a) with re-
- 21 spect to such claims denial.".
- (c) Conforming Amendments.—
- 23 (1) Section 732(a) of the Employee Retirement
- 24 Income Security Act of 1974 (29 U.S.C. 1185(a)) is

- 1 amended by striking "section 711" and inserting 2 "sections 711 and 714".
- 3 (2) The table of contents in section 1 of the
- 4 Employee Retirement Income Security Act of 1974,
- 5 as amended by the Omnibus Consolidated and
- 6 Emergency Supplemental Appropriations Act, 1999
- 7 (Public Law 105–277), is amended by inserting
- 8 after the item relating to section 713 the following
- 9 new item:

"Sec. 714. Patient protection standards.".

- 10 (3) Section 502(b)(3) of the Employee Retire-
- ment Income Security Act of 1974 (29 U.S.C.
- 12 1132(b)(3)) is amended by inserting "(other than
- 13 section 144(b))" after "part 7".
- 14 SEC. 302. ERISA PREEMPTION NOT TO APPLY TO CER-
- 15 TAIN ACTIONS INVOLVING HEALTH INSUR-
- 16 ANCE POLICYHOLDERS.
- 17 (a) In General.—Section 514 of the Employee Re-
- 18 tirement Income Security Act of 1974 (29 U.S.C. 1144)
- 19 is amended by adding at the end the following subsection:
- 20 "(e) Preemption Not To Apply to Certain Ac-
- 21 TIONS ARISING OUT OF PROVISION OF HEALTH BENE-
- 22 FITS.—
- 23 "(1) IN GENERAL.—Except as provided in this
- subsection, nothing in this title shall be construed to
- invalidate, impair, or supersede any cause of action

1	brought by a plan participant or beneficiary (or the
2	estate of a plan participant or beneficiary) under
3	State law to recover damages resulting from per-
4	sonal injury or for wrongful death against any
5	person—
6	"(A) in connection with the provision of in-
7	surance, administrative services, or medical
8	services by such person to or for a group health
9	plan (as defined in section 733), or
10	"(B) that arises out of the arrangement by
11	such person for the provision of such insurance,
12	administrative services, or medical services by
13	other persons.
14	"(2) Exception for employers and other
15	PLAN SPONSORS.—
16	"(A) In general.—Subject to subpara-
17	graph (B), paragraph (1) does not authorize—
18	"(i) any cause of action against an
19	employer or other plan sponsor maintain-
20	ing the group health plan or against an
21	employee of such an employer or sponsor
22	acting within the scope of employment, or
23	"(ii) a right of recovery or indemnity
24	by a person against an employer or other
25	plan sponsor (or such an employee) for

1	damages assessed against the person pur-
2	suant to a cause of action under paragraph
3	(1).
4	"(B) Special Rule.—Subparagraph (A)
5	shall not preclude any cause of action described
6	in paragraph (1) against an employer or other
7	plan sponsor (or against an employee of such
8	an employer or sponsor acting within the scope
9	of employment) if—
10	"(i) such action is based on the em-
11	ployer's or other plan sponsor's (or em-
12	ployee's) exercise of discretionary authority
13	to make a decision on a claim for benefits
14	covered under the plan or health insurance
15	coverage in the case at issue; and
16	"(ii) the exercise by such employer or
17	other plan sponsor (or employee of such
18	authority) resulted in personal injury or
19	wrongful death.
20	"(3) Construction.—Nothing in this sub-
21	section shall be construed as permitting a cause of
22	action under State law for the failure to provide an
23	item or service which is not covered under the group
24	health plan involved.

1	"(4) Personal injury defined.—For pur-
2	poses of this subsection, the term 'personal injury'
3	means a physical injury and includes an injury aris-
4	ing out of the treatment (or failure to treat) a men-
5	tal illness or disease.".
6	(b) Effective Date.—The amendment made by
7	subsection (a) shall apply to acts and omissions occurring
8	on or after the date of the enactment of this Act from
9	which a cause of action arises.
10	SEC303. LIMITATION IN ACTIONS.
11	Section 502 of Employee Retirement Income Security
12	Act of 1974 (29 U.S.C. 1132) is amended by adding at
13	the end the following:
14	"(n)(1) Except as provided in this section, no action
15	may be brought under subsection (a)(1)(B), (a)(2), or
16	(a)(3) by a participant or beneficiary seeking relief based
17	on the application of any provision in chapter 1 (other
18	than section109) of subtitle A, chapter 5 of subtitle
19	A, or section115 or151 of the Patient's Bill
20	of Rights Act of 1999 (as incorporated under section 714).
21	"(2) An action may be brought under subsection
22	(a)(1)(B), (a)(2), or (a)(3) by a participant or beneficiary
23	seeking relief based on the application of section101,
24	104,105,106,107(a)(3),107(b),
25	115. or 151 of the Patient's Bill of Rights Act

1	of 1999 (as incorporated under section 714) to the indi-
2	vidual circumstances of that participant or beneficiary; ex-
3	cept that—
4	"(A) such an action may not be brought or
5	maintained as a class action; and
6	"(B) in such an action relief may only provide
7	for the provision of (or payment for) benefits, items,
8	or services denied to the individual participant or
9	beneficiary involved (and for attorney's fees and the
10	costs of the action, at the discretion of the court)
11	and shall not provide for any other relief to the par-
12	ticipant or beneficiary and for any relief to any other
13	person.
14	"(3) Nothing in this subsection shall be construed as
15	affecting any action brought by the Secretary.".
16	Subtitle D-Application to Group
17	Health Plans under the Internal
18	Revenue Code of 1986
19	SEC401. AMENDMENTS TO THE INTERNAL REVENUE
20	<b>CODE OF 1986.</b>
21	Subchapter B of chapter 100 of the Internal Revenue
22	Code of 1986 (as amended by section 1531(a) of the Tax-

23 payer Relief Act of 1997) is amended—

1	(1) in the table of sections, by inserting after
2	the item relating to section 9812 the following new
3	item:
	"Sec. 9813. Standard relating to patient freedom of choice."; and
4	(2) by inserting after section 9812 the fol-
5	lowing:
6	"SEC. 9813. STANDARD RELATING TO PATIENTS' BILL OF
7	RIGHTS.
8	"A group health plan shall comply with the require-
9	ments of subtitle A of the Patients' Bill of Rights Act of
10	1999 (as in effect as of the date of the enactment of such
11	Act), and such requirements shall be deemed to be incor-
12	porated into this section.".
13	Subtitle E—Effective Dates;
14	<b>Coordination in Implementation</b>
15	SEC501. EFFECTIVE DATES AND RELATED RULES.
16	(a) Group Health Coverage.—
17	(1) In general.—Subject to paragraph (2),
18	the amendments made by sections 201(a), 301, and
19	401 (and subtitle A insofar as it relates to such sec-
20	tions) shall apply with respect to group health plans,
21	and health insurance coverage offered in connection
22	with group health plans, for plan years beginning on
23	or after October 1, 2000 (in this section referred to
24	as the "general effective date".

1	(2) Treatment of collective bargaining
2	AGREEMENTS.—In the case of a group health plan
3	maintained pursuant to 1 or more collective bar-
4	gaining agreements between employee representa-
5	tives and 1 or more employers ratified before the
6	date of enactment of this title, the amendments
7	made by sections201(a),301, and
8	401 (and subtitle A insofar as it relates to such
9	sections) shall not apply to plan years beginning be-
10	fore the later of—
11	(A) the date on which the last collective
12	bargaining agreements relating to the plan ter-
13	minates (determined without regard to any ex-
14	tension thereof agreed to after the date of en-
15	actment of this Act), or
16	(B) the general effective date.
17	For purposes of subparagraph (A), any plan amend-
18	ment made pursuant to a collective bargaining
19	agreement relating to the plan which amends the
20	plan solely to conform to any requirement added by
21	this title shall not be treated as a termination of
22	such collective bargaining agreement.
23	(b) Individual Health Insurance Coverage.—
24	The amendments made by section202 shall apply
25	with respect to individual health insurance coverage of-

1	fered, sold, issued, renewed, in effect, or operated in the
2	individual market on or after the general effective date
3	(c) Treatment of Religious Nonmedical Pro-
4	VIDERS.—
5	(1) In general.—Nothing in this title (or the
6	amendments made thereby) shall be construed to—
7	(A) restrict or limit the right of group
8	health plans, and of health insurance issuers of-
9	fering health insurance coverage, to include as
10	providers religious nonmedical providers;
11	(B) require such plans or issuers to—
12	(i) utilize medically based eligibility
13	standards or criteria in deciding provider
14	status of religious nonmedical providers;
15	(ii) use medical professionals or cri-
16	teria to decide patient access to religious
17	nonmedical providers;
18	(iii) utilize medical professionals or
19	criteria in making decisions in internal or
20	external appeals regarding coverage for
21	care by religious nonmedical providers; or
22	(iv) compel a participant or bene-
23	ficiary to undergo a medical examination
24	or test as a condition of receiving health

1	insurance coverage for treatment by a reli-
2	gious nonmedical provider; or
3	(C) require such plans or issuers to ex-
4	clude religious nonmedical providers because
5	they do not provide medical or other required
6	data, if such data is inconsistent with the reli-
7	gious nonmedical treatment or nursing care
8	provided by the provider.
9	(2) Religious nonmedical provider.—For
10	purposes of this subsection, the term "religious non-
11	medical provider" means a provider who provides no
12	medical care but who provides only religious non-
13	medical treatment or religious nonmedical nursing
14	care.
15	SEC502. COORDINATION IN IMPLEMENTATION.
16	Section 104(1) of Health Insurance Portability and
17	Accountability Act of 1996 is amended by striking "this
18	subtitle (and the amendments made by this subtitle and
19	section 401)" and inserting "the provisions of part 7 of

subtitle B of title I of the Employee Retirement Income

Security Act of 1974, the provisions of parts A and C of

title XXVII of the Public Health Service Act, chapter 100

of the Internal Revenue Code of 1986, and subtitle A of

21

1	SEC503. NO IMPACT ON SOCIAL SECURITY TRUST
2	FUND.
3	(a) In General.—Nothing in this title shall be con-
4	strued to alter or amend the Social Security Act (or any
5	regulation promulgated under that Act).
6	(b) Transfers.—
7	(1) Estimate of Secretary.—The Secretary
8	of the Treasury shall annually estimate the impact
9	that the enactment of this title has on the income
10	and balances of the trust funds established under
11	section 201 of the Social Security Act (42 U.S.C.
12	401).
13	(2) Transfer of funds.—If, under para-
14	graph (1), the Secretary of the Treasury estimates
15	that the enactment of this title has a negative im-
16	pact on the income and balances of the trust funds
17	established under section 201 of the Social Security
18	Act (42 U.S.C. 401), the Secretary shall transfer,
19	not less frequently than quarterly, from the general
20	revenues of the Federal Government an amount suf-
21	ficient so as to ensure that the income and balances
22	of such trust funds are not reduced as a result of

the enactment of such title.

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## Subtitle F—Revenue-Related Provisions

2	Provisions
3	SEC601. INFORMATION REQUIREMENTS.
4	(a) Information From Group Health Plans.—
5	Section 1862(b) of the Social Security Act (42 U.S.C.
6	1395y(b)) is amended by adding at the end the following:
7	"(7) Information from group health
8	PLANS.—
9	"(A) Provision of Information by
10	GROUP HEALTH PLANS.—The administrator of
11	a group health plan subject to the requirements
12	of paragraph (1) shall provide to the Secretary
13	such of the information elements described in
14	subparagraph (C) as the Secretary specifies,
15	and in such manner and at such times as the
16	Secretary may specify (but not more frequently
17	than 4 times per year), with respect to each in-
18	dividual covered under the plan who is entitled
19	to any benefits under this title.
20	"(B) Provision of Information by Em-
21	PLOYERS AND EMPLOYEE ORGANIZATIONS.—An
22	employer (or employee organization) that main-
23	tains or participates in a group health plan sub-
24	ject to the requirements of paragraph (1) shall
25	provide to the administrator of the plan such of

1	the information elements required to be pro-
2	vided under subparagraph (A), and in such
3	manner and at such times as the Secretary may
4	specify, at a frequency consistent with that re-
5	quired under subparagraph (A) with respect to
6	each individual described in subparagraph (A)
7	who is covered under the plan by reason of em-
8	ployment with that employer or membership in
9	the organization.
10	"(C) Information elements.—The in-
11	formation elements described in this subpara-
12	graph are the following:
13	"(i) Elements concerning the in-
14	DIVIDUAL.—
15	"(I) The individual's name.
16	"(II) The individual's date of
17	birth.
18	"(III) The individual's sex.
19	"(IV) The individual's social se-
20	curity insurance number.
21	"(V) The number assigned by the
22	Secretary to the individual for claims
23	under this title.
24	"(VI) The family relationship of
25	the individual to the person who has

1	or had current or employment status
2	with the employer.
3	"(ii) Elements concerning the
4	FAMILY MEMBER WITH CURRENT OR
5	FORMER EMPLOYMENT STATUS.—
6	"(I) The name of the person in
7	the individual's family who has cur-
8	rent or former employment status
9	with the employer.
10	"(II) That person's social secu-
11	rity insurance number.
12	"(III) The number or other iden-
13	tifier assigned by the plan to that per-
14	son.
15	"(IV) The periods of coverage for
16	that person under the plan.
17	"(V) The employment status of
18	that person (current or former) dur-
19	ing those periods of coverage.
20	"(VI) The classes (of that per-
21	son's family members) covered under
22	the plan.
23	"(iii) Plan elements.—
24	"(I) The items and services cov-
25	ered under the plan.

1	"(II) The name and address to
2	which claims under the plan are to be
3	sent.
4	"(iv) Elements concerning the
5	EMPLOYER.—
6	"(I) The employer's name.
7	"(II) The employer's address.
8	"(III) The employer identifica-
9	tion number of the employer.
10	"(D) Use of identifiers.—The adminis-
11	trator of a group health plan shall utilize a
12	unique identifier for the plan in providing infor-
13	mation under subparagraph (A) and in other
14	transactions, as may be specified by the Sec-
15	retary, related to the provisions of this sub-
16	section. The Secretary may provide to the ad-
17	ministrator the unique identifier described in
18	the preceding sentence.
19	"(E) Penalty for noncompliance.—
20	Any entity that knowingly and willfully fails to
21	comply with a requirement imposed by the pre-
22	vious subparagraphs shall be subject to a civil
23	money penalty not to exceed \$1,000 for each in-
24	cident of such failure. The provisions of section
25	1128A (other than subsections (a) and (b))

1	shall apply to a civil money penalty under the
2	previous sentence in the same manner as those
3	provisions apply to a penalty or proceeding
4	under section 1128A(a)."
5	(b) Effective Date.—The amendment made by
6	subsection (a) shall take effect 180 days after the date
7	of the enactment of this Act.
8	SEC602. EXTENSION OF HAZARDOUS SUBSTANCE
9	SUPERFUND TAXES.
10	(a) Extension of Taxes.—
11	(1) Environmental Tax.—Section 59A(e) of
12	the Internal Revenue Code of 1986 is amended to
13	read as follows:
14	"(e) Application of Tax.—The tax imposed by this
15	section shall apply to taxable years beginning after De-
16	cember 31, 1986, and before January 1, 1996, and to tax-
17	able years beginning after December 31, 1998, and before
	• 0
18	January 1, 2010."
18 19	·
	January 1, 2010."
19	January 1, 2010."  (2) Excise Taxes.—Section 4611(e) of such

stance Superfund financing rate under this section shall

apply after December 31, 1986, and before January 1,

1 1996, and after September 15, 1999, and before October

1, 2009."
(b) Effective Dates.—
(1) Income tax.—The amendment made by
subsection (a)(1) shall apply to taxable years begin-
ning after December 31, 1998.
(2) Excise Tax.—The amendment made by
subsection (a)(2) shall take effect on September 15,
1999.
SEC603. MODIFICATION TO FOREIGN TAX CREDIT
CARRYBACK AND CARRYOVER PERIODS.
(a) In General.—Section 904(c) of the Internal
Revenue Code of 1986 (relating to limitation on credit)
is amended—
(1) by striking "in the second preceding taxable
year,", and
(2) by striking "or fifth" and inserting "fifth,
sixth, or seventh".
(b) Effective Date.—The amendment made by
subsection (a) shall apply to credits arising in taxable
years beginning after December 31, 2001.
SEC604. LIMITATIONS ON WELFARE BENEFIT FUNDS
OF 10 OR MORE EMPLOYER PLANS.
(a) Benefits to Which Exception Applies.—
Section 419A(f)(6)(A) of the Internal Revenue Code of

1	1986 (relating to exception for 10 or more employer plans)
2	is amended to read as follows:
3	"(A) IN GENERAL.—This subpart shall not
4	apply to a welfare benefit fund which is part of
5	a 10 or more employer plan if the only benefits
6	provided through the fund are 1 or more of the
7	following:
8	"(i) Medical benefits.
9	"(ii) Disability benefits.
10	"(iii) Group term life insurance bene-
11	fits which do not provide for any cash sur-
12	render value or other money that can be
13	paid, assigned, borrowed, or pledged for
14	collateral for a loan.
15	The preceding sentence shall not apply to any
16	plan which maintains experience-rating arrange-
17	ments with respect to individual employers."
18	(b) Limitation on Use of Amounts for Other
19	Purposes.—Section 4976(b) of the Internal Revenue
20	Code of 1986 (defining disqualified benefit) is amended
21	by adding at the end the following new paragraph:
22	"(5) Special rule for 10 or more em-
23	PLOYER PLANS EXEMPTED FROM PREFUNDING LIM-
24	ITS.—For purposes of paragraph (1)(C), if—

1	"(A) subpart D of part I of subchapter D
2	of chapter 1 does not apply by reason of section
3	419A(f)(6) to contributions to provide 1 or
4	more welfare benefits through a welfare benefit
5	fund under a 10 or more employer plan, and
6	"(B) any portion of the welfare benefit
7	fund attributable to such contributions is used
8	for a purpose other than that for which the con-
9	tributions were made,
10	then such portion shall be treated as reverting to the
11	benefit of the employers maintaining the fund."
12	(c) Effective Date.—The amendments made by
13	this section shall apply to contributions paid or accrued
14	after the date of the enactment of this Act, in taxable
15	years ending after such date.
16	SEC605. MODIFICATION OF INSTALLMENT METHOD
17	AND REPEAL OF INSTALLMENT METHOD FOR
18	ACCRUAL METHOD TAXPAYERS.
19	(a) Repeal of Installment Method for Ac-
20	CRUAL BASIS TAXPAYERS.—
21	(1) In general.—Subsection (a) of section
22	453 of the Internal Revenue Code of 1986 (relating
23	to installment method) is amended to read as fol-
24	lows:
25	"(a) Use of Installment Method.—

- "(1) IN GENERAL.—Except as otherwise provided in this section, income from an installment sale shall be taken into account for purposes of this title under the installment method.
- 5 "(2) ACCRUAL METHOD TAXPAYER.—The in-6 stallment method shall not apply to income from an 7 installment sale if such income would be reported 8 under an accrual method of accounting without re-9 gard to this section. The preceding sentence shall 10 not apply to a disposition described in subparagraph 11 (A) or (B) of subsection (l)(2)."
- 12 (2) CONFORMING AMENDMENTS.—Sections
  13 453(d)(1), 453(i)(1), and 453(k) of the Internal
  14 Revenue Code of 1986 are each amended by striking
  15 "(a)" each place it appears and inserting "(a)(1)".

(b) Modification of Pledge Rules.—Paragraph

- 17 (4) of section 453A(d) (relating to pledges, etc., of install18 ment obligations) is amended by adding at the end the
  19 following: "A payment shall be treated as directly secured
  20 by an interest in an installment obligation to the extent
  21 an arrangement allows the taxpayer to satisfy all or a por-
- 22 tion of the indebtedness with the installment obligation."
- 23 (c) Effective Date.—The amendments made by 24 this section shall apply to sales or other dispositions occur-25 ring on or after the date of the enactment of this Act.

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